

## Disclaimer

The following report(s) provides findings from an FDA-initiated query using Sentinel. While Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Sentinel, and seeking to better understand Sentinel capabilities.

Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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## Overview for Request: cder\_mpl2r\_wp010

**Request ID:** cder\_mpl2r\_wp010\_ndsp\_v01

**Request Description:** In this report we identified individuals with asthma and without chronic obstructive pulmonary disease (COPD) who were dispensed either montelukast or inhaled corticosteroids (ICS) in the Sentinel Distributed Database (SDD). We examined the association between montelukast versus ICS use and inpatient depressive disorder, outpatient depressive disorder, and self-harm.

**Sentinel Modular Program Tool Used:** Cohort Identification and Descriptive Analysis (CIDA) tool, version 7.3.3, with Propensity Score Matched Analysis

**Data Source:** Data between January 1, 2000 to September 30, 2015 from 16 Data Partners contributing to the SDD were included in this report. This request was distributed to Data Partners on July 17, 2019. See Appendix A for a list of the latest dates of available data for each included Data Partner.

**Study Design:** This study used a retrospective active comparator new-user cohort design. We used a CIDA Type 2 with Propensity Score Analysis (PSA).

**Exposures of Interest:** The exposure of interest, montelukast, and the comparator of interest, ICS, were defined using National Drug Codes (NDCs). We defined new use as no prior use of montelukast, ICS monotherapy, ICS combination therapies, long-acting beta agonists (LABAs), or leukotriene receptor antagonists (LTRAs) in the 183 days prior to the first qualifying dispensing (index). For a list of generic and brand names used to define the exposure and comparator drugs, please see Appendix B. For a list of codes used to define the washout criteria, please see Appendix C.

**Outcomes of Interest:** The outcome of interest was defined as one of the following: inpatient depressive disorder in the primary diagnosis position, outpatient depressive disorder, self-harm hospitalizations,<sup>1</sup> or E-codes for self-harm. Please see Appendices D and E for a list of the codes used to define the outcomes in this report. We excluded members with evidence of death in the Death Table or Encounter Table any time in the member's history prior to the index date.

**Cohort Eligibility Criteria:** We required patients to be enrolled in health plans with medical and drug coverage in the 183 days prior to their first qualifying index date. A gap in coverage of up to 45 days was allowed and treated as continuous enrollment. We also required evidence of an asthma diagnosis in the 183 days (6 months) prior to the index dispensing. We excluded index exposure episodes if there was evidence of COPD in the 183 days (6 months) prior to the index dispensing. We excluded index episodes with both the exposure and comparator dispensed on the same day. We additionally excluded index episodes with any of the outcomes of interest on the index date. See Appendix F for a list of codes used to define the inclusion and exclusion criteria in this request. The following age groups were included in the cohort: 6-11, 12-17, and 18+ years.

**Follow-up:** Exposure episode lengths were defined using days supplied from the outpatient pharmacy dispensing to create a sequence of continuous exposure. Exposure episodes were considered continuous if gaps in days supplied were 15 days or less. Follow-up began on the first day of exposure initiation and continued until the first occurrence of any of the following:

- 1) Dispensing of comparator exposure, combination corticosteroid, LABA, or LTRA; or
- 2) Dispensing of oral corticosteroid; or
- 3) Hospitalization unrelated to self-harm or depression; or
- 4) Death; or
- 5) Data Partner end date; or
- 6) Query end date; or
- 7) Disenrollment; or
- 8) Outcome; or
- 9) End of treatment episode.

Please see Appendices G and H for a list of codes defining censoring criteria. Only the first valid exposure episode that occurred during the study period was included per patient.

## Overview for Request: cder\_mpl2r\_wp010, Continued

**Covariates:** We assessed the following covariates in the 183 days prior to and including the index date: age, year, sex, Charlson/Elixhauser combined comorbidity score,<sup>2</sup> health service and drug utilization, substance abuse, allergic rhinitis, respiratory disorder (at least 1 code, at least 2 codes, and at least 3 codes), asthma diagnosis (in an emergency care setting, inpatient care setting, and ambulatory/other ambulatory care setting), asthma exacerbations, oral corticosteroid (no use, at least 1 code, at least 2 codes, at least 3 codes), short-acting beta-agonists, anticholinergic agents, phosphodiesterase inhibitors, history of psychiatric disorder (i.e., psychiatric and psychotropic drugs, self-harm, or any other psychiatric events), psychiatric and psychotropic drugs, self-harm, and any other psychiatric event. Please see Appendices I and J for a list of codes defining covariates in this request.

**Propensity Score Estimation:** The following covariates were assessed and included in the propensity score: age, year, sex, Charlson/Elixhauser combined comorbidity score,<sup>2</sup> substance abuse, allergic rhinitis, respiratory disorder use (at least 1 code, at least 2 codes, and at least 3 codes), asthma diagnosis (in an emergency care setting, inpatient care setting, and ambulatory/other ambulatory care setting), asthma exacerbations, oral corticosteroid use, anticholinergic agents, phosphodiesterase inhibitors, and history of psychiatric disorder. The covariates were evaluated in the 183 days prior to and including exposure initiation dispensing date. The Propensity Score Analysis (PSA) tool was used to calculate the propensity scores and identify matched cohorts based on propensity scores within each Data Partner. Please see Appendices I and J for a list of codes defining covariates used in the propensity score in this request.

**Matching:** We used a 1:1 matching ratio based on propensity score. Members in the exposed and comparator cohorts were nearest neighbor matched without replacement to an exposed member using a matching caliper of 0.050.

**Analysis:** For each comparison, Cox proportional hazards regression models were used to estimate hazard ratios and corresponding 95% confidence intervals for the unmatched analyses, 1:1 conditional matched analyses, and 1:1 unconditional matched analyses. We further analyzed the association between the exposure and outcome by the following subgroups: history of psychiatric disorder (yes vs. no), age group (6-11, 12-17, 18+ years), sex (female vs. male), and labeling year (2000-2007 vs. 2008-2015).

**Please see Appendices K, L, M, N, and O for the specification of parameters and design diagram used in this request.**

**Limitations:** Algorithms to define exposures, outcomes, inclusion and exclusion criteria, and covariates are imperfect and may be misclassified. Therefore, data should be interpreted with this limitation in mind.

**Notes:** Please contact the Sentinel Operations Center ([info@sentinelssystem.org](mailto:info@sentinelssystem.org)) for questions and to provide comments/suggestions for future enhancements to this document.

<sup>1</sup> Patrick AR, Miller M, Barber CW, Wang PS, Canning CF, Schneeweiss S. Identification of hospitalizations for intentional self-harm when E-codes are incompletely recorded. *Pharmacoepidemiol Drug Saf.* 2010;19(12):1263-1275.

<sup>2</sup> Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. *J Clin Epidemiol.* 2011;64(7):749-759

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### Glossary of Terms for Analyses Using Propensity Score Analysis (PSA) Tool\*

**Covariate** - requester defined binary variable to include in the propensity score estimation model (e.g., diabetes, heart failure, etc.) during requester-defined lookback period. Requester may also choose to add any of the following categorical, continuous, or count metrics to the propensity score estimation model:

1. Age (continuous)
2. Sex
3. Time period (i.e., monitoring period for sequential analyses)
4. Year of exposure
5. Comorbidity score
6. Medical utilization – number of inpatient stays
7. Medical utilization – number of institutional stays
8. Medical utilization – number of emergency department visits
9. Medical utilization – number of outpatient visits
10. Health care utilization – number of other ambulatory encounters (e.g., telemedicine, email consults)
11. Drug utilization – number of dispensings
12. Drug utilization – number of unique generics dispensed
13. Drug Utilization – number of unique drug classes dispensed

**Covariate Evaluation Window** - specified number of days relative to index date to evaluate the occurrence of covariates of interest. Note: members are required to have continuous enrollment during the covariate evaluation window, regardless of the value included in the "Continuous enrollment before exposure" field.

**Individual Level Data Return** - program may return individual-level, de-identified datasets to the Sentinel Operations Center (SOC). While the datasets contain a single row per patient for each specified analysis, patient identifiers such as a patient ID are not included in the output. Individual-level datasets are returned to the SOC, aggregated, and used to calculate effect estimates via Cox (proportional hazards) regression.

**Mahalanobis Distance** - provides a measure of balance across all variables while accounting for their correlation.

**Matching Caliper** - maximum allowed difference in propensity scores between treatment and control patients. Requester may select any caliper (e.g., 0.01, 0.025, and 0.05).

**Matching Ratio** - patients in exposed and comparator groups are nearest neighbor matched by a 1:1 or 1:n (up to 10) matching ratio.

**Matched Conditional and Unconditional Analysis** - in a conditional matched analysis, a Cox model, stratified by Data Partner site and matched set, is run on the matched population. This can be done for both the both 1:1 and 1:n matched cohorts. In an unconditional analysis, a Cox model, stratified by Data Partner site only, is run on the matched population. This can be done for the 1:1 matched cohort only.

**Propensity Score Stratification** - option to stratify propensity scores based on requester-defined percentiles in the unmatched population. In a stratified analysis, a Cox model, stratified by Data Partner site, is run on the stratified population. Note that all patients identified in exposure and comparator cohorts are used in the analysis.

**PSM Tool** - performs effect estimation by comparing exposure propensity-score matched parallel new user cohorts. Propensity score estimation and matching are conducted within each Sentinel Data Partner site via distributed programming code; data are returned to the SOC, aggregated, and used to calculate effect estimates.

**Risk-set Level Data Return** - alternative to the patient-level data return approach. In this approach, the PSM tool will produce de-identified, risk-set level datasets instead of or in addition to individual-level output. Whereas each observation in the patient-level datasets represents one patient in the cohort, each observation in the risk set dataset represents one event. Risk sets are created at the Data Partner site, returned to the SOC, aggregated, and used to calculate effect estimates via case-centered logistic regression.

**Subgroup Analysis** - may be conducted using any requester-defined covariates. Subgroup analyses may be performed in the unmatched and the matched population.

**Zero Cell Correction** - indicator for whether to screen variables with a zero correction added to each cell in the confounder/outcome 2x2 table. Recommended when the number of exposed outcomes is fewer than 150.

\*all terms may not be used in this report

**Table 1a. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inpatient Depressive Disorder (Unmatched, Aggregated), Ratio: 1:1, Caliper: 0.051**

| Characteristic  | Medical Product |                           |                         |                           | Covariate Balance          |                                |
|---|-----------------|---------------------------|-------------------------|---------------------------|----------------------------|--------------------------------|
|   | Montelukast     |                           | Inhaled Corticosteroids |                           | Absolute Difference        | Standardized Difference        |
|   | Number          | Percent                   | Number                  | Percent                   |                            |                                |
| Number of Patients  | 513,519         | 100.0%                    | 1,332,531               | 100.0%                    |                            |                                |
| <b>Patient Characteristics</b>                                      | <b>Mean</b>     | <b>Standard Deviation</b> | <b>Mean</b>             | <b>Standard Deviation</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Mean age (years)  | 38.9            | 18.3                      | 37                      | 20.2                      | 1.916                      | 0.1                            |
| Age (years)   | <b>Number</b>   | <b>Percent</b>            | <b>Number</b>           | <b>Percent</b>            | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| 6-11  | 92,294          | 18.0%                     | 269,772                 | 20.2%                     | -2.272                     | -0.058                         |
| 12-17   | 61,854          | 12.0%                     | 152,571                 | 11.4%                     | 0.595                      | 0.018                          |
| 18+   | 359,371         | 70.0%                     | 910,188                 | 68.3%                     | 1.677                      | 0.036                          |
| Sex   |                 |                           |                         |                           |                            |                                |
| Female  | 321,937         | 62.7%                     | 789,900                 | 59.3%                     | 3.414                      | 0.07                           |
| Male  | 191,582         | 37.3%                     | 542,631                 | 40.7%                     | -3.414                     | -0.07                          |
| Year  |                 |                           |                         |                           |                            |                                |
| 2000  | 993             | 0.2%                      | 20,656                  | 1.6%                      | -1.357                     | -0.146                         |
| 2001  | 2,668           | 0.5%                      | 52,695                  | 4.0%                      | -3.435                     | -0.234                         |
| 2002  | 3,209           | 0.6%                      | 47,932                  | 3.6%                      | -2.972                     | -0.208                         |
| 2003  | 4,509           | 0.9%                      | 46,582                  | 3.5%                      | -2.618                     | -0.18                          |
| 2004  | 4,692           | 0.9%                      | 41,556                  | 3.1%                      | -2.205                     | -0.157                         |
| 2005  | 3,705           | 0.7%                      | 47,388                  | 3.6%                      | -2.835                     | -0.197                         |
| 2006  | 12,042          | 2.3%                      | 59,295                  | 4.4%                      | -2.105                     | -0.116                         |
| 2007  | 21,264          | 4.1%                      | 64,676                  | 4.9%                      | -0.713                     | -0.034                         |
| 2008  | 33,614          | 6.5%                      | 85,934                  | 6.4%                      | 0.097                      | 0.004                          |
| 2009  | 46,554          | 9.1%                      | 111,211                 | 8.3%                      | 0.72                       | 0.026                          |
| 2010  | 49,003          | 9.5%                      | 119,065                 | 8.9%                      | 0.607                      | 0.021                          |
| 2011  | 54,444          | 10.6%                     | 133,165                 | 10.0%                     | 0.609                      | 0.02                           |
| 2012  | 62,475          | 12.2%                     | 132,780                 | 10.0%                     | 2.202                      | 0.07                           |
| 2013  | 71,989          | 14.0%                     | 134,967                 | 10.1%                     | 3.89                       | 0.12                           |
| 2014  | 78,216          | 15.2%                     | 135,435                 | 10.2%                     | 5.068                      | 0.153                          |
| 2015  | 64,142          | 12.5%                     | 99,194                  | 7.4%                      | 5.047                      | 0.169                          |
| <b>Recorded History within 183 Days Prior to Index:</b>             | <b>Mean</b>     | <b>Standard Deviation</b> | <b>Mean</b>             | <b>Standard Deviation</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Charlson/Elixhauser combined comorbidity raw score <sup>2</sup>     | 1.2             | 1.1                       | 1.2                     | 1                         | 0.058                      | 0.055                          |
| <b>History of Psychiatric Disorder</b>                              | <b>Number</b>   | <b>Percent</b>            | <b>Number</b>           | <b>Percent</b>            | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| History of Psychiatric Disorder: Any Other Psychiatric Event        | 136,101         | 26.5%                     | 300,278                 | 22.5%                     | 3.969                      | 0.092                          |
| History of Psychiatric Disorder: Self-harm                          | 366             | 0.1%                      | 774                     | 0.1%                      | 0.013                      | 0.005                          |
| History of Psychiatric Disorder: Psychiatric and Psychotropic Drugs | 151,108         | 29.4%                     | 325,423                 | 24.4%                     | 5.005                      | 0.113                          |
| Self-harm: Depression   | 6,266           | 1.2%                      | 12,865                  | 1.0%                      | 0.255                      | 0.025                          |
| Self-harm: Personality disorder                                     | 429             | 0.1%                      | 1,116                   | 0.1%                      | 0                          | 0                              |
| Self-harm: Mania  | 1,720           | 0.3%                      | 3,509                   | 0.3%                      | 0.072                      | 0.013                          |
| Self-harm: Adjustment reaction                                      | 614             | 0.1%                      | 1,505                   | 0.1%                      | 0.007                      | 0.002                          |

**Table 1a. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inpatient Depressive Disorder (Unmatched, Aggregated), Ratio: 1:1, Caliper: 0.051**

| Characteristic   | Medical Product |         |                         |         | Covariate Balance   |                         |
|--|-----------------|---------|-------------------------|---------|---------------------|-------------------------|
|  | Montelukast     |         | Inhaled Corticosteroids |         | Absolute Difference | Standardized Difference |
| Recorded History within 183 Days Prior to Index:             | Number          | Percent | Number                  | Percent |                     |                         |
| Self-harm: Unspecified nonpsychotic mental disorder          | 399             | 0.1%    | 988                     | 0.1%    | 0.004               | 0.001                   |
| Self-harm: Poisoning   | 523             | 0.1%    | 1,088                   | 0.1%    | 0.02                | 0.007                   |
| Self-harm: Toxicity  | 80              | 0.0%    | 192                     | 0.0%    | 0.001               | 0.001                   |
| Self-harm: Asphyxiation                                      | 7               | 0.0%    | 10                      | 0.0%    | 0.001               | 0.002                   |
| Self-harm: Open wound  | 0               | 0.0%    | 0                       | 0.0%    | 0                   | -                       |
| Substance Abuse  | 3,607           | 0.7%    | 15,230                  | 1.1%    | -0.441              | -0.046                  |
| Allergic Rhinitis  | 249,160         | 48.5%   | 366,987                 | 27.5%   | 20.98               | 0.443                   |
| Other Respiratory Disorder - At Least Two Claims             | 260,341         | 50.7%   | 465,933                 | 35.0%   | 15.731              | 0.322                   |
| Asthma - Emergency Care Setting                              | 42,512          | 8.3%    | 89,980                  | 6.8%    | 1.526               | 0.058                   |
| Asthma - Inpatient Care Setting, Primary Diagnosis           | 2,190           | 0.4%    | 4,443                   | 0.3%    | 0.093               | 0.015                   |
| Asthma - Inpatient Care Setting, Secondary/Unknown Diagnosis | 19,003          | 3.7%    | 40,224                  | 3.0%    | 0.682               | 0.038                   |
| Asthma - Outpatient Care Setting                             | 149,886         | 29.2%   | 308,554                 | 23.2%   | 6.033               | 0.138                   |
| Asthma Exacerbation  | 55,780          | 10.9%   | 147,857                 | 11.1%   | -0.234              | -0.007                  |
| Recorded History of Use within 183 Days Prior to Index:      | Number          | Percent | Number                  | Percent | Absolute Difference | Standardized Difference |
| Oral Corticosteroids   | 109,785         | 21.4%   | 193,116                 | 14.5%   | 6.887               | 0.18                    |
| Other Asthma Medication: Short Acting Beta-Agonist           | 296,329         | 57.7%   | 1,041,200               | 78.1%   | -20.431             | -0.449                  |
| Other Asthma Medication: Anticholinergic Agents              | 5,578           | 1.1%    | 7,904                   | 0.6%    | 0.493               | 0.054                   |
| Other Asthma Medication: Phosphodiesterase Inhibitors        | 3,039           | 0.6%    | 6,091                   | 0.5%    | 0.135               | 0.019                   |

<sup>1</sup>Values in blue represent a standardized difference greater than 10% between the montelukast and inhaled corticosteroid cohorts

<sup>2</sup>Charlson/Elixhauser combined comorbidity score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date

**Table 1b. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inpatient Depressive Disorder (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05**

| Characteristic  | Medical Product |                           |                         |                           | Covariate Balance          |                                |
|---|-----------------|---------------------------|-------------------------|---------------------------|----------------------------|--------------------------------|
|   | Montelukast     |                           | Inhaled Corticosteroids |                           | Absolute Difference        | Standardized Difference        |
|   | Number          | Percent                   | Number                  | Percent                   |                            |                                |
| Number of Patients  | 457,377         | 89.1%                     | 457,377                 | 34.3%                     |                            |                                |
| <b>Patient Characteristics</b>                                      | <b>Mean</b>     | <b>Standard Deviation</b> | <b>Mean</b>             | <b>Standard Deviation</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Mean age (years)  | 38.5            | 18.3                      | 38.5                    | 19.3                      | -0.009                     | 0                              |
| Age (years)   | <b>Number</b>   | <b>Percent</b>            | <b>Number</b>           | <b>Percent</b>            | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| 6-11  | 83,239          | 18.2%                     | 97,037                  | 21.2%                     | -3.017                     | -0.076                         |
| 12-17   | 56,377          | 12.3%                     | 50,393                  | 11.0%                     | 1.308                      | 0.041                          |
| 18+   | 317,761         | 69.5%                     | 309,947                 | 67.8%                     | 1.708                      | 0.037                          |
| Sex   |                 |                           |                         |                           |                            |                                |
| Female  | 283,424         | 62.0%                     | 283,222                 | 61.9%                     | 0.044                      | 0.001                          |
| Male  | 173,953         | 38.0%                     | 174,155                 | 38.1%                     | -0.044                     | -0.001                         |
| Year  |                 |                           |                         |                           |                            |                                |
| 2000  | 993             | 0.2%                      | 1,049                   | 0.2%                      | -0.012                     | -0.003                         |
| 2001  | 2,664           | 0.6%                      | 2,767                   | 0.6%                      | -0.023                     | -0.003                         |
| 2002  | 3,135           | 0.7%                      | 3,137                   | 0.7%                      | 0                          | 0                              |
| 2003  | 3,764           | 0.8%                      | 3,714                   | 0.8%                      | 0.011                      | 0.001                          |
| 2004  | 3,398           | 0.7%                      | 3,424                   | 0.7%                      | -0.006                     | -0.001                         |
| 2005  | 2,875           | 0.6%                      | 2,917                   | 0.6%                      | -0.009                     | -0.001                         |
| 2006  | 10,677          | 2.3%                      | 10,870                  | 2.4%                      | -0.042                     | -0.003                         |
| 2007  | 18,198          | 4.0%                      | 18,410                  | 4.0%                      | -0.046                     | -0.002                         |
| 2008  | 29,858          | 6.5%                      | 30,015                  | 6.6%                      | -0.034                     | -0.001                         |
| 2009  | 42,432          | 9.3%                      | 42,466                  | 9.3%                      | -0.007                     | 0                              |
| 2010  | 45,433          | 9.9%                      | 45,473                  | 9.9%                      | -0.009                     | 0                              |
| 2011  | 51,023          | 11.2%                     | 50,977                  | 11.1%                     | 0.01                       | 0                              |
| 2012  | 57,054          | 12.5%                     | 57,180                  | 12.5%                     | -0.028                     | -0.001                         |
| 2013  | 64,104          | 14.0%                     | 64,028                  | 14.0%                     | 0.017                      | 0                              |
| 2014  | 68,339          | 14.9%                     | 67,988                  | 14.9%                     | 0.077                      | 0.002                          |
| 2015  | 53,430          | 11.7%                     | 52,962                  | 11.6%                     | 0.102                      | 0.003                          |
| <b>Recorded History within 183 Days Prior to Index:</b>             | <b>Mean</b>     | <b>Standard Deviation</b> | <b>Mean</b>             | <b>Standard Deviation</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Charlson/Elixhauser combined comorbidity raw score <sup>1</sup>     | 1.3             | 1.1                       | 1.3                     | 1.1                       | 0                          | 0                              |
|   | <b>Number</b>   | <b>Percent</b>            | <b>Number</b>           | <b>Percent</b>            | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| History of Psychiatric Disorder                                     | 168,552         | 36.9%                     | 168,375                 | 36.8%                     | 0.039                      | 0.001                          |
| History of Psychiatric Disorder: Any Other Psychiatric Event        | 119,702         | 26.2%                     | 120,787                 | 26.4%                     | -0.237                     | -0.005                         |
| History of Psychiatric Disorder: Self-harm                          | 332             | 0.1%                      | 333                     | 0.1%                      | 0                          | 0                              |
| History of Psychiatric Disorder: Psychiatric and Psychotropic Drugs | 132,598         | 29.0%                     | 131,809                 | 28.8%                     | 0.173                      | 0.004                          |
| Self-harm: Depression   | 5,578           | 1.2%                      | 5,680                   | 1.2%                      | -0.022                     | -0.002                         |
| Self-harm: Personality disorder                                     | 388             | 0.1%                      | 507                     | 0.1%                      | -0.026                     | -0.008                         |
| Self-harm: Mania  | 1,543           | 0.3%                      | 1,636                   | 0.4%                      | -0.02                      | -0.003                         |
| Self-harm: Adjustment reaction                                      | 554             | 0.1%                      | 683                     | 0.1%                      | -0.028                     | -0.008                         |



**Table 1b. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inpatient Depressive Disorder (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05**

| Characteristic   | Medical Product |                |                         |                | Covariate Balance          |                                |
|--|-----------------|----------------|-------------------------|----------------|----------------------------|--------------------------------|
|  | Montelukast     |                | Inhaled Corticosteroids |                | Absolute Difference        | Standardized Difference        |
| <b>Recorded History within 183 Days Prior to Index:</b>        | <b>Number</b>   | <b>Percent</b> | <b>Number</b>           | <b>Percent</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Self-harm: Unspecified nonpsychotic mental disorder            | 364             | 0.1%           | 414                     | 0.1%           | -0.011                     | -0.004                         |
| Self-harm: Poisoning   | 479             | 0.1%           | 457                     | 0.1%           | 0.005                      | 0.002                          |
| Self-harm: Toxicity  | 71              | 0.0%           | 86                      | 0.0%           | -0.003                     | -0.003                         |
| Self-harm: Asphyxiation  | 6               | 0.0%           | 3                       | 0.0%           | 0.001                      | 0.002                          |
| Self-harm: Open wound  | 0               | 0.0%           | 0                       | 0.0%           | 0                          | -                              |
| Substance Abuse  | 3,305           | 0.7%           | 3,252                   | 0.7%           | 0.012                      | 0.001                          |
| Allergic Rhinitis  | 198,462         | 43.4%          | 198,332                 | 43.4%          | 0.028                      | 0.001                          |
| Other Respiratory Disorder - At Least Two Claims               | 221,495         | 48.4%          | 220,785                 | 48.3%          | 0.155                      | 0.003                          |
| Asthma - Emergency Care Setting                                | 38,053          | 8.3%           | 38,058                  | 8.3%           | -0.001                     | 0                              |
| Asthma - Inpatient Care Setting, Primary Diagnosis             | 2,000           | 0.4%           | 1,990                   | 0.4%           | 0.002                      | 0                              |
| Asthma - Inpatient Care Setting, Secondary/Unknown Diagnosis   | 17,111          | 3.7%           | 17,054                  | 3.7%           | 0.012                      | 0.001                          |
| Asthma - Outpatient Care Setting                               | 135,439         | 29.6%          | 136,353                 | 29.8%          | -0.2                       | -0.004                         |
| Asthma Exacerbation  | 52,615          | 11.5%          | 52,297                  | 11.4%          | 0.07                       | 0.002                          |
| <b>Recorded of Use History within 183 Days Prior to Index:</b> | <b>Number</b>   | <b>Percent</b> | <b>Number</b>           | <b>Percent</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Oral Corticosteroids   | 94,546          | 20.7%          | 94,159                  | 20.6%          | 0.085                      | 0.002                          |
| Other Asthma Medication: Short Acting Beta-Agonist             | 288,111         | 63.0%          | 287,886                 | 62.9%          | 0.049                      | 0.001                          |
| Other Asthma Medication: Anticholinergic Agents                | 4,952           | 1.1%           | 4,940                   | 1.1%           | 0.003                      | 0                              |
| Other Asthma Medication: Phosphodiesterase Inhibitors          | 2,564           | 0.6%           | 2,578                   | 0.6%           | -0.003                     | 0                              |

<sup>1</sup>Charlson/Elixhauser combined comorbidity score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date

**Table 1c. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inpatient Depressive Disorder, ICS 30-day Extension and Gap (Unmatched, Aggregated), Ratio: 1:1, Caliper: 0.051**

| Characteristic  | Medical Product |                    |                         |                    | Covariate Balance   |                         |
|---|-----------------|--------------------|-------------------------|--------------------|---------------------|-------------------------|
|   | Montelukast     |                    | Inhaled Corticosteroids |                    | Absolute Difference | Standardized Difference |
|   | Number          | Percent            | Number                  | Percent            |                     |                         |
| Number of patients  | 513,519         | 100.0%             | 1,332,531               | 100.0%             |                     |                         |
| Patient Characteristics   | Mean            | Standard Deviation | Mean                    | Standard Deviation | Absolute Difference | Standardized Difference |
| Mean age (years)  | 38.9            | 18.3               | 37                      | 20.2               | 1.916               | 0.1                     |
| Age (years)   | Number          | Percent            | Number                  | Percent            | Absolute Difference | Standardized Difference |
| 6-11  | 92,294          | 18.0%              | 269,772                 | 20.2%              | -2.272              | -0.058                  |
| 12-17   | 61,854          | 12.0%              | 152,571                 | 11.4%              | 0.595               | 0.018                   |
| 18+   | 359,371         | 70.0%              | 910,188                 | 68.3%              | 1.677               | 0.036                   |
| Sex   |                 |                    |                         |                    |                     |                         |
| Female  | 321,937         | 62.7%              | 789,900                 | 59.3%              | 3.414               | 0.07                    |
| Male  | 191,582         | 37.3%              | 542,631                 | 40.7%              | -3.414              | -0.07                   |
| Year  |                 |                    |                         |                    |                     |                         |
| 2000  | 993             | 0.2%               | 20,656                  | 1.6%               | -1.357              | -0.146                  |
| 2001  | 2,668           | 0.5%               | 52,695                  | 4.0%               | -3.435              | -0.234                  |
| 2002  | 3,209           | 0.6%               | 47,932                  | 3.6%               | -2.972              | -0.208                  |
| 2003  | 4,509           | 0.9%               | 46,582                  | 3.5%               | -2.618              | -0.18                   |
| 2004  | 4,692           | 0.9%               | 41,556                  | 3.1%               | -2.205              | -0.157                  |
| 2005  | 3,705           | 0.7%               | 47,388                  | 3.6%               | -2.835              | -0.197                  |
| 2006  | 12,042          | 2.3%               | 59,295                  | 4.4%               | -2.105              | -0.116                  |
| 2007  | 21,264          | 4.1%               | 64,676                  | 4.9%               | -0.713              | -0.034                  |
| 2008  | 33,614          | 6.5%               | 85,934                  | 6.4%               | 0.097               | 0.004                   |
| 2009  | 46,554          | 9.1%               | 111,211                 | 8.3%               | 0.72                | 0.026                   |
| 2010  | 49,003          | 9.5%               | 119,065                 | 8.9%               | 0.607               | 0.021                   |
| 2011  | 54,444          | 10.6%              | 133,165                 | 10.0%              | 0.609               | 0.02                    |
| 2012  | 62,475          | 12.2%              | 132,780                 | 10.0%              | 2.202               | 0.07                    |
| 2013  | 71,989          | 14.0%              | 134,967                 | 10.1%              | 3.89                | 0.12                    |
| 2014  | 78,216          | 15.2%              | 135,435                 | 10.2%              | 5.068               | 0.153                   |
| 2015  | 64,142          | 12.5%              | 99,194                  | 7.4%               | 5.047               | 0.169                   |
| Recorded History within 183 Days Prior to Index:                    | Mean            | Standard Deviation | Mean                    | Standard Deviation | Absolute Difference | Standardized Difference |
| Charlson/Elixhauser combined comorbidity raw score <sup>2</sup>     | 1.2             | 1.1                | 1.2                     | 1                  | 0.058               | 0.055                   |
|   | Number          | Percent            | Number                  | Percent            | Absolute Difference | Standardized Difference |
| History of Psychiatric Disorder                                     | 191,922         | 37.4%              | 421,649                 | 31.6%              | 5.731               | 0.121                   |
| History of Psychiatric Disorder: Any Other Psychiatric Event        | 136,101         | 26.5%              | 300,278                 | 22.5%              | 3.969               | 0.092                   |
| History of Psychiatric Disorder: Self-harm                          | 366             | 0.1%               | 774                     | 0.1%               | 0.013               | 0.005                   |
| History of Psychiatric Disorder: Psychiatric and Psychotropic Drugs | 151,108         | 29.4%              | 325,423                 | 24.4%              | 5.005               | 0.113                   |
| Self-harm: Depression   | 6,266           | 1.2%               | 12,865                  | 1.0%               | 0.255               | 0.025                   |
| Self-harm: Personality disorder                                     | 429             | 0.1%               | 1,116                   | 0.1%               | 0                   | 0                       |
| Self-harm: Mania  | 1,720           | 0.3%               | 3,509                   | 0.3%               | 0.072               | 0.013                   |
| Self-harm: Adjustment reaction                                      | 614             | 0.1%               | 1,505                   | 0.1%               | 0.007               | 0.002                   |

**Table 1c. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inpatient Depressive Disorder, ICS 30-day Extension and Gap (Unmatched, Aggregated), Ratio: 1:1, Caliper: 0.051**

| Characteristic   | Medical Product |         |                         |         | Covariate Balance   |                         |
|--|-----------------|---------|-------------------------|---------|---------------------|-------------------------|
|  | Montelukast     |         | Inhaled Corticosteroids |         | Absolute Difference | Standardized Difference |
| Recorded History within 183 Days Prior to Index:             | Number          | Percent | Number                  | Percent | Absolute Difference | Standardized Difference |
| Self-harm: Unspecified nonpsychotic mental disorder          | 399             | 0.1%    | 988                     | 0.1%    | 0.004               | 0.001                   |
| Self-harm: Poisoning   | 523             | 0.1%    | 1,088                   | 0.1%    | 0.02                | 0.007                   |
| Self-harm: Toxicity  | 80              | 0.0%    | 192                     | 0.0%    | 0.001               | 0.001                   |
| Self-harm: Asphyxiation                                      | 7               | 0.0%    | 10                      | 0.0%    | 0.001               | 0.002                   |
| Self-harm: Open wound  | 0               | 0.0%    | 0                       | 0.0%    | 0                   | -                       |
| Substance Abuse  | 3,607           | 0.7%    | 15,230                  | 1.1%    | -0.441              | -0.046                  |
| Allergic Rhinitis  | 249,160         | 48.5%   | 366,987                 | 27.5%   | 20.98               | 0.443                   |
| Other Respiratory Disorder - At Least Two Claims             | 260,341         | 50.7%   | 465,933                 | 35.0%   | 15.731              | 0.322                   |
| Asthma - Emergency Care Setting                              | 42,512          | 8.3%    | 89,980                  | 6.8%    | 1.526               | 0.058                   |
| Asthma - Inpatient Care Setting, Primary Diagnosis           | 2,190           | 0.4%    | 4,443                   | 0.3%    | 0.093               | 0.015                   |
| Asthma - Inpatient Care Setting, Secondary/Unknown Diagnosis | 19,003          | 3.7%    | 40,224                  | 3.0%    | 0.682               | 0.038                   |
| Asthma - Outpatient Care Setting                             | 149,886         | 29.2%   | 308,554                 | 23.2%   | 6.033               | 0.138                   |
| Asthma Exacerbation  | 55,780          | 10.9%   | 147,857                 | 11.1%   | -0.234              | -0.007                  |
| Recorded History of Use within 183 Days Prior to Index:      | Number          | Percent | Number                  | Percent | Absolute Difference | Standardized Difference |
| Oral Corticosteroids   | 109,785         | 21.4%   | 193,116                 | 14.5%   | 6.887               | 0.18                    |
| Other Asthma Medication: Short Acting Beta-Agonist           | 296,329         | 57.7%   | 1,041,200               | 78.1%   | -20.431             | -0.449                  |
| Other Asthma Medication: Anticholinergic Agents              | 5,578           | 1.1%    | 7,904                   | 0.6%    | 0.493               | 0.054                   |
| Other Asthma Medication: Phosphodiesterase Inhibitors        | 3,039           | 0.6%    | 6,091                   | 0.5%    | 0.135               | 0.019                   |

<sup>1</sup>Values in blue represent a standardized difference greater than 10% between the montelukast and inhaled corticosteroid cohorts

<sup>2</sup>Charlson/Elixhauser combined comorbidity score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date

**Table 1d. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inpatient Depressive Disorder, ICS 30-day Extension and Gap (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05**

| Characteristic  | Medical Product |                           |                         |                           | Covariate Balance          |                                |
|---|-----------------|---------------------------|-------------------------|---------------------------|----------------------------|--------------------------------|
|   | Montelukast     |                           | Inhaled Corticosteroids |                           | Absolute Difference        | Standardized Difference        |
|   | Number          | Percent                   | Number                  | Percent                   |                            |                                |
| Number of Patients  | 457,377         | 89.1%                     | 457,377                 | 34.3%                     |                            |                                |
| <b>Patient Characteristics</b>                                      | <b>Mean</b>     | <b>Standard Deviation</b> | <b>Mean</b>             | <b>Standard Deviation</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Mean age (years)  | 38.5            | 18.3                      | 38.5                    | 19.3                      | -0.009                     | 0                              |
| Age (years)   | <b>Number</b>   | <b>Percent</b>            | <b>Number</b>           | <b>Percent</b>            | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| 6-11  | 83,239          | 18.2%                     | 97,037                  | 21.2%                     | -3.017                     | -0.076                         |
| 12-17   | 56,377          | 12.3%                     | 50,393                  | 11.0%                     | 1.308                      | 0.041                          |
| 18+   | 317,761         | 69.5%                     | 309,947                 | 67.8%                     | 1.708                      | 0.037                          |
| Sex   |                 |                           |                         |                           |                            |                                |
| Female  | 283,424         | 62.0%                     | 283,222                 | 61.9%                     | 0.044                      | 0.001                          |
| Male  | 173,953         | 38.0%                     | 174,155                 | 38.1%                     | -0.044                     | -0.001                         |
| Year  |                 |                           |                         |                           |                            |                                |
| 2000  | 993             | 0.2%                      | 1,049                   | 0.2%                      | -0.012                     | -0.003                         |
| 2001  | 2,664           | 0.6%                      | 2,767                   | 0.6%                      | -0.023                     | -0.003                         |
| 2002  | 3,135           | 0.7%                      | 3,137                   | 0.7%                      | 0                          | 0                              |
| 2003  | 3,764           | 0.8%                      | 3,714                   | 0.8%                      | 0.011                      | 0.001                          |
| 2004  | 3,398           | 0.7%                      | 3,424                   | 0.7%                      | -0.006                     | -0.001                         |
| 2005  | 2,875           | 0.6%                      | 2,917                   | 0.6%                      | -0.009                     | -0.001                         |
| 2006  | 10,677          | 2.3%                      | 10,870                  | 2.4%                      | -0.042                     | -0.003                         |
| 2007  | 18,198          | 4.0%                      | 18,410                  | 4.0%                      | -0.046                     | -0.002                         |
| 2008  | 29,858          | 6.5%                      | 30,015                  | 6.6%                      | -0.034                     | -0.001                         |
| 2009  | 42,432          | 9.3%                      | 42,466                  | 9.3%                      | -0.007                     | 0                              |
| 2010  | 45,433          | 9.9%                      | 45,473                  | 9.9%                      | -0.009                     | 0                              |
| 2011  | 51,023          | 11.2%                     | 50,977                  | 11.1%                     | 0.01                       | 0                              |
| 2012  | 57,054          | 12.5%                     | 57,180                  | 12.5%                     | -0.028                     | -0.001                         |
| 2013  | 64,104          | 14.0%                     | 64,028                  | 14.0%                     | 0.017                      | 0                              |
| 2014  | 68,339          | 14.9%                     | 67,988                  | 14.9%                     | 0.077                      | 0.002                          |
| 2015  | 53,430          | 11.7%                     | 52,962                  | 11.6%                     | 0.102                      | 0.003                          |
| <b>Recorded History within 183 Days Prior to Index:</b>             | <b>Mean</b>     | <b>Standard Deviation</b> | <b>Mean</b>             | <b>Standard Deviation</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Charlson/Elixhauser combined comorbidity raw score <sup>1</sup>     | 1.3             | 1.1                       | 1.3                     | 1.1                       | 0                          | 0                              |
|   | <b>Number</b>   | <b>Percent</b>            | <b>Number</b>           | <b>Percent</b>            | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| History of Psychiatric Disorder                                     | 168,552         | 36.9%                     | 168,375                 | 36.8%                     | 0.039                      | 0.001                          |
| History of Psychiatric Disorder: Any Other Psychiatric Event        | 119,702         | 26.2%                     | 120,787                 | 26.4%                     | -0.237                     | -0.005                         |
| History of Psychiatric Disorder: Self-harm                          | 332             | 0.1%                      | 333                     | 0.1%                      | 0                          | 0                              |
| History of Psychiatric Disorder: Psychiatric and Psychotropic Drugs | 132,598         | 29.0%                     | 131,809                 | 28.8%                     | 0.173                      | 0.004                          |
| Self-harm: Depression   | 5,578           | 1.2%                      | 5,680                   | 1.2%                      | -0.022                     | -0.002                         |
| Self-harm: Personality disorder                                     | 388             | 0.1%                      | 507                     | 0.1%                      | -0.026                     | -0.008                         |
| Self-harm: Mania  | 1,543           | 0.3%                      | 1,636                   | 0.4%                      | -0.02                      | -0.003                         |
| Self-harm: Adjustment reaction                                      | 554             | 0.1%                      | 683                     | 0.1%                      | -0.028                     | -0.008                         |

**Table 1d. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inpatient Depressive Disorder, ICS 30-day Extension and Gap (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05**

| Characteristic   | Medical Product |                |                         |                | Covariate Balance          |                                |
|--|-----------------|----------------|-------------------------|----------------|----------------------------|--------------------------------|
|  | Montelukast     |                | Inhaled Corticosteroids |                | Absolute Difference        | Standardized Difference        |
| <b>Recorded History within 183 Days Prior to Index:</b>        | <b>Number</b>   | <b>Percent</b> | <b>Number</b>           | <b>Percent</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Self-harm: Unspecified nonpsychotic mental disorder            | 364             | 0.1%           | 414                     | 0.1%           | -0.011                     | -0.004                         |
| Self-harm: Poisoning   | 479             | 0.1%           | 457                     | 0.1%           | 0.005                      | 0.002                          |
| Self-harm: Toxicity  | 71              | 0.0%           | 86                      | 0.0%           | -0.003                     | -0.003                         |
| Self-harm: Asphyxiation  | 6               | 0.0%           | 3                       | 0.0%           | 0.001                      | 0.002                          |
| Self-harm: Open wound  | 0               | 0.0%           | 0                       | 0.0%           | 0                          | -                              |
| Substance Abuse  | 3,305           | 0.7%           | 3,252                   | 0.7%           | 0.012                      | 0.001                          |
| Allergic Rhinitis  | 198,462         | 43.4%          | 198,332                 | 43.4%          | 0.028                      | 0.001                          |
| Other Respiratory Disorder - At Least Two Claims               | 221,495         | 48.4%          | 220,785                 | 48.3%          | 0.155                      | 0.003                          |
| Asthma - Emergency Care Setting                                | 38,053          | 8.3%           | 38,058                  | 8.3%           | -0.001                     | 0                              |
| Asthma - Inpatient Care Setting, Primary Diagnosis             | 2,000           | 0.4%           | 1,990                   | 0.4%           | 0.002                      | 0                              |
| Asthma - Inpatient Care Setting, Secondary/Unknown Diagnosis   | 17,111          | 3.7%           | 17,054                  | 3.7%           | 0.012                      | 0.001                          |
| Asthma - Outpatient Care Setting                               | 135,439         | 29.6%          | 136,353                 | 29.8%          | -0.2                       | -0.004                         |
| Asthma Exacerbation  | 52,615          | 11.5%          | 52,297                  | 11.4%          | 0.07                       | 0.002                          |
| <b>Recorded History of Use within 183 Days Prior to Index:</b> | <b>Number</b>   | <b>Percent</b> | <b>Number</b>           | <b>Percent</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Oral Corticosteroids   | 94,546          | 20.7%          | 94,159                  | 20.6%          | 0.085                      | 0.002                          |
| Other Asthma Medication: Short Acting Beta-Agonist             | 288,111         | 63.0%          | 287,886                 | 62.9%          | 0.049                      | 0.001                          |
| Other Asthma Medication: Anticholinergic Agents                | 4,952           | 1.1%           | 4,940                   | 1.1%           | 0.003                      | 0                              |
| Other Asthma Medication: Phosphodiesterase Inhibitors          | 2,564           | 0.6%           | 2,578                   | 0.6%           | -0.003                     | 0                              |

<sup>1</sup>Charlson/Elixhauser combined comorbidity score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date

**Table 1e. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inpatient Depressive Disorder, No Episode Extension (Unmatched, Aggregated), Ratio: 1:1, Caliper: 0.051**

| Characteristic  | Medical Product |                           |                         |                           | Covariate Balance          |                                |
|---|-----------------|---------------------------|-------------------------|---------------------------|----------------------------|--------------------------------|
|   | Montelukast     |                           | Inhaled Corticosteroids |                           | Absolute Difference        | Standardized Difference        |
|   | Number          | Percent                   | Number                  | Percent                   |                            |                                |
| Number of patients  | 513,510         | 100.0%                    | 1,331,472               | 100.0%                    |                            |                                |
| <b>Patient Characteristics</b>                                      | <b>Mean</b>     | <b>Standard Deviation</b> | <b>Mean</b>             | <b>Standard Deviation</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Mean age (years)  | 38.9            | 18.3                      | 37                      | 20.2                      | 1.916                      | 0.1                            |
| Age (years)   | <b>Number</b>   | <b>Percent</b>            | <b>Number</b>           | <b>Percent</b>            | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| 6-11  | 92,286          | 18.0%                     | 269,565                 | 20.2%                     | -2.274                     | -0.058                         |
| 12-17   | 61,863          | 12.0%                     | 152,438                 | 11.4%                     | 0.598                      | 0.019                          |
| 18+   | 359,361         | 70.0%                     | 909,469                 | 68.3%                     | 1.676                      | 0.036                          |
| Sex   |                 |                           |                         |                           |                            |                                |
| Female  | 321,937         | 62.7%                     | 789,256                 | 59.3%                     | 3.416                      | 0.07                           |
| Male  | 191,573         | 37.3%                     | 542,216                 | 40.7%                     | -3.416                     | -0.07                          |
| Year  |                 |                           |                         |                           |                            |                                |
| 2000  | 992             | 0.2%                      | 20,617                  | 1.5%                      | -1.355                     | -0.146                         |
| 2001  | 2,668           | 0.5%                      | 52,632                  | 4.0%                      | -3.433                     | -0.234                         |
| 2002  | 3,211           | 0.6%                      | 47,868                  | 3.6%                      | -2.97                      | -0.208                         |
| 2003  | 4,509           | 0.9%                      | 46,548                  | 3.5%                      | -2.618                     | -0.18                          |
| 2004  | 4,694           | 0.9%                      | 41,530                  | 3.1%                      | -2.205                     | -0.157                         |
| 2005  | 3,704           | 0.7%                      | 47,372                  | 3.6%                      | -2.837                     | -0.197                         |
| 2006  | 12,041          | 2.3%                      | 59,206                  | 4.4%                      | -2.102                     | -0.116                         |
| 2007  | 21,259          | 4.1%                      | 64,583                  | 4.9%                      | -0.711                     | -0.034                         |
| 2008  | 33,613          | 6.5%                      | 85,854                  | 6.4%                      | 0.098                      | 0.004                          |
| 2009  | 46,555          | 9.1%                      | 111,132                 | 8.3%                      | 0.719                      | 0.026                          |
| 2010  | 48,996          | 9.5%                      | 118,968                 | 8.9%                      | 0.606                      | 0.021                          |
| 2011  | 54,441          | 10.6%                     | 133,045                 | 10.0%                     | 0.609                      | 0.02                           |
| 2012  | 62,476          | 12.2%                     | 132,654                 | 10.0%                     | 2.204                      | 0.07                           |
| 2013  | 71,991          | 14.0%                     | 134,871                 | 10.1%                     | 3.89                       | 0.12                           |
| 2014  | 78,217          | 15.2%                     | 135,408                 | 10.2%                     | 5.062                      | 0.152                          |
| 2015  | 64,143          | 12.5%                     | 99,184                  | 7.4%                      | 5.042                      | 0.169                          |
| <b>Recorded History within 183 Days Prior to Index:</b>             | <b>Mean</b>     | <b>Standard Deviation</b> | <b>Mean</b>             | <b>Standard Deviation</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Charlson/Elixhauser combined comorbidity raw score <sup>2</sup>     | 1.2             | 1.1                       | 1.2                     | 1                         | 0.058                      | 0.055                          |
|   | <b>Number</b>   | <b>Percent</b>            | <b>Number</b>           | <b>Percent</b>            | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| <b>History of Psychiatric Disorder</b>                              | <b>191,916</b>  | <b>37.4%</b>              | <b>421,287</b>          | <b>31.6%</b>              | <b>5.733</b>               | <b>0.121</b>                   |
| History of Psychiatric Disorder: Any Other Psychiatric Event        | 136,092         | 26.5%                     | 300,031                 | 22.5%                     | 3.969                      | 0.092                          |
| History of Psychiatric Disorder: Self-harm                          | 366             | 0.1%                      | 772                     | 0.1%                      | 0.013                      | 0.005                          |
| History of Psychiatric Disorder: Psychiatric and Psychotropic Drugs | 151,104         | 29.4%                     | 325,149                 | 24.4%                     | 5.005                      | 0.113                          |
| Self-harm: Depression   | 6,262           | 1.2%                      | 12,856                  | 1.0%                      | 0.254                      | 0.024                          |
| Self-harm: Personality disorder                                     | 428             | 0.1%                      | 1,115                   | 0.1%                      | 0                          | 0                              |
| Self-harm: Mania  | 1,718           | 0.3%                      | 3,506                   | 0.3%                      | 0.071                      | 0.013                          |
| Self-harm: Adjustment reaction                                      | 613             | 0.1%                      | 1,502                   | 0.1%                      | 0.007                      | 0.002                          |

**Table 1e. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inpatient Depressive Disorder, No Episode Extension (Unmatched, Aggregated), Ratio: 1:1, Caliper: 0.051**

| Characteristic   | Medical Product |         |                         |         | Covariate Balance   |                         |
|--|-----------------|---------|-------------------------|---------|---------------------|-------------------------|
|  | Montelukast     |         | Inhaled Corticosteroids |         | Absolute Difference | Standardized Difference |
| Recorded History within 183 Days Prior to Index:             | Number          | Percent | Number                  | Percent | Absolute Difference | Standardized Difference |
| Self-harm: Unspecified nonpsychotic mental disorder          | 398             | 0.1%    | 986                     | 0.1%    | 0.003               | 0.001                   |
| Self-harm: Poisoning   | 523             | 0.1%    | 1,086                   | 0.1%    | 0.02                | 0.007                   |
| Self-harm: Toxicity  | 80              | 0.0%    | 192                     | 0.0%    | 0.001               | 0.001                   |
| Self-harm: Asphyxiation                                      | 7               | 0.0%    | 10                      | 0.0%    | 0.001               | 0.002                   |
| Self-harm: Open wound  | 0               | 0.0%    | 0                       | 0.0%    | 0                   | -                       |
| Substance Abuse  | 3,607           | 0.7%    | 15,219                  | 1.1%    | -0.441              | -0.046                  |
| Allergic Rhinitis  | 249,167         | 48.5%   | 366,582                 | 27.5%   | 20.99               | 0.443                   |
| Other Respiratory Disorder - At Least Two Claims             | 260,336         | 50.7%   | 465,422                 | 35.0%   | 15.742              | 0.322                   |
| Asthma - Emergency Care Setting                              | 42,514          | 8.3%    | 89,890                  | 6.8%    | 1.528               | 0.058                   |
| Asthma - Inpatient Care Setting, Primary Diagnosis           | 2,189           | 0.4%    | 4,439                   | 0.3%    | 0.093               | 0.015                   |
| Asthma - Inpatient Care Setting, Secondary/Unknown Diagnosis | 18,995          | 3.7%    | 40,182                  | 3.0%    | 0.681               | 0.038                   |
| Asthma - Outpatient Care Setting                             | 149,895         | 29.2%   | 308,237                 | 23.2%   | 6.04                | 0.138                   |
| Asthma Exacerbation  | 55,780          | 10.9%   | 147,751                 | 11.1%   | -0.234              | -0.007                  |
| Recorded History of Use within 183 Days Prior to Index:      | Number          | Percent | Number                  | Percent | Absolute Difference | Standardized Difference |
| Oral Corticosteroids   | 109,786         | 21.4%   | 192,882                 | 14.5%   | 6.893               | 0.18                    |
| Other Asthma Medication: Short Acting Beta-Agonist           | 296,335         | 57.7%   | 1,040,457               | 78.1%   | -20.436             | -0.449                  |
| Other Asthma Medication: Anticholinergic Agents              | 5,578           | 1.1%    | 7,894                   | 0.6%    | 0.493               | 0.054                   |
| Other Asthma Medication: Phosphodiesterase Inhibitors        | 3,039           | 0.6%    | 6,072                   | 0.5%    | 0.136               | 0.019                   |

<sup>1</sup>Values in blue represent a standardized difference greater than 10% between the montelukast and inhaled corticosteroid cohorts

<sup>2</sup>Charlson/Elixhauser combined comorbidity score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date



**Table 1f. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inpatient Depressive Disorder, No Episode Extension (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05**

| Characteristic  | Medical Product |                           |                         |                           | Covariate Balance          |                                |
|---|-----------------|---------------------------|-------------------------|---------------------------|----------------------------|--------------------------------|
|   | Montelukast     |                           | Inhaled Corticosteroids |                           | Absolute Difference        | Standardized Difference        |
|   | Number          | Percent                   | Number                  | Percent                   |                            |                                |
| Number of Patients  | 457,152         | 89.0%                     | 457,152                 | 34.3%                     |                            |                                |
| <b>Patient Characteristics</b>                                      | <b>Mean</b>     | <b>Standard Deviation</b> | <b>Mean</b>             | <b>Standard Deviation</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Mean age (years)  | 38.5            | 18.3                      | 38.5                    | 19.3                      | -0.025                     | -0.001                         |
| Age (years)   | <b>Number</b>   | <b>Percent</b>            | <b>Number</b>           | <b>Percent</b>            | <b>Difference</b>          | <b>Difference</b>              |
| 6-11  | 83,216          | 18.2%                     | 96,841                  | 21.2%                     | -2.98                      | -0.075                         |
| 12-17   | 56,432          | 12.3%                     | 50,411                  | 11.0%                     | 1.317                      | 0.041                          |
| 18+   | 317,504         | 69.5%                     | 309,900                 | 67.8%                     | 1.663                      | 0.036                          |
| Sex   |                 |                           |                         |                           |                            |                                |
| Female  | 283,114         | 61.9%                     | 283,133                 | 61.9%                     | -0.004                     | 0                              |
| Male  | 174,038         | 38.1%                     | 174,019                 | 38.1%                     | 0.004                      | 0                              |
| Year  |                 |                           |                         |                           |                            |                                |
| 2000  | 992             | 0.2%                      | 1,027                   | 0.2%                      | -0.008                     | -0.002                         |
| 2001  | 2,666           | 0.6%                      | 2,693                   | 0.6%                      | -0.006                     | -0.001                         |
| 2002  | 3,138           | 0.7%                      | 3,079                   | 0.7%                      | 0.013                      | 0.002                          |
| 2003  | 3,757           | 0.8%                      | 3,722                   | 0.8%                      | 0.008                      | 0.001                          |
| 2004  | 3,383           | 0.7%                      | 3,358                   | 0.7%                      | 0.005                      | 0.001                          |
| 2005  | 2,876           | 0.6%                      | 2,860                   | 0.6%                      | 0.003                      | 0                              |
| 2006  | 10,694          | 2.3%                      | 10,775                  | 2.4%                      | -0.018                     | -0.001                         |
| 2007  | 18,187          | 4.0%                      | 18,409                  | 4.0%                      | -0.049                     | -0.002                         |
| 2008  | 29,848          | 6.5%                      | 30,024                  | 6.6%                      | -0.038                     | -0.002                         |
| 2009  | 42,366          | 9.3%                      | 42,671                  | 9.3%                      | -0.067                     | -0.002                         |
| 2010  | 45,322          | 9.9%                      | 45,611                  | 10.0%                     | -0.063                     | -0.002                         |
| 2011  | 50,970          | 11.1%                     | 51,006                  | 11.2%                     | -0.008                     | 0                              |
| 2012  | 57,104          | 12.5%                     | 57,379                  | 12.6%                     | -0.06                      | -0.002                         |
| 2013  | 64,194          | 14.0%                     | 63,708                  | 13.9%                     | 0.106                      | 0.003                          |
| 2014  | 68,205          | 14.9%                     | 68,022                  | 14.9%                     | 0.04                       | 0.001                          |
| 2015  | 53,450          | 11.7%                     | 52,808                  | 11.6%                     | 0.14                       | 0.004                          |
| <b>Recorded History within 183 Days Prior to Index:</b>             | <b>Mean</b>     | <b>Standard Deviation</b> | <b>Mean</b>             | <b>Standard Deviation</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Charlson/Elixhauser combined comorbidity raw score <sup>1</sup>     | 1.3             | 1.1                       | 1.3                     | 1.1                       | -0.001                     | -0.001                         |
|   | <b>Number</b>   | <b>Percent</b>            | <b>Number</b>           | <b>Percent</b>            | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| History of Psychiatric Disorder                                     | 168,368         | 36.8%                     | 168,144                 | 36.8%                     | 0.049                      | 0.001                          |
| History of Psychiatric Disorder: Any Other Psychiatric Event        | 119,597         | 26.2%                     | 120,682                 | 26.4%                     | -0.237                     | -0.005                         |
| History of Psychiatric Disorder: Self-harm                          | 331             | 0.1%                      | 331                     | 0.1%                      | 0                          | 0                              |
| History of Psychiatric Disorder: Psychiatric and Psychotropic Drugs | 132,408         | 29.0%                     | 131,583                 | 28.8%                     | 0.18                       | 0.004                          |
| Self-harm: Depression   | 5,568           | 1.2%                      | 5,622                   | 1.2%                      | -0.012                     | -0.001                         |
| Self-harm: Personality disorder                                     | 389             | 0.1%                      | 464                     | 0.1%                      | -0.016                     | -0.005                         |
| Self-harm: Mania  | 1,557           | 0.3%                      | 1,592                   | 0.3%                      | -0.008                     | -0.001                         |
| Self-harm: Adjustment reaction                                      | 554             | 0.1%                      | 689                     | 0.2%                      | -0.03                      | -0.008                         |

**Table 1f. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inpatient Depressive Disorder, No Episode Extension (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05**

| Characteristic   | Medical Product |                |                         |                | Covariate Balance          |                                |
|--|-----------------|----------------|-------------------------|----------------|----------------------------|--------------------------------|
|  | Montelukast     |                | Inhaled Corticosteroids |                | Absolute Difference        | Standardized Difference        |
| <b>Recorded History within 183 Days Prior to Index:</b>        | <b>Number</b>   | <b>Percent</b> | <b>Number</b>           | <b>Percent</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Self-harm: Unspecified nonpsychotic mental disorder            | 366             | 0.1%           | 421                     | 0.1%           | -0.012                     | -0.004                         |
| Self-harm: Poisoning   | 477             | 0.1%           | 454                     | 0.1%           | 0.005                      | 0.002                          |
| Self-harm: Toxicity  | 72              | 0.0%           | 77                      | 0.0%           | -0.001                     | -0.001                         |
| Self-harm: Asphyxiation  | 6               | 0.0%           | 3                       | 0.0%           | 0.001                      | 0.002                          |
| Self-harm: Open wound  | 0               | 0.0%           | 0                       | 0.0%           | 0                          | -                              |
| Substance Abuse  | 3,310           | 0.7%           | 3,328                   | 0.7%           | -0.004                     | 0                              |
| Allergic Rhinitis  | 198,347         | 43.4%          | 197,795                 | 43.3%          | 0.121                      | 0.002                          |
| Other Respiratory Disorder - At Least Two Claims               | 221,303         | 48.4%          | 220,719                 | 48.3%          | 0.128                      | 0.003                          |
| Asthma - Emergency Care Setting                                | 38,112          | 8.3%           | 38,140                  | 8.3%           | -0.006                     | 0                              |
| Asthma - Inpatient Care Setting, Primary Diagnosis             | 2,003           | 0.4%           | 2,020                   | 0.4%           | -0.004                     | -0.001                         |
| Asthma - Inpatient Care Setting, Secondary/Unknown Diagnosis   | 17,070          | 3.7%           | 16,950                  | 3.7%           | 0.026                      | 0.001                          |
| Asthma - Outpatient Care Setting                               | 135,631         | 29.7%          | 136,351                 | 29.8%          | -0.157                     | -0.003                         |
| Asthma Exacerbation  | 52,668          | 11.5%          | 52,536                  | 11.5%          | 0.029                      | 0.001                          |
| <b>Recorded History of Use within 183 Days Prior to Index:</b> | <b>Number</b>   | <b>Percent</b> | <b>Number</b>           | <b>Percent</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Oral Corticosteroids   | 94,513          | 20.7%          | 94,368                  | 20.6%          | 0.032                      | 0.001                          |
| Other Asthma Medication: Short Acting Beta-Agonist             | 287,969         | 63.0%          | 287,626                 | 62.9%          | 0.075                      | 0.002                          |
| Other Asthma Medication: Anticholinergic Agents                | 4,958           | 1.1%           | 5,019                   | 1.1%           | -0.013                     | -0.001                         |
| Other Asthma Medication: Phosphodiesterase Inhibitors          | 2,554           | 0.6%           | 2,560                   | 0.6%           | -0.001                     | 0                              |

<sup>1</sup>Charlson/Elixhauser combined comorbidity score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date

**Table 1g. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Outpatient Depressive Disorder (Unmatched, Aggregated), Ratio: 1:1, Caliper: 0.051**

| Characteristic  | Medical Product |                           |                         |                           | Covariate Balance          |                                |
|---|-----------------|---------------------------|-------------------------|---------------------------|----------------------------|--------------------------------|
|   | Montelukast     |                           | Inhaled Corticosteroids |                           | Absolute Difference        | Standardized Difference        |
|   | Number          | Percent                   | Number                  | Percent                   |                            |                                |
| Number of patients  | 513,519         | 100.0%                    | 1,332,531               | 100.0%                    |                            |                                |
| <b>Patient Characteristics</b>                                      | <b>Mean</b>     | <b>Standard Deviation</b> | <b>Mean</b>             | <b>Standard Deviation</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Mean age (years)  | 38.9            | 18.3                      | 37                      | 20.2                      | 1.916                      | 0.1                            |
| Age (years)   | <b>Number</b>   | <b>Percent</b>            | <b>Number</b>           | <b>Percent</b>            | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| 6-11  | 92,294          | 18.0%                     | 269,772                 | 20.2%                     | -2.272                     | -0.058                         |
| 12-17   | 61,854          | 12.0%                     | 152,571                 | 11.4%                     | 0.595                      | 0.018                          |
| 18+   | 359,371         | 70.0%                     | 910,188                 | 68.3%                     | 1.677                      | 0.036                          |
| Sex   |                 |                           |                         |                           |                            |                                |
| Female  | 321,937         | 62.7%                     | 789,900                 | 59.3%                     | 3.414                      | 0.07                           |
| Male  | 191,582         | 37.3%                     | 542,631                 | 40.7%                     | -3.414                     | -0.07                          |
| Year  |                 |                           |                         |                           |                            |                                |
| 2000  | 993             | 0.2%                      | 20,656                  | 1.6%                      | -1.357                     | -0.146                         |
| 2001  | 2,668           | 0.5%                      | 52,695                  | 4.0%                      | -3.435                     | -0.234                         |
| 2002  | 3,209           | 0.6%                      | 47,932                  | 3.6%                      | -2.972                     | -0.208                         |
| 2003  | 4,509           | 0.9%                      | 46,582                  | 3.5%                      | -2.618                     | -0.18                          |
| 2004  | 4,692           | 0.9%                      | 41,556                  | 3.1%                      | -2.205                     | -0.157                         |
| 2005  | 3,705           | 0.7%                      | 47,388                  | 3.6%                      | -2.835                     | -0.197                         |
| 2006  | 12,042          | 2.3%                      | 59,295                  | 4.4%                      | -2.105                     | -0.116                         |
| 2007  | 21,264          | 4.1%                      | 64,676                  | 4.9%                      | -0.713                     | -0.034                         |
| 2008  | 33,614          | 6.5%                      | 85,934                  | 6.4%                      | 0.097                      | 0.004                          |
| 2009  | 46,554          | 9.1%                      | 111,211                 | 8.3%                      | 0.72                       | 0.026                          |
| 2010  | 49,003          | 9.5%                      | 119,065                 | 8.9%                      | 0.607                      | 0.021                          |
| 2011  | 54,444          | 10.6%                     | 133,165                 | 10.0%                     | 0.609                      | 0.02                           |
| 2012  | 62,475          | 12.2%                     | 132,780                 | 10.0%                     | 2.202                      | 0.07                           |
| 2013  | 71,989          | 14.0%                     | 134,967                 | 10.1%                     | 3.89                       | 0.12                           |
| 2014  | 78,216          | 15.2%                     | 135,435                 | 10.2%                     | 5.068                      | 0.153                          |
| 2015  | 64,142          | 12.5%                     | 99,194                  | 7.4%                      | 5.047                      | 0.169                          |
| <b>Recorded History within 183 Days Prior to Index:</b>             | <b>Mean</b>     | <b>Standard Deviation</b> | <b>Mean</b>             | <b>Standard Deviation</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Charlson/Elixhauser combined comorbidity raw score <sup>2</sup>     | 1.2             | 1.1                       | 1.2                     | 1                         | 0.058                      | 0.055                          |
|   | <b>Number</b>   | <b>Percent</b>            | <b>Number</b>           | <b>Percent</b>            | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| <b>History of Psychiatric Disorder</b>                              | <b>191,922</b>  | <b>37.4%</b>              | <b>421,649</b>          | <b>31.6%</b>              | <b>5.731</b>               | <b>0.121</b>                   |
| History of Psychiatric Disorder: Any Other Psychiatric Event        | 136,101         | 26.5%                     | 300,278                 | 22.5%                     | 3.969                      | 0.092                          |
| History of Psychiatric Disorder: Self-harm                          | 366             | 0.1%                      | 774                     | 0.1%                      | 0.013                      | 0.005                          |
| History of Psychiatric Disorder: Psychiatric and Psychotropic Drugs | 151,108         | 29.4%                     | 325,423                 | 24.4%                     | 5.005                      | 0.113                          |
| Self-harm: Depression   | 6,266           | 1.2%                      | 12,865                  | 1.0%                      | 0.255                      | 0.025                          |
| Self-harm: Personality disorder                                     | 429             | 0.1%                      | 1,116                   | 0.1%                      | 0                          | 0                              |
| Self-harm: Mania  | 1,720           | 0.3%                      | 3,509                   | 0.3%                      | 0.072                      | 0.013                          |
| Self-harm: Adjustment reaction                                      | 614             | 0.1%                      | 1,505                   | 0.1%                      | 0.007                      | 0.002                          |

**Table 1g. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Outpatient Depressive Disorder (Unmatched, Aggregated), Ratio: 1:1, Caliper: 0.051**

| Characteristic   | Medical Product |         |                         |         | Covariate Balance   |                         |
|--|-----------------|---------|-------------------------|---------|---------------------|-------------------------|
|  | Montelukast     |         | Inhaled Corticosteroids |         | Absolute Difference | Standardized Difference |
| Recorded History within 183 Days Prior to Index:             | Number          | Percent | Number                  | Percent | Absolute Difference | Standardized Difference |
| Self-harm: Unspecified nonpsychotic mental disorder          | 399             | 0.1%    | 988                     | 0.1%    | 0.004               | 0.001                   |
| Self-harm: Poisoning   | 523             | 0.1%    | 1,088                   | 0.1%    | 0.02                | 0.007                   |
| Self-harm: Toxicity  | 80              | 0.0%    | 192                     | 0.0%    | 0.001               | 0.001                   |
| Self-harm: Asphyxiation                                      | 7               | 0.0%    | 10                      | 0.0%    | 0.001               | 0.002                   |
| Self-harm: Open wound  | 0               | 0.0%    | 0                       | 0.0%    | 0                   | -                       |
| Substance Abuse  | 3,607           | 0.7%    | 15,230                  | 1.1%    | -0.441              | -0.046                  |
| Allergic Rhinitis  | 249,160         | 48.5%   | 366,987                 | 27.5%   | 20.98               | 0.443                   |
| Other Respiratory Disorder - At Least Two Claims             | 260,341         | 50.7%   | 465,933                 | 35.0%   | 15.731              | 0.322                   |
| Asthma - Emergency Care Setting                              | 42,512          | 8.3%    | 89,980                  | 6.8%    | 1.526               | 0.058                   |
| Asthma - Inpatient Care Setting, Primary Diagnosis           | 2,190           | 0.4%    | 4,443                   | 0.3%    | 0.093               | 0.015                   |
| Asthma - Inpatient Care Setting, Secondary/Unknown Diagnosis | 19,003          | 3.7%    | 40,224                  | 3.0%    | 0.682               | 0.038                   |
| Asthma - Outpatient Care Setting                             | 149,886         | 29.2%   | 308,554                 | 23.2%   | 6.033               | 0.138                   |
| Asthma Exacerbation  | 55,780          | 10.9%   | 147,857                 | 11.1%   | -0.234              | -0.007                  |
| Recorded History of Use within 183 Days Prior to Index:      | Number          | Percent | Number                  | Percent | Absolute Difference | Standardized Difference |
| Oral Corticosteroids   | 109,785         | 21.4%   | 193,116                 | 14.5%   | 6.887               | 0.18                    |
| Other Asthma Medication: Short Acting Beta-Agonist           | 296,329         | 57.7%   | 1,041,200               | 78.1%   | -20.431             | -0.449                  |
| Other Asthma Medication: Anticholinergic Agents              | 5,578           | 1.1%    | 7,904                   | 0.6%    | 0.493               | 0.054                   |
| Other Asthma Medication: Phosphodiesterase Inhibitors        | 3,039           | 0.6%    | 6,091                   | 0.5%    | 0.135               | 0.019                   |

<sup>1</sup>Values in blue represent a standardized difference greater than 10% between the montelukast and inhaled corticosteroid cohorts

<sup>2</sup>Charlson/Elixhauser combined comorbidity score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date

**Table 1h. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Outpatient Depressive Disorder (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05**

| Characteristic  | Medical Product |                           |                         |                           | Covariate Balance          |                                |
|---|-----------------|---------------------------|-------------------------|---------------------------|----------------------------|--------------------------------|
|   | Montelukast     |                           | Inhaled Corticosteroids |                           | Absolute Difference        | Standardized Difference        |
|   | Number          | Percent                   | Number                  | Percent                   |                            |                                |
| Number of patients  | 457,377         | 89.1%                     | 457,377                 | 34.3%                     |                            |                                |
| <b>Patient Characteristics</b>                                      | <b>Mean</b>     | <b>Standard Deviation</b> | <b>Mean</b>             | <b>Standard Deviation</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Mean age (years)  | 38.5            | 18.3                      | 38.5                    | 19.3                      | -0.009                     | 0                              |
| Age (years)   | <b>Number</b>   | <b>Percent</b>            | <b>Number</b>           | <b>Percent</b>            | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| 6-11  | 83,239          | 18.2%                     | 97,037                  | 21.2%                     | -3.017                     | -0.076                         |
| 12-17   | 56,377          | 12.3%                     | 50,393                  | 11.0%                     | 1.308                      | 0.041                          |
| 18+   | 317,761         | 69.5%                     | 309,947                 | 67.8%                     | 1.708                      | 0.037                          |
| Sex   |                 |                           |                         |                           |                            |                                |
| Female  | 283,424         | 62.0%                     | 283,222                 | 61.9%                     | 0.044                      | 0.001                          |
| Male  | 173,953         | 38.0%                     | 174,155                 | 38.1%                     | -0.044                     | -0.001                         |
| Year  |                 |                           |                         |                           |                            |                                |
| 2000  | 993             | 0.2%                      | 1,049                   | 0.2%                      | -0.012                     | -0.003                         |
| 2001  | 2,664           | 0.6%                      | 2,767                   | 0.6%                      | -0.023                     | -0.003                         |
| 2002  | 3,135           | 0.7%                      | 3,137                   | 0.7%                      | 0                          | 0                              |
| 2003  | 3,764           | 0.8%                      | 3,714                   | 0.8%                      | 0.011                      | 0.001                          |
| 2004  | 3,398           | 0.7%                      | 3,424                   | 0.7%                      | -0.006                     | -0.001                         |
| 2005  | 2,875           | 0.6%                      | 2,917                   | 0.6%                      | -0.009                     | -0.001                         |
| 2006  | 10,677          | 2.3%                      | 10,870                  | 2.4%                      | -0.042                     | -0.003                         |
| 2007  | 18,198          | 4.0%                      | 18,410                  | 4.0%                      | -0.046                     | -0.002                         |
| 2008  | 29,858          | 6.5%                      | 30,015                  | 6.6%                      | -0.034                     | -0.001                         |
| 2009  | 42,432          | 9.3%                      | 42,466                  | 9.3%                      | -0.007                     | 0                              |
| 2010  | 45,433          | 9.9%                      | 45,473                  | 9.9%                      | -0.009                     | 0                              |
| 2011  | 51,023          | 11.2%                     | 50,977                  | 11.1%                     | 0.01                       | 0                              |
| 2012  | 57,054          | 12.5%                     | 57,180                  | 12.5%                     | -0.028                     | -0.001                         |
| 2013  | 64,104          | 14.0%                     | 64,028                  | 14.0%                     | 0.017                      | 0                              |
| 2014  | 68,339          | 14.9%                     | 67,988                  | 14.9%                     | 0.077                      | 0.002                          |
| 2015  | 53,430          | 11.7%                     | 52,962                  | 11.6%                     | 0.102                      | 0.003                          |
| <b>Recorded History within 183 Days Prior to Index:</b>             | <b>Mean</b>     | <b>Standard Deviation</b> | <b>Mean</b>             | <b>Standard Deviation</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Charlson/Elixhauser combined comorbidity raw score <sup>1</sup>     | 1.3             | 1.1                       | 1.3                     | 1.1                       | 0                          | 0                              |
|   | <b>Number</b>   | <b>Percent</b>            | <b>Number</b>           | <b>Percent</b>            | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| History of Psychiatric Disorder                                     | 168,552         | 36.9%                     | 168,375                 | 36.8%                     | 0.039                      | 0.001                          |
| History of Psychiatric Disorder: Any Other Psychiatric Event        | 119,702         | 26.2%                     | 120,787                 | 26.4%                     | -0.237                     | -0.005                         |
| History of Psychiatric Disorder: Self-harm                          | 332             | 0.1%                      | 333                     | 0.1%                      | 0                          | 0                              |
| History of Psychiatric Disorder: Psychiatric and Psychotropic Drugs | 132,598         | 29.0%                     | 131,809                 | 28.8%                     | 0.173                      | 0.004                          |
| Self-harm: Depression   | 5,578           | 1.2%                      | 5,680                   | 1.2%                      | -0.022                     | -0.002                         |
| Self-harm: Personality disorder                                     | 388             | 0.1%                      | 507                     | 0.1%                      | -0.026                     | -0.008                         |
| Self-harm: Mania  | 1,543           | 0.3%                      | 1,636                   | 0.4%                      | -0.02                      | -0.003                         |
| Self-harm: Adjustment reaction                                      | 554             | 0.1%                      | 683                     | 0.1%                      | -0.028                     | -0.008                         |

**Table 1h. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Outpatient Depressive Disorder (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05**

| Characteristic   | Medical Product |                |                         |                | Covariate Balance          |                                |
|--|-----------------|----------------|-------------------------|----------------|----------------------------|--------------------------------|
|  | Montelukast     |                | Inhaled Corticosteroids |                | Absolute Difference        | Standardized Difference        |
| <b>Recorded History within 183 Days Prior to Index:</b>        | <b>Number</b>   | <b>Percent</b> | <b>Number</b>           | <b>Percent</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Self-harm: Unspecified nonpsychotic mental disorder            | 364             | 0.1%           | 414                     | 0.1%           | -0.011                     | -0.004                         |
| Self-harm: Poisoning   | 479             | 0.1%           | 457                     | 0.1%           | 0.005                      | 0.002                          |
| Self-harm: Toxicity  | 71              | 0.0%           | 86                      | 0.0%           | -0.003                     | -0.003                         |
| Self-harm: Asphyxiation  | 6               | 0.0%           | 3                       | 0.0%           | 0.001                      | 0.002                          |
| Self-harm: Open wound  | 0               | 0.0%           | 0                       | 0.0%           | 0                          | -                              |
| Substance Abuse  | 3,305           | 0.7%           | 3,252                   | 0.7%           | 0.012                      | 0.001                          |
| Allergic Rhinitis  | 198,462         | 43.4%          | 198,332                 | 43.4%          | 0.028                      | 0.001                          |
| Other Respiratory Disorder - At Least Two Claims               | 221,495         | 48.4%          | 220,785                 | 48.3%          | 0.155                      | 0.003                          |
| Asthma - Emergency Care Setting                                | 38,053          | 8.3%           | 38,058                  | 8.3%           | -0.001                     | 0                              |
| Asthma - Inpatient Care Setting, Primary Diagnosis             | 2,000           | 0.4%           | 1,990                   | 0.4%           | 0.002                      | 0                              |
| Asthma - Inpatient Care Setting, Secondary/Unknown Diagnosis   | 17,111          | 3.7%           | 17,054                  | 3.7%           | 0.012                      | 0.001                          |
| Asthma - Outpatient Care Setting                               | 135,439         | 29.6%          | 136,353                 | 29.8%          | -0.2                       | -0.004                         |
| Asthma Exacerbation  | 52,615          | 11.5%          | 52,297                  | 11.4%          | 0.07                       | 0.002                          |
| <b>Recorded History of Use within 183 Days Prior to Index:</b> | <b>Number</b>   | <b>Percent</b> | <b>Number</b>           | <b>Percent</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Oral Corticosteroids   | 94,546          | 20.7%          | 94,159                  | 20.6%          | 0.085                      | 0.002                          |
| Other Asthma Medication: Short Acting Beta-Agonist             | 288,111         | 63.0%          | 287,886                 | 62.9%          | 0.049                      | 0.001                          |
| Other Asthma Medication: Anticholinergic Agents                | 4,952           | 1.1%           | 4,940                   | 1.1%           | 0.003                      | 0                              |
| Other Asthma Medication: Phosphodiesterase Inhibitors          | 2,564           | 0.6%           | 2,578                   | 0.6%           | -0.003                     | 0                              |

<sup>1</sup>Charlson/Elixhauser combined comorbidity score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date

**Table 1i. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Self-Harm (Unmatched, Aggregated), Ratio: 1:1, Caliper: 0.05<sup>1</sup>**

| Characteristic  | Medical Product |                    |                         |                    | Covariate Balance   |                         |
|---|-----------------|--------------------|-------------------------|--------------------|---------------------|-------------------------|
|   | Montelukast     |                    | Inhaled Corticosteroids |                    | Absolute Difference | Standardized Difference |
|   | Number          | Percent            | Number                  | Percent            |                     |                         |
| Number of patients  | 513,519         | 100.0%             | 1,332,531               | 100.0%             |                     |                         |
| Patient Characteristics   | Mean            | Standard Deviation | Mean                    | Standard Deviation | Absolute Difference | Standardized Difference |
| Mean age (years)  | 38.9            | 18.3               | 37                      | 20.2               | 1.916               | 0.1                     |
| Age (years)   | Number          | Percent            | Number                  | Percent            | Absolute Difference | Standardized Difference |
| 6-11  | 92,294          | 18.0%              | 269,772                 | 20.2%              | -2.272              | -0.058                  |
| 12-17   | 61,854          | 12.0%              | 152,571                 | 11.4%              | 0.595               | 0.018                   |
| 18+   | 359,371         | 70.0%              | 910,188                 | 68.3%              | 1.677               | 0.036                   |
| Sex   |                 |                    |                         |                    |                     |                         |
| Female  | 321,937         | 62.7%              | 789,900                 | 59.3%              | 3.414               | 0.07                    |
| Male  | 191,582         | 37.3%              | 542,631                 | 40.7%              | -3.414              | -0.07                   |
| Year  |                 |                    |                         |                    |                     |                         |
| 2000  | 993             | 0.2%               | 20,656                  | 1.6%               | -1.357              | -0.146                  |
| 2001  | 2,668           | 0.5%               | 52,695                  | 4.0%               | -3.435              | -0.234                  |
| 2002  | 3,209           | 0.6%               | 47,932                  | 3.6%               | -2.972              | -0.208                  |
| 2003  | 4,509           | 0.9%               | 46,582                  | 3.5%               | -2.618              | -0.18                   |
| 2004  | 4,692           | 0.9%               | 41,556                  | 3.1%               | -2.205              | -0.157                  |
| 2005  | 3,705           | 0.7%               | 47,388                  | 3.6%               | -2.835              | -0.197                  |
| 2006  | 12,042          | 2.3%               | 59,295                  | 4.4%               | -2.105              | -0.116                  |
| 2007  | 21,264          | 4.1%               | 64,676                  | 4.9%               | -0.713              | -0.034                  |
| 2008  | 33,614          | 6.5%               | 85,934                  | 6.4%               | 0.097               | 0.004                   |
| 2009  | 46,554          | 9.1%               | 111,211                 | 8.3%               | 0.72                | 0.026                   |
| 2010  | 49,003          | 9.5%               | 119,065                 | 8.9%               | 0.607               | 0.021                   |
| 2011  | 54,444          | 10.6%              | 133,165                 | 10.0%              | 0.609               | 0.02                    |
| 2012  | 62,475          | 12.2%              | 132,780                 | 10.0%              | 2.202               | 0.07                    |
| 2013  | 71,989          | 14.0%              | 134,967                 | 10.1%              | 3.89                | 0.12                    |
| 2014  | 78,216          | 15.2%              | 135,435                 | 10.2%              | 5.068               | 0.153                   |
| 2015  | 64,142          | 12.5%              | 99,194                  | 7.4%               | 5.047               | 0.169                   |
| Recorded History within 183 Days Prior to Index:                    | Mean            | Standard Deviation | Mean                    | Standard Deviation | Absolute Difference | Standardized Difference |
| Charlson/Elixhauser combined comorbidity raw score <sup>2</sup>     | 1.2             | 1.1                | 1.2                     | 1                  | 0.058               | 0.055                   |
|   | Number          | Percent            | Number                  | Percent            | Absolute Difference | Standardized Difference |
| History of Psychiatric Disorder                                     | 191,922         | 37.4%              | 421,649                 | 31.6%              | 5.731               | 0.121                   |
| History of Psychiatric Disorder: Any Other Psychiatric Event        | 136,101         | 26.5%              | 300,278                 | 22.5%              | 3.969               | 0.092                   |
| History of Psychiatric Disorder: Self-harm                          | 366             | 0.1%               | 774                     | 0.1%               | 0.013               | 0.005                   |
| History of Psychiatric Disorder: Psychiatric and Psychotropic Drugs | 151,108         | 29.4%              | 325,423                 | 24.4%              | 5.005               | 0.113                   |
| Self-harm: Depression   | 6,266           | 1.2%               | 12,865                  | 1.0%               | 0.255               | 0.025                   |
| Self-harm: Personality disorder                                     | 429             | 0.1%               | 1,116                   | 0.1%               | 0                   | 0                       |
| Self-harm: Mania  | 1,720           | 0.3%               | 3,509                   | 0.3%               | 0.072               | 0.013                   |
| Self-harm: Adjustment reaction                                      | 614             | 0.1%               | 1,505                   | 0.1%               | 0.007               | 0.002                   |



**Table 1i. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Self-Harm (Unmatched, Aggregated), Ratio: 1:1, Caliper: 0.05<sup>1</sup>**

| Characteristic   | Medical Product |         |                         |         | Covariate Balance   |                         |
|--|-----------------|---------|-------------------------|---------|---------------------|-------------------------|
|  | Montelukast     |         | Inhaled Corticosteroids |         | Absolute Difference | Standardized Difference |
| Recorded History within 183 Days Prior to Index:             | Number          | Percent | Number                  | Percent | Absolute Difference | Standardized Difference |
| Self-harm: Unspecified nonpsychotic mental disorder          | 399             | 0.1%    | 988                     | 0.1%    | 0.004               | 0.001                   |
| Self-harm: Poisoning   | 523             | 0.1%    | 1,088                   | 0.1%    | 0.02                | 0.007                   |
| Self-harm: Toxicity  | 80              | 0.0%    | 192                     | 0.0%    | 0.001               | 0.001                   |
| Self-harm: Asphyxiation                                      | 7               | 0.0%    | 10                      | 0.0%    | 0.001               | 0.002                   |
| Self-harm: Open wound  | 0               | 0.0%    | 0                       | 0.0%    | 0                   | -                       |
| Substance Abuse  | 3,607           | 0.7%    | 15,230                  | 1.1%    | -0.441              | -0.046                  |
| Allergic Rhinitis  | 249,160         | 48.5%   | 366,987                 | 27.5%   | 20.98               | 0.443                   |
| Other Respiratory Disorder - At Least Two Claims             | 260,341         | 50.7%   | 465,933                 | 35.0%   | 15.731              | 0.322                   |
| Asthma - Emergency Care Setting                              | 42,512          | 8.3%    | 89,980                  | 6.8%    | 1.526               | 0.058                   |
| Asthma - Inpatient Care Setting, Primary Diagnosis           | 2,190           | 0.4%    | 4,443                   | 0.3%    | 0.093               | 0.015                   |
| Asthma - Inpatient Care Setting, Secondary/Unknown Diagnosis | 19,003          | 3.7%    | 40,224                  | 3.0%    | 0.682               | 0.038                   |
| Asthma - Outpatient Care Setting                             | 149,886         | 29.2%   | 308,554                 | 23.2%   | 6.033               | 0.138                   |
| Asthma Exacerbation  | 55,780          | 10.9%   | 147,857                 | 11.1%   | -0.234              | -0.007                  |
| Recorded History of Use within 183 Days Prior to Index:      | Number          | Percent | Number                  | Percent | Absolute Difference | Standardized Difference |
| Oral Corticosteroids   | 109,785         | 21.4%   | 193,116                 | 14.5%   | 6.887               | 0.18                    |
| Other Asthma Medication: Short Acting Beta-Agonist           | 296,329         | 57.7%   | 1,041,200               | 78.1%   | -20.431             | -0.449                  |
| Other Asthma Medication: Anticholinergic Agents              | 5,578           | 1.1%    | 7,904                   | 0.6%    | 0.493               | 0.054                   |
| Other Asthma Medication: Phosphodiesterase Inhibitors        | 3,039           | 0.6%    | 6,091                   | 0.5%    | 0.135               | 0.019                   |

<sup>1</sup>Values in blue represent a standardized difference greater than 10% between the montelukast and inhaled corticosteroid cohorts

<sup>2</sup>Charlson/Elixhauser combined comorbidity score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date

**Table 1j. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Self-Harm (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05**

| Characteristic  | Medical Product |                           |                         |                           | Covariate Balance          |                                |
|---|-----------------|---------------------------|-------------------------|---------------------------|----------------------------|--------------------------------|
|   | Montelukast     |                           | Inhaled Corticosteroids |                           | Absolute Difference        | Standardized Difference        |
|   | Number          | Percent                   | Number                  | Percent                   |                            |                                |
| Number of patients  | 457,377         | 89.1%                     | 457,377                 | 34.3%                     |                            |                                |
| <b>Patient Characteristics</b>                                      | <b>Mean</b>     | <b>Standard Deviation</b> | <b>Mean</b>             | <b>Standard Deviation</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Mean age (years)  | 38.5            | 18.3                      | 38.5                    | 19.3                      | -0.009                     | 0                              |
| Age (years)   | <b>Number</b>   | <b>Percent</b>            | <b>Number</b>           | <b>Percent</b>            | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| 6-11  | 83,239          | 18.2%                     | 97,037                  | 21.2%                     | -3.017                     | -0.076                         |
| 12-17   | 56,377          | 12.3%                     | 50,393                  | 11.0%                     | 1.308                      | 0.041                          |
| 18+   | 317,761         | 69.5%                     | 309,947                 | 67.8%                     | 1.708                      | 0.037                          |
| Sex   |                 |                           |                         |                           |                            |                                |
| Female  | 283,424         | 62.0%                     | 283,222                 | 61.9%                     | 0.044                      | 0.001                          |
| Male  | 173,953         | 38.0%                     | 174,155                 | 38.1%                     | -0.044                     | -0.001                         |
| Year  |                 |                           |                         |                           |                            |                                |
| 2000  | 993             | 0.2%                      | 1,049                   | 0.2%                      | -0.012                     | -0.003                         |
| 2001  | 2,664           | 0.6%                      | 2,767                   | 0.6%                      | -0.023                     | -0.003                         |
| 2002  | 3,135           | 0.7%                      | 3,137                   | 0.7%                      | 0                          | 0                              |
| 2003  | 3,764           | 0.8%                      | 3,714                   | 0.8%                      | 0.011                      | 0.001                          |
| 2004  | 3,398           | 0.7%                      | 3,424                   | 0.7%                      | -0.006                     | -0.001                         |
| 2005  | 2,875           | 0.6%                      | 2,917                   | 0.6%                      | -0.009                     | -0.001                         |
| 2006  | 10,677          | 2.3%                      | 10,870                  | 2.4%                      | -0.042                     | -0.003                         |
| 2007  | 18,198          | 4.0%                      | 18,410                  | 4.0%                      | -0.046                     | -0.002                         |
| 2008  | 29,858          | 6.5%                      | 30,015                  | 6.6%                      | -0.034                     | -0.001                         |
| 2009  | 42,432          | 9.3%                      | 42,466                  | 9.3%                      | -0.007                     | 0                              |
| 2010  | 45,433          | 9.9%                      | 45,473                  | 9.9%                      | -0.009                     | 0                              |
| 2011  | 51,023          | 11.2%                     | 50,977                  | 11.1%                     | 0.01                       | 0                              |
| 2012  | 57,054          | 12.5%                     | 57,180                  | 12.5%                     | -0.028                     | -0.001                         |
| 2013  | 64,104          | 14.0%                     | 64,028                  | 14.0%                     | 0.017                      | 0                              |
| 2014  | 68,339          | 14.9%                     | 67,988                  | 14.9%                     | 0.077                      | 0.002                          |
| 2015  | 53,430          | 11.7%                     | 52,962                  | 11.6%                     | 0.102                      | 0.003                          |
| <b>Recorded History within 183 Days Prior to Index:</b>             | <b>Mean</b>     | <b>Standard Deviation</b> | <b>Mean</b>             | <b>Standard Deviation</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Charlson/Elixhauser combined comorbidity raw score <sup>1</sup>     | 1.3             | 1.1                       | 1.3                     | 1.1                       | 0                          | 0                              |
|   | <b>Number</b>   | <b>Percent</b>            | <b>Number</b>           | <b>Percent</b>            | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| History of Psychiatric Disorder                                     | 168,552         | 36.9%                     | 168,375                 | 36.8%                     | 0.039                      | 0.001                          |
| History of Psychiatric Disorder: Any Other Psychiatric Event        | 119,702         | 26.2%                     | 120,787                 | 26.4%                     | -0.237                     | -0.005                         |
| History of Psychiatric Disorder: Self-harm                          | 332             | 0.1%                      | 333                     | 0.1%                      | 0                          | 0                              |
| History of Psychiatric Disorder: Psychiatric and Psychotropic Drugs | 132,598         | 29.0%                     | 131,809                 | 28.8%                     | 0.173                      | 0.004                          |
| Self-harm: Depression   | 5,578           | 1.2%                      | 5,680                   | 1.2%                      | -0.022                     | -0.002                         |
| Self-harm: Personality disorder                                     | 388             | 0.1%                      | 507                     | 0.1%                      | -0.026                     | -0.008                         |
| Self-harm: Mania  | 1,543           | 0.3%                      | 1,636                   | 0.4%                      | -0.02                      | -0.003                         |
| Self-harm: Adjustment reaction                                      | 554             | 0.1%                      | 683                     | 0.1%                      | -0.028                     | -0.008                         |

**Table 1j. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Self-Harm (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05**

| Characteristic   | Medical Product |                |                         |                | Covariate Balance          |                                |
|--|-----------------|----------------|-------------------------|----------------|----------------------------|--------------------------------|
|  | Montelukast     |                | Inhaled Corticosteroids |                | Absolute Difference        | Standardized Difference        |
| <b>Recorded History within 183 Days Prior to Index:</b>        | <b>Number</b>   | <b>Percent</b> | <b>Number</b>           | <b>Percent</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Self-harm: Unspecified nonpsychotic mental disorder            | 364             | 0.1%           | 414                     | 0.1%           | -0.011                     | -0.004                         |
| Self-harm: Poisoning   | 479             | 0.1%           | 457                     | 0.1%           | 0.005                      | 0.002                          |
| Self-harm: Toxicity  | 71              | 0.0%           | 86                      | 0.0%           | -0.003                     | -0.003                         |
| Self-harm: Asphyxiation  | 6               | 0.0%           | 3                       | 0.0%           | 0.001                      | 0.002                          |
| Self-harm: Open wound  | 0               | 0.0%           | 0                       | 0.0%           | 0                          | -                              |
| Substance Abuse  | 3,305           | 0.7%           | 3,252                   | 0.7%           | 0.012                      | 0.001                          |
| Allergic Rhinitis  | 198,462         | 43.4%          | 198,332                 | 43.4%          | 0.028                      | 0.001                          |
| Other Respiratory Disorder - At Least Two Claims               | 221,495         | 48.4%          | 220,785                 | 48.3%          | 0.155                      | 0.003                          |
| Asthma - Emergency Care Setting                                | 38,053          | 8.3%           | 38,058                  | 8.3%           | -0.001                     | 0                              |
| Asthma - Inpatient Care Setting, Primary Diagnosis             | 2,000           | 0.4%           | 1,990                   | 0.4%           | 0.002                      | 0                              |
| Asthma - Inpatient Care Setting, Secondary/Unknown Diagnosis   | 17,111          | 3.7%           | 17,054                  | 3.7%           | 0.012                      | 0.001                          |
| Asthma - Outpatient Care Setting                               | 135,439         | 29.6%          | 136,353                 | 29.8%          | -0.2                       | -0.004                         |
| Asthma Exacerbation  | 52,615          | 11.5%          | 52,297                  | 11.4%          | 0.07                       | 0.002                          |
| <b>Recorded History of Use within 183 Days Prior to Index:</b> | <b>Number</b>   | <b>Percent</b> | <b>Number</b>           | <b>Percent</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Oral Corticosteroids   | 94,546          | 20.7%          | 94,159                  | 20.6%          | 0.085                      | 0.002                          |
| Other Asthma Medication: Short Acting Beta-Agonist             | 288,111         | 63.0%          | 287,886                 | 62.9%          | 0.049                      | 0.001                          |
| Other Asthma Medication: Anticholinergic Agents                | 4,952           | 1.1%           | 4,940                   | 1.1%           | 0.003                      | 0                              |
| Other Asthma Medication: Phosphodiesterase Inhibitors          | 2,564           | 0.6%           | 2,578                   | 0.6%           | -0.003                     | 0                              |

<sup>1</sup>Charlson/Elixhauser combined comorbidity score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date

**Table 1k. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Self-Harm or E-code (Unmatched, Aggregated), Ratio: 1:1, Caliper: 0.05<sup>1</sup>**

| Characteristic  | Medical Product |                           |                         |                           | Covariate Balance          |                                |
|---|-----------------|---------------------------|-------------------------|---------------------------|----------------------------|--------------------------------|
|   | Montelukast     |                           | Inhaled Corticosteroids |                           | Absolute Difference        | Standardized Difference        |
|   | Number          | Percent                   | Number                  | Percent                   |                            |                                |
| Number of patients  | 513,519         | 100.0%                    | 1,332,531               | 100.0%                    |                            |                                |
| <b>Patient Characteristics</b>                                      | <b>Mean</b>     | <b>Standard Deviation</b> | <b>Mean</b>             | <b>Standard Deviation</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Mean age (years)  | 38.9            | 18.3                      | 37                      | 20.2                      | 1.916                      | 0.1                            |
| Age (years)   | <b>Number</b>   | <b>Percent</b>            | <b>Number</b>           | <b>Percent</b>            | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| 6-11  | 92,294          | 18.0%                     | 269,772                 | 20.2%                     | -2.272                     | -0.058                         |
| 12-17   | 61,854          | 12.0%                     | 152,571                 | 11.4%                     | 0.595                      | 0.018                          |
| 18+   | 359,371         | 70.0%                     | 910,188                 | 68.3%                     | 1.677                      | 0.036                          |
| Sex   |                 |                           |                         |                           |                            |                                |
| Female  | 321,937         | 62.7%                     | 789,900                 | 59.3%                     | 3.414                      | 0.07                           |
| Male  | 191,582         | 37.3%                     | 542,631                 | 40.7%                     | -3.414                     | -0.07                          |
| Year  |                 |                           |                         |                           |                            |                                |
| 2000  | 993             | 0.2%                      | 20,656                  | 1.6%                      | -1.357                     | -0.146                         |
| 2001  | 2,668           | 0.5%                      | 52,695                  | 4.0%                      | -3.435                     | -0.234                         |
| 2002  | 3,209           | 0.6%                      | 47,932                  | 3.6%                      | -2.972                     | -0.208                         |
| 2003  | 4,509           | 0.9%                      | 46,582                  | 3.5%                      | -2.618                     | -0.18                          |
| 2004  | 4,692           | 0.9%                      | 41,556                  | 3.1%                      | -2.205                     | -0.157                         |
| 2005  | 3,705           | 0.7%                      | 47,388                  | 3.6%                      | -2.835                     | -0.197                         |
| 2006  | 12,042          | 2.3%                      | 59,295                  | 4.4%                      | -2.105                     | -0.116                         |
| 2007  | 21,264          | 4.1%                      | 64,676                  | 4.9%                      | -0.713                     | -0.034                         |
| 2008  | 33,614          | 6.5%                      | 85,934                  | 6.4%                      | 0.097                      | 0.004                          |
| 2009  | 46,554          | 9.1%                      | 111,211                 | 8.3%                      | 0.72                       | 0.026                          |
| 2010  | 49,003          | 9.5%                      | 119,065                 | 8.9%                      | 0.607                      | 0.021                          |
| 2011  | 54,444          | 10.6%                     | 133,165                 | 10.0%                     | 0.609                      | 0.02                           |
| 2012  | 62,475          | 12.2%                     | 132,780                 | 10.0%                     | 2.202                      | 0.07                           |
| 2013  | 71,989          | 14.0%                     | 134,967                 | 10.1%                     | 3.89                       | 0.12                           |
| 2014  | 78,216          | 15.2%                     | 135,435                 | 10.2%                     | 5.068                      | 0.153                          |
| 2015  | 64,142          | 12.5%                     | 99,194                  | 7.4%                      | 5.047                      | 0.169                          |
| <b>Recorded History within 183 Days Prior to Index:</b>             | <b>Mean</b>     | <b>Standard Deviation</b> | <b>Mean</b>             | <b>Standard Deviation</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Charlson/Elixhauser combined comorbidity raw score <sup>2</sup>     | 1.2             | 1.1                       | 1.2                     | 1                         | 0.058                      | 0.055                          |
|   | <b>Number</b>   | <b>Percent</b>            | <b>Number</b>           | <b>Percent</b>            | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| <b>History of Psychiatric Disorder</b>                              | <b>191,922</b>  | <b>37.4%</b>              | <b>421,649</b>          | <b>31.6%</b>              | <b>5.731</b>               | <b>0.121</b>                   |
| History of Psychiatric Disorder: Any Other Psychiatric Event        | 136,101         | 26.5%                     | 300,278                 | 22.5%                     | 3.969                      | 0.092                          |
| History of Psychiatric Disorder: Self-harm                          | 366             | 0.1%                      | 774                     | 0.1%                      | 0.013                      | 0.005                          |
| History of Psychiatric Disorder: Psychiatric and Psychotropic Drugs | 151,108         | 29.4%                     | 325,423                 | 24.4%                     | 5.005                      | 0.113                          |
| Self-harm: Depression   | 6,266           | 1.2%                      | 12,865                  | 1.0%                      | 0.255                      | 0.025                          |
| Self-harm: Personality disorder                                     | 429             | 0.1%                      | 1,116                   | 0.1%                      | 0                          | 0                              |
| Self-harm: Mania  | 1,720           | 0.3%                      | 3,509                   | 0.3%                      | 0.072                      | 0.013                          |
| Self-harm: Adjustment reaction                                      | 614             | 0.1%                      | 1,505                   | 0.1%                      | 0.007                      | 0.002                          |

**Table 1k. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Self-Harm or E-code (Unmatched, Aggregated), Ratio: 1:1, Caliper: 0.05<sup>1</sup>**

| Characteristic   | Medical Product |         |                         |         | Covariate Balance   |                         |
|--|-----------------|---------|-------------------------|---------|---------------------|-------------------------|
|  | Montelukast     |         | Inhaled Corticosteroids |         | Absolute Difference | Standardized Difference |
| Recorded History within 183 Days Prior to Index:             | Number          | Percent | Number                  | Percent |                     |                         |
| Self-harm: Unspecified nonpsychotic mental disorder          | 399             | 0.1%    | 988                     | 0.1%    | 0.004               | 0.001                   |
| Self-harm: Poisoning   | 523             | 0.1%    | 1,088                   | 0.1%    | 0.02                | 0.007                   |
| Self-harm: Toxicity  | 80              | 0.0%    | 192                     | 0.0%    | 0.001               | 0.001                   |
| Self-harm: Asphyxiation                                      | 7               | 0.0%    | 10                      | 0.0%    | 0.001               | 0.002                   |
| Self-harm: Open wound  | 0               | 0.0%    | 0                       | 0.0%    | 0                   | -                       |
| Substance Abuse  | 3,607           | 0.7%    | 15,230                  | 1.1%    | -0.441              | -0.046                  |
| Allergic Rhinitis  | 249,160         | 48.5%   | 366,987                 | 27.5%   | 20.98               | 0.443                   |
| Other Respiratory Disorder - At Least Two Claims             | 260,341         | 50.7%   | 465,933                 | 35.0%   | 15.731              | 0.322                   |
| Asthma - Emergency Care Setting                              | 42,512          | 8.3%    | 89,980                  | 6.8%    | 1.526               | 0.058                   |
| Asthma - Inpatient Care Setting, Primary Diagnosis           | 2,190           | 0.4%    | 4,443                   | 0.3%    | 0.093               | 0.015                   |
| Asthma - Inpatient Care Setting, Secondary/Unknown Diagnosis | 19,003          | 3.7%    | 40,224                  | 3.0%    | 0.682               | 0.038                   |
| Asthma - Outpatient Care Setting                             | 149,886         | 29.2%   | 308,554                 | 23.2%   | 6.033               | 0.138                   |
| Asthma Exacerbation  | 55,780          | 10.9%   | 147,857                 | 11.1%   | -0.234              | -0.007                  |
| Recorded History of Use within 183 Days Prior to Index:      | Number          | Percent | Number                  | Percent | Absolute Difference | Standardized Difference |
| Oral Corticosteroids   | 109,785         | 21.4%   | 193,116                 | 14.5%   | 6.887               | 0.18                    |
| Other Asthma Medication: Short Acting Beta-Agonist           | 296,329         | 57.7%   | 1,041,200               | 78.1%   | -20.431             | -0.449                  |
| Other Asthma Medication: Anticholinergic Agents              | 5,578           | 1.1%    | 7,904                   | 0.6%    | 0.493               | 0.054                   |
| Other Asthma Medication: Phosphodiesterase Inhibitors        | 3,039           | 0.6%    | 6,091                   | 0.5%    | 0.135               | 0.019                   |

<sup>1</sup>Values in blue represent a standardized difference greater than 10% between the montelukast and inhaled corticosteroid cohorts

<sup>2</sup>Charlson/Elixhauser combined comorbidity score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date

**Table 11. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Self-Harm or E-code (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05**

| Characteristic  | Medical Product |                           |                         |                           | Covariate Balance          |                                |
|---|-----------------|---------------------------|-------------------------|---------------------------|----------------------------|--------------------------------|
|   | Montelukast     |                           | Inhaled Corticosteroids |                           | Absolute Difference        | Standardized Difference        |
|   | Number          | Percent                   | Number                  | Percent                   |                            |                                |
| Number of patients  | 457,377         | 89.1%                     | 457,377                 | 34.3%                     |                            |                                |
| <b>Patient Characteristics</b>                                      | <b>Mean</b>     | <b>Standard Deviation</b> | <b>Mean</b>             | <b>Standard Deviation</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Mean age (years)  | 38.5            | 18.3                      | 38.5                    | 19.3                      | -0.009                     | 0                              |
| Age (years)   | <b>Number</b>   | <b>Percent</b>            | <b>Number</b>           | <b>Percent</b>            | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| 6-11  | 83,239          | 18.2%                     | 97,037                  | 21.2%                     | -3.017                     | -0.076                         |
| 12-17   | 56,377          | 12.3%                     | 50,393                  | 11.0%                     | 1.308                      | 0.041                          |
| 18+   | 317,761         | 69.5%                     | 309,947                 | 67.8%                     | 1.708                      | 0.037                          |
| Sex   |                 |                           |                         |                           |                            |                                |
| Female  | 283,424         | 62.0%                     | 283,222                 | 61.9%                     | 0.044                      | 0.001                          |
| Male  | 173,953         | 38.0%                     | 174,155                 | 38.1%                     | -0.044                     | -0.001                         |
| Year  |                 |                           |                         |                           |                            |                                |
| 2000  | 993             | 0.2%                      | 1,049                   | 0.2%                      | -0.012                     | -0.003                         |
| 2001  | 2,664           | 0.6%                      | 2,767                   | 0.6%                      | -0.023                     | -0.003                         |
| 2002  | 3,135           | 0.7%                      | 3,137                   | 0.7%                      | 0                          | 0                              |
| 2003  | 3,764           | 0.8%                      | 3,714                   | 0.8%                      | 0.011                      | 0.001                          |
| 2004  | 3,398           | 0.7%                      | 3,424                   | 0.7%                      | -0.006                     | -0.001                         |
| 2005  | 2,875           | 0.6%                      | 2,917                   | 0.6%                      | -0.009                     | -0.001                         |
| 2006  | 10,677          | 2.3%                      | 10,870                  | 2.4%                      | -0.042                     | -0.003                         |
| 2007  | 18,198          | 4.0%                      | 18,410                  | 4.0%                      | -0.046                     | -0.002                         |
| 2008  | 29,858          | 6.5%                      | 30,015                  | 6.6%                      | -0.034                     | -0.001                         |
| 2009  | 42,432          | 9.3%                      | 42,466                  | 9.3%                      | -0.007                     | 0                              |
| 2010  | 45,433          | 9.9%                      | 45,473                  | 9.9%                      | -0.009                     | 0                              |
| 2011  | 51,023          | 11.2%                     | 50,977                  | 11.1%                     | 0.01                       | 0                              |
| 2012  | 57,054          | 12.5%                     | 57,180                  | 12.5%                     | -0.028                     | -0.001                         |
| 2013  | 64,104          | 14.0%                     | 64,028                  | 14.0%                     | 0.017                      | 0                              |
| 2014  | 68,339          | 14.9%                     | 67,988                  | 14.9%                     | 0.077                      | 0.002                          |
| 2015  | 53,430          | 11.7%                     | 52,962                  | 11.6%                     | 0.102                      | 0.003                          |
| <b>Recorded History within 183 Days Prior to Index:</b>             | <b>Mean</b>     | <b>Standard Deviation</b> | <b>Mean</b>             | <b>Standard Deviation</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Charlson/Elixhauser combined comorbidity raw score <sup>1</sup>     | 1.3             | 1.1                       | 1.3                     | 1.1                       | 0                          | 0                              |
|   | <b>Number</b>   | <b>Percent</b>            | <b>Number</b>           | <b>Percent</b>            | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| History of Psychiatric Disorder                                     | 168,552         | 36.9%                     | 168,375                 | 36.8%                     | 0.039                      | 0.001                          |
| History of Psychiatric Disorder: Any Other Psychiatric Event        | 119,702         | 26.2%                     | 120,787                 | 26.4%                     | -0.237                     | -0.005                         |
| History of Psychiatric Disorder: Self-harm                          | 332             | 0.1%                      | 333                     | 0.1%                      | 0                          | 0                              |
| History of Psychiatric Disorder: Psychiatric and Psychotropic Drugs | 132,598         | 29.0%                     | 131,809                 | 28.8%                     | 0.173                      | 0.004                          |
| Self-harm: Depression   | 5,578           | 1.2%                      | 5,680                   | 1.2%                      | -0.022                     | -0.002                         |
| Self-harm: Personality disorder                                     | 388             | 0.1%                      | 507                     | 0.1%                      | -0.026                     | -0.008                         |
| Self-harm: Mania  | 1,543           | 0.3%                      | 1,636                   | 0.4%                      | -0.02                      | -0.003                         |
| Self-harm: Adjustment reaction                                      | 554             | 0.1%                      | 683                     | 0.1%                      | -0.028                     | -0.008                         |

**Table 11. Baseline Characteristics of New Initiators of Montelukast and Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Self-Harm or E-code (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05**

| Characteristic   | Medical Product |                |                         |                | Covariate Balance          |                                |
|--|-----------------|----------------|-------------------------|----------------|----------------------------|--------------------------------|
|  | Montelukast     |                | Inhaled Corticosteroids |                | Absolute Difference        | Standardized Difference        |
| <b>Recorded History within 183 Days Prior to Index:</b>        | <b>Number</b>   | <b>Percent</b> | <b>Number</b>           | <b>Percent</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Self-harm: Unspecified nonpsychotic mental disorder            | 364             | 0.1%           | 414                     | 0.1%           | -0.011                     | -0.004                         |
| Self-harm: Poisoning   | 479             | 0.1%           | 457                     | 0.1%           | 0.005                      | 0.002                          |
| Self-harm: Toxicity  | 71              | 0.0%           | 86                      | 0.0%           | -0.003                     | -0.003                         |
| Self-harm: Asphyxiation  | 6               | 0.0%           | 3                       | 0.0%           | 0.001                      | 0.002                          |
| Self-harm: Open wound  | 0               | 0.0%           | 0                       | 0.0%           | 0                          | -                              |
| Substance Abuse  | 3,305           | 0.7%           | 3,252                   | 0.7%           | 0.012                      | 0.001                          |
| Allergic Rhinitis  | 198,462         | 43.4%          | 198,332                 | 43.4%          | 0.028                      | 0.001                          |
| Other Respiratory Disorder - At Least Two Claims               | 221,495         | 48.4%          | 220,785                 | 48.3%          | 0.155                      | 0.003                          |
| Asthma - Emergency Care Setting                                | 38,053          | 8.3%           | 38,058                  | 8.3%           | -0.001                     | 0                              |
| Asthma - Inpatient Care Setting, Primary Diagnosis             | 2,000           | 0.4%           | 1,990                   | 0.4%           | 0.002                      | 0                              |
| Asthma - Inpatient Care Setting, Secondary/Unknown Diagnosis   | 17,111          | 3.7%           | 17,054                  | 3.7%           | 0.012                      | 0.001                          |
| Asthma - Outpatient Care Setting                               | 135,439         | 29.6%          | 136,353                 | 29.8%          | -0.2                       | -0.004                         |
| Asthma Exacerbation  | 52,615          | 11.5%          | 52,297                  | 11.4%          | 0.07                       | 0.002                          |
| <b>Recorded History of Use within 183 Days Prior to Index:</b> | <b>Number</b>   | <b>Percent</b> | <b>Number</b>           | <b>Percent</b> | <b>Absolute Difference</b> | <b>Standardized Difference</b> |
| Oral Corticosteroids   | 94,546          | 20.7%          | 94,159                  | 20.6%          | 0.085                      | 0.002                          |
| Other Asthma Medication: Short Acting Beta-Agonist             | 288,111         | 63.0%          | 287,886                 | 62.9%          | 0.049                      | 0.001                          |
| Other Asthma Medication: Anticholinergic Agents                | 4,952           | 1.1%           | 4,940                   | 1.1%           | 0.003                      | 0                              |
| Other Asthma Medication: Phosphodiesterase Inhibitors          | 2,564           | 0.6%           | 2,578                   | 0.6%           | -0.003                     | 0                              |

<sup>1</sup>Charlson/Elixhauser combined comorbidity score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date



**Table 2a. Summary of Inpatient Depressive Disorder Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type**

| Medical Product  | Number of New Users | Person-Years at Risk | Average Person-Days at Risk | Average Person-Years at Risk | Number of Events | Incidence Rate per 1,000 Person-Years | Risk per 1,000 New Users | Incidence Rate Difference per 1,000 Person-Years | Difference in Risk per 1,000 New Users | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|----------------------|-----------------------------|------------------------------|------------------|---------------------------------------|--------------------------|--|--|-----------------------|--------------|
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast  | 513,519             | 114,418.46           | 81.38                       | 0.22                         | 420              | 3.67                                  | 0.82                     | 0.31   | 0.30                                   | 0.96 (0.84, 1.10)     | 0.583        |
| Inhaled Corticosteroids                                      | 1,332,531           | 204,834.02           | 56.15                       | 0.15                         | 689              | 3.36                                  | 0.52                     |  |  |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast  | 457,377             | 48,730.54            | 38.92                       | 0.11                         | 202              | 4.15                                  | 0.44                     | 0.00   | 0.00                                   | 1.00 (0.82, 1.22)     | 1.000        |
| Inhaled Corticosteroids                                      | 457,377             | 48,730.54            | 38.92                       | 0.11                         | 202              | 4.15                                  | 0.44                     |  |  |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast  | 457,377             | 102,042.72           | 81.49                       | 0.22                         | 381              | 3.73                                  | 0.83                     | -0.20  | 0.25                                   | 1.06 (0.90, 1.24)     | 0.494        |
| Inhaled Corticosteroids                                      | 457,377             | 67,662.03            | 54.03                       | 0.15                         | 266              | 3.93                                  | 0.58                     |  |  |                       |              |

**Table 2b. Summary of Inpatient Depressive Disorder Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type**

| Medical Product  | Number of<br>New Users | Hazard Ratio<br>(95% CI) | Wald<br>P-Value |
|--|------------------------|--------------------------|-----------------|
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 513,519                | 0.97 (0.85, 1.11)        | 0.645           |
| Inhaled Corticosteroids                                      | 1,332,531              |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 457,377                | 1.00 (0.82, 1.22)        | 1.000           |
| Inhaled Corticosteroids                                      | 457,377                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 457,377                | 1.06 (0.90, 1.25)        | 0.470           |
| Inhaled Corticosteroids                                      | 457,377                |                          |                 |

**Table 3a. Summary of Inpatient Depressive Disorder Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and History of Psychiatric Disorder**

| Medical Product   | Number of New Users | Person-Years at Risk | Average Person-Days at Risk | Average Person-Years at Risk | Number of Events | Incidence Rate per 1,000 Person-Years | Risk per 1,000 New Users | Incidence Rate Difference per 1,000 Person-Years | Difference in Risk per 1,000 New Users | Hazard Ratio (95% CI) | Wald P-Value |
|---|---------------------|----------------------|-----------------------------|------------------------------|------------------|---------------------------------------|--------------------------|--|--|-----------------------|--------------|
| <b>No History of Psychiatric Disorder</b>                           |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 321,597             | 66,926.75            | 76.01                       | 0.21                         | 32               | 0.48                                  | 0.10                     | -0.13  | 0.01                                   | 0.78 (0.49, 1.24)     | 0.291        |
| Inhaled Corticosteroids   | 910,882             | 138,635.37           | 55.59                       | 0.15                         | 85               | 0.61                                  | 0.09                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 287,233             | 30,488.96            | 38.77                       | 0.11                         | 13               | 0.43                                  | 0.05                     | -0.46  | -0.05                                  | 0.48 (0.25, 0.93)     | 0.030        |
| Inhaled Corticosteroids   | 287,233             | 30,488.96            | 38.77                       | 0.11                         | 27               | 0.89                                  | 0.09                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 287,233             | 59,791.12            | 76.03                       | 0.21                         | 26               | 0.43                                  | 0.09                     | -0.34  | -0.02                                  | 0.63 (0.37, 1.07)     | 0.088        |
| Inhaled Corticosteroids   | 287,233             | 41,416.22            | 52.67                       | 0.14                         | 32               | 0.77                                  | 0.11                     |  |  |                       |              |
| <b>History of Psychiatric Disorder</b>                              |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 191,922             | 47,491.72            | 90.38                       | 0.25                         | 388              | 8.17                                  | 2.02                     | -0.95  | 0.59                                   | 0.98 (0.85, 1.13)     | 0.786        |
| Inhaled Corticosteroids   | 421,649             | 66,198.65            | 57.34                       | 0.16                         | 604              | 9.12                                  | 1.43                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 166,750             | 17,899.64            | 39.21                       | 0.11                         | 186              | 10.39                                 | 1.12                     | 0.61   | 0.07                                   | 1.06 (0.86, 1.31)     | 0.563        |
| Inhaled Corticosteroids   | 166,750             | 17,899.64            | 39.21                       | 0.11                         | 175              | 9.78                                  | 1.05                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 166,750             | 41,437.47            | 90.76                       | 0.25                         | 350              | 8.45                                  | 2.10                     | -0.53  | 0.71                                   | 1.10 (0.93, 1.31)     | 0.271        |
| Inhaled Corticosteroids   | 166,750             | 25,721.45            | 56.34                       | 0.15                         | 231              | 8.98                                  | 1.39                     |  |  |                       |              |

**Table 3b. Summary of Inpatient Depressive Disorder Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and History of Psychiatric Disorder**

| Medical Product  | Number of<br>New Users | Hazard Ratio<br>(95% CI) | Wald<br>P-Value |
|--|------------------------|--------------------------|-----------------|
| No History of Psychiatric Disorder                           |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 321,597                | 0.77 (0.48, 1.23)        | 0.270           |
| Inhaled Corticosteroids                                      | 910,882                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 287,233                | 0.48 (0.25, 0.93)        | 0.030           |
| Inhaled Corticosteroids                                      | 287,233                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 287,233                | 0.61 (0.36, 1.05)        | 0.075           |
| Inhaled Corticosteroids                                      | 287,233                |                          |                 |
| History of Psychiatric Disorder                              |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 191,922                | 0.99 (0.86, 1.14)        | 0.886           |
| Inhaled Corticosteroids                                      | 421,649                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 166,750                | 1.07 (0.87, 1.31)        | 0.527           |
| Inhaled Corticosteroids                                      | 166,750                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 166,750                | 1.11 (0.93, 1.32)        | 0.239           |
| Inhaled Corticosteroids                                      | 166,750                |                          |                 |

**Table 4a. Summary of Inpatient Depressive Disorder Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Sex**

| Medical Product  | Number of New Users | Person-Years at Risk | Average             | Average              | Number of Events | Incidence                   | Risk per        | Incidence                              | Difference in            | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|----------------------|---------------------|----------------------|------------------|-----------------------------|-----------------|--|--------------------------|-----------------------|--------------|
|  |                     |                      | Person-Days at Risk | Person-Years at Risk |                  | Rate per 1,000 Person-Years | 1,000 New Users | Rate Difference per 1,000 Person-Years | Risk per 1,000 New Users |                       |              |
| Male   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 191,582             | 40,834.60            | 77.85               | 0.21                 | 117              | 2.87                        | 0.61            | 0.59                                   | 0.26                     | 1.03 (0.80, 1.34)     | 0.797        |
| Inhaled Corticosteroids                                      | 542,631             | 83,872.22            | 56.46               | 0.15                 | 191              | 2.28                        | 0.35            |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 172,540             | 18,454.39            | 39.07               | 0.11                 | 58               | 3.14                        | 0.34            | 0.11                                   | 0.01                     | 1.04 (0.72, 1.50)     | 0.851        |
| Inhaled Corticosteroids                                      | 172,540             | 18,454.39            | 39.07               | 0.11                 | 56               | 3.03                        | 0.32            |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 172,540             | 36,793.88            | 77.89               | 0.21                 | 107              | 2.91                        | 0.62            | 0.21                                   | 0.23                     | 1.15 (0.84, 1.58)     | 0.373        |
| Inhaled Corticosteroids                                      | 172,540             | 25,244.28            | 53.44               | 0.15                 | 68               | 2.69                        | 0.39            |  |                          |                       |              |
| Female   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 321,937             | 73,583.86            | 83.48               | 0.23                 | 303              | 4.12                        | 0.94            | 0.00                                   | 0.31                     | 0.93 (0.79, 1.09)     | 0.361        |
| Inhaled Corticosteroids                                      | 789,900             | 120,961.80           | 55.93               | 0.15                 | 498              | 4.12                        | 0.63            |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 281,810             | 29,929.89            | 38.79               | 0.11                 | 146              | 4.88                        | 0.52            | -0.10                                  | -0.01                    | 0.98 (0.78, 1.23)     | 0.861        |
| Inhaled Corticosteroids                                      | 281,810             | 29,929.89            | 38.79               | 0.11                 | 149              | 4.98                        | 0.53            |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 281,810             | 64,512.63            | 83.61               | 0.23                 | 272              | 4.22                        | 0.97            | -0.41                                  | 0.28                     | 1.04 (0.86, 1.26)     | 0.678        |
| Inhaled Corticosteroids                                      | 281,810             | 41,936.36            | 54.35               | 0.15                 | 194              | 4.63                        | 0.69            |  |                          |                       |              |

**Table 4b. Summary of Inpatient Depressive Disorder Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Sex**

| Medical Product  | Number of New Users | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|-----------------------|--------------|
| Male   |                     |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 191,582             | 1.02 (0.79, 1.33)     | 0.851        |
| Inhaled Corticosteroids                                      | 542,631             |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 172,540             | 1.04 (0.72, 1.50)     | 0.851        |
| Inhaled Corticosteroids                                      | 172,540             |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 172,540             | 1.14 (0.83, 1.56)     | 0.407        |
| Inhaled Corticosteroids                                      | 172,540             |                       |              |
| Female   |                     |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 321,937             | 0.94 (0.80, 1.10)     | 0.444        |
| Inhaled Corticosteroids                                      | 789,900             |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 281,810             | 0.98 (0.78, 1.23)     | 0.861        |
| Inhaled Corticosteroids                                      | 281,810             |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 281,810             | 1.05 (0.87, 1.27)     | 0.614        |
| Inhaled Corticosteroids                                      | 281,810             |                       |              |

**Table 5a. Summary of Inpatient Depressive Disorder Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Age Group**

| Medical Product   | Number of New Users | Person-Years at Risk | Average Person-Days at Risk | Average Person-Years at Risk | Number of Events | Incidence Rate per 1,000 Person-Years | Risk per 1,000 New Users | Incidence Rate Difference per 1,000 Person-Years | Difference in Risk per 1,000 New Users | Hazard Ratio (95% CI) | Wald P-Value |
|---|---------------------|----------------------|-----------------------------|------------------------------|------------------|---------------------------------------|--------------------------|--|--|-----------------------|--------------|
| <b>6-11 years</b>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 92,294              | 17,293.63            | 68.44                       | 0.19                         | 11               | 0.64                                  | 0.12                     | -0.07  | 0.02                                   | 0.60 (0.28, 1.31)     | 0.202        |
| Inhaled Corticosteroids   | 269,772             | 39,750.80            | 53.82                       | 0.15                         | 28               | 0.70                                  | 0.10                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 82,660              | 8,680.02             | 38.35                       | 0.11                         | 5                | 0.58                                  | 0.06                     | -0.69  | -0.07                                  | 0.45 (0.16, 1.31)     | 0.144        |
| Inhaled Corticosteroids   | 82,660              | 8,680.02             | 38.35                       | 0.11                         | 11               | 1.27                                  | 0.13                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 82,660              | 15,522.96            | 68.59                       | 0.19                         | 10               | 0.64                                  | 0.12                     | -0.44  | -0.02                                  | 0.62 (0.26, 1.48)     | 0.281        |
| Inhaled Corticosteroids   | 82,660              | 11,037.34            | 48.77                       | 0.13                         | 12               | 1.09                                  | 0.15                     |  |  |                       |              |
| <b>12-17 years</b>  |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 61,854              | 10,741.68            | 63.43                       | 0.17                         | 74               | 6.89                                  | 1.20                     | 0.38   | 0.26                                   | 1.01 (0.73, 1.38)     | 0.972        |
| Inhaled Corticosteroids   | 152,571             | 21,985.29            | 52.63                       | 0.14                         | 143              | 6.50                                  | 0.94                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 50,191              | 5,219.66             | 37.98                       | 0.10                         | 37               | 7.09                                  | 0.74                     | -0.77  | -0.08                                  | 0.90 (0.58, 1.41)     | 0.651        |
| Inhaled Corticosteroids   | 50,191              | 5,219.66             | 37.98                       | 0.10                         | 41               | 7.85                                  | 0.82                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 50,191              | 8,711.32             | 63.39                       | 0.17                         | 59               | 6.77                                  | 1.18                     | -0.11  | 0.28                                   | 1.09 (0.73, 1.61)     | 0.683        |
| Inhaled Corticosteroids   | 50,191              | 6,534.69             | 47.55                       | 0.13                         | 45               | 6.89                                  | 0.90                     |  |  |                       |              |
| <b>18+ years</b>  |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 359,371             | 86,383.15            | 87.80                       | 0.24                         | 335              | 3.88                                  | 0.93                     | 0.26   | 0.36                                   | 1.01 (0.86, 1.17)     | 0.940        |
| Inhaled Corticosteroids   | 910,188             | 143,097.93           | 57.42                       | 0.16                         | 518              | 3.62                                  | 0.57                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 308,196             | 33,208.68            | 39.36                       | 0.11                         | 152              | 4.58                                  | 0.49                     | 0.09   | 0.01                                   | 1.02 (0.81, 1.28)     | 0.863        |
| Inhaled Corticosteroids   | 308,196             | 33,208.68            | 39.36                       | 0.11                         | 149              | 4.49                                  | 0.48                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 308,196             | 74,636.76            | 88.45                       | 0.24                         | 303              | 4.06                                  | 0.98                     | -0.18  | 0.32                                   | 1.08 (0.90, 1.29)     | 0.424        |
| Inhaled Corticosteroids   | 308,196             | 47,928.90            | 56.80                       | 0.16                         | 203              | 4.24                                  | 0.66                     |  |  |                       |              |

**Table 5b. Summary of Inpatient Depressive Disorder Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Age Group**

| Medical Product  | Number of<br>New Users | Hazard Ratio<br>(95% CI) | Wald<br>P-Value |
|--|------------------------|--------------------------|-----------------|
| 6-11 years   |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 92,294                 | 0.58 (0.26, 1.28)        | 0.175           |
| Inhaled Corticosteroids                                      | 269,772                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 82,660                 | 0.45 (0.16, 1.31)        | 0.144           |
| Inhaled Corticosteroids                                      | 82,660                 |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 82,660                 | 0.60 (0.25, 1.45)        | 0.253           |
| Inhaled Corticosteroids                                      | 82,660                 |                          |                 |
| 12-17 years  |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 61,854                 | 1.02 (0.74, 1.40)        | 0.891           |
| Inhaled Corticosteroids                                      | 152,571                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 50,191                 | 0.90 (0.58, 1.41)        | 0.651           |
| Inhaled Corticosteroids                                      | 50,191                 |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 50,191                 | 1.09 (0.73, 1.61)        | 0.683           |
| Inhaled Corticosteroids                                      | 50,191                 |                          |                 |
| 18+ years  |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 359,371                | 1.01 (0.87, 1.18)        | 0.876           |
| Inhaled Corticosteroids                                      | 910,188                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 308,196                | 1.02 (0.81, 1.28)        | 0.863           |
| Inhaled Corticosteroids                                      | 308,196                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 308,196                | 1.08 (0.90, 1.30)        | 0.391           |
| Inhaled Corticosteroids                                      | 308,196                |                          |                 |



**Table 6a. Summary of Inpatient Depressive Disorder Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Year**

| Medical Product  | Number of New Users | Person-Years at Risk | Average Person-Days at Risk | Average Person-Years at Risk | Number of Events | Incidence                   | Risk per        | Incidence                   | Difference in            | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|----------------------|-----------------------------|------------------------------|------------------|-----------------------------|-----------------|-----------------------------|--------------------------|-----------------------|--------------|
|  |                     |                      |                             |                              |                  | Rate per 1,000 Person-Years | 1,000 New Users | Rate per 1,000 Person-Years | Risk per 1,000 New Users |                       |              |
| 2000-2007  |                     |                      |                             |                              |                  |                             |                 |                             |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                             |                              |                  |                             |                 |                             |                          |                       |              |
| Montelukast  | 53,082              | 12,027.03            | 82.76                       | 0.23                         | 52               | 4.32                        | 0.98            | 1.04                        | 0.49                     | 0.65 (0.46, 0.93)     | 0.019        |
| Inhaled Corticosteroids                                      | 380,780             | 56,636.10            | 54.33                       | 0.15                         | 186              | 3.28                        | 0.49            |                             |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                             |                              |                  |                             |                 |                             |                          |                       |              |
| Montelukast  | 44,926              | 4,595.34             | 37.36                       | 0.10                         | 29               | 6.31                        | 0.65            | -0.65                       | -0.07                    | 0.91 (0.55, 1.50)     | 0.701        |
| Inhaled Corticosteroids                                      | 44,926              | 4,595.34             | 37.36                       | 0.10                         | 32               | 6.96                        | 0.71            |                             |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                             |                              |                  |                             |                 |                             |                          |                       |              |
| Montelukast  | 44,926              | 10,334.11            | 84.02                       | 0.23                         | 46               | 4.45                        | 1.02            | -1.60                       | 0.22                     | 0.94 (0.60, 1.48)     | 0.795        |
| Inhaled Corticosteroids                                      | 44,926              | 5,948.29             | 48.36                       | 0.13                         | 36               | 6.05                        | 0.80            |                             |                          |                       |              |
| 2008-2015  |                     |                      |                             |                              |                  |                             |                 |                             |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                             |                              |                  |                             |                 |                             |                          |                       |              |
| Montelukast  | 460,437             | 102,391.43           | 81.22                       | 0.22                         | 368              | 3.59                        | 0.80            | 0.20                        | 0.27                     | 1.04 (0.90, 1.20)     | 0.601        |
| Inhaled Corticosteroids                                      | 951,751             | 148,197.92           | 56.87                       | 0.16                         | 503              | 3.39                        | 0.53            |                             |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                             |                              |                  |                             |                 |                             |                          |                       |              |
| Montelukast  | 410,335             | 43,923.58            | 39.10                       | 0.11                         | 174              | 3.96                        | 0.42            | 0.16                        | 0.02                     | 1.04 (0.84, 1.29)     | 0.705        |
| Inhaled Corticosteroids                                      | 410,335             | 43,923.58            | 39.10                       | 0.11                         | 167              | 3.80                        | 0.41            |                             |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                             |                              |                  |                             |                 |                             |                          |                       |              |
| Montelukast  | 410,335             | 91,286.65            | 81.26                       | 0.22                         | 334              | 3.66                        | 0.81            | -0.05                       | 0.26                     | 1.08 (0.91, 1.29)     | 0.365        |
| Inhaled Corticosteroids                                      | 410,335             | 61,426.10            | 54.68                       | 0.15                         | 228              | 3.71                        | 0.56            |                             |                          |                       |              |

**Table 6b. Summary of Inpatient Depressive Disorder Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Year**

| Medical Product  | Number of<br>New Users | Hazard Ratio<br>(95% CI) | Wald<br>P-Value |
|--|------------------------|--------------------------|-----------------|
| 2000-2007  |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 53,082                 | 0.65 (0.45, 0.92)        | 0.017           |
| Inhaled Corticosteroids                                      | 380,780                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 44,926                 | 0.91 (0.55, 1.50)        | 0.701           |
| Inhaled Corticosteroids                                      | 44,926                 |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 44,926                 | 0.94 (0.59, 1.48)        | 0.776           |
| Inhaled Corticosteroids                                      | 44,926                 |                          |                 |
| 2008-2015  |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 460,437                | 1.05 (0.91, 1.22)        | 0.514           |
| Inhaled Corticosteroids                                      | 951,751                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 410,335                | 1.04 (0.84, 1.29)        | 0.705           |
| Inhaled Corticosteroids                                      | 410,335                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 410,335                | 1.09 (0.91, 1.30)        | 0.339           |
| Inhaled Corticosteroids                                      | 410,335                |                          |                 |

**Table 7a. Summary of Inpatient Depressive Disorder Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inhaled Corticosteroid 30-day Extension and Gap by Analysis Type**

| Medical Product  | Number of New Users | Person-Years at Risk | Average Person-Days at Risk | Average Person-Years at Risk | Number of Events | Incidence Rate per 1,000 Person-Years | Risk per 1,000 New Users | Incidence Rate Difference per 1,000 Person-Years | Difference in Risk per 1,000 New Users | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|----------------------|-----------------------------|------------------------------|------------------|---------------------------------------|--------------------------|--|--|-----------------------|--------------|
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast  | 513,519             | 114,418.46           | 81.38                       | 0.22                         | 420              | 3.67                                  | 0.82                     | 0.38   | 0.15                                   | 0.95 (0.84, 1.08)     | 0.465        |
| Inhaled Corticosteroids                                      | 1,332,531           | 269,995.16           | 74.01                       | 0.20                         | 889              | 3.29                                  | 0.67                     |  |  |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast  | 457,377             | 55,017.00            | 43.94                       | 0.12                         | 232              | 4.22                                  | 0.51                     | -0.15  | -0.02                                  | 0.97 (0.81, 1.16)     | 0.713        |
| Inhaled Corticosteroids                                      | 457,377             | 55,017.00            | 43.94                       | 0.12                         | 240              | 4.36                                  | 0.52                     |  |  |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast  | 457,377             | 102,042.72           | 81.49                       | 0.22                         | 381              | 3.73                                  | 0.83                     | -0.12  | 0.07                                   | 1.04 (0.90, 1.20)     | 0.616        |
| Inhaled Corticosteroids                                      | 457,377             | 90,527.75            | 72.29                       | 0.20                         | 349              | 3.86                                  | 0.76                     |  |  |                       |              |

**Table 7b. Summary of Inpatient Depressive Disorder Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inhaled Corticosteroid 30-day Extension and Gap by Analysis Type**

| Medical Product  | Number of New Users | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|-----------------------|--------------|
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 513,519             | 0.96 (0.84, 1.09)     | 0.523        |
| Inhaled Corticosteroids                                      | 1,332,531           |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 457,377             | 0.97 (0.81, 1.16)     | 0.713        |
| Inhaled Corticosteroids                                      | 457,377             |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 457,377             | 1.04 (0.90, 1.21)     | 0.58         |
| Inhaled Corticosteroids                                      | 457,377             |                       |              |

**Table 8a. Summary of Inpatient Depressive Disorder Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inhaled Corticosteroid 30-day Extension and Gap by Analysis Type and History of Psychiatric Disorder**

| Medical Product   | Number of New Users | Person-Years at Risk | Average Person-Days at Risk | Average Person-Years at Risk | Number of Events | Incidence Rate per 1,000 Person-Years | Risk per 1,000 New Users | Incidence Rate Difference per 1,000 Person-Years | Difference in Risk per 1,000 New Users | Hazard Ratio (95% CI) | Wald P-Value |
|---|---------------------|----------------------|-----------------------------|------------------------------|------------------|---------------------------------------|--------------------------|--|--|-----------------------|--------------|
| <b>No History of Psychiatric Disorder</b>                           |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 321,597             | 66,926.75            | 76.01                       | 0.21                         | 32               | 0.48                                  | 0.10                     | -0.11  | -0.02                                  | 0.83 (0.54, 1.29)     | 0.414        |
| Inhaled Corticosteroids   | 910,882             | 182,558.40           | 73.20                       | 0.20                         | 107              | 0.59                                  | 0.12                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 287,233             | 34,234.52            | 43.53                       | 0.12                         | 15               | 0.44                                  | 0.05                     | -0.47  | -0.06                                  | 0.48 (0.26, 0.90)     | 0.021        |
| Inhaled Corticosteroids   | 287,233             | 34,234.52            | 43.53                       | 0.12                         | 31               | 0.91                                  | 0.11                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 287,233             | 59,791.12            | 76.03                       | 0.21                         | 26               | 0.43                                  | 0.09                     | -0.25  | -0.04                                  | 0.65 (0.39, 1.09)     | 0.101        |
| Inhaled Corticosteroids   | 287,233             | 55,678.05            | 70.80                       | 0.19                         | 38               | 0.68                                  | 0.13                     |  |  |                       |              |
| <b>History of Psychiatric Disorder</b>                              |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 191,922             | 47,491.72            | 90.38                       | 0.25                         | 388              | 8.17                                  | 2.02                     | -0.77  | 0.17                                   | 0.95 (0.84, 1.09)     | 0.485        |
| Inhaled Corticosteroids   | 421,649             | 87,436.76            | 75.74                       | 0.21                         | 782              | 8.94                                  | 1.85                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 166,750             | 20,403.83            | 44.69                       | 0.12                         | 212              | 10.39                                 | 1.27                     | 0.25   | 0.03                                   | 1.02 (0.85, 1.24)     | 0.807        |
| Inhaled Corticosteroids   | 166,750             | 20,403.83            | 44.69                       | 0.12                         | 207              | 10.15                                 | 1.24                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 166,750             | 41,437.47            | 90.76                       | 0.25                         | 350              | 8.45                                  | 2.10                     | -0.57  | 0.25                                   | 1.06 (0.90, 1.24)     | 0.485        |
| Inhaled Corticosteroids   | 166,750             | 34,149.89            | 74.80                       | 0.20                         | 308              | 9.02                                  | 1.85                     |  |  |                       |              |

**Table 8b. Summary of Inpatient Depressive Disorder Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inhaled Corticosteroid 30-day Extension and Gap by Analysis Type and History of Psychiatric Disorder**

| Medical Product  | Number of<br>New Users | Hazard Ratio<br>(95% CI) | Wald<br>P-Value |
|--|------------------------|--------------------------|-----------------|
| No History of Psychiatric Disorder                           |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 321,597                | 0.81 (0.52, 1.26)        | 0.35            |
| Inhaled Corticosteroids                                      | 910,882                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 287,233                | 0.48 (0.26, 0.90)        | 0.021           |
| Inhaled Corticosteroids                                      | 287,233                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 287,233                | 0.63 (0.37, 1.05)        | 0.076           |
| Inhaled Corticosteroids                                      | 287,233                |                          |                 |
| History of Psychiatric Disorder                              |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 191,922                | 0.96 (0.84, 1.10)        | 0.587           |
| Inhaled Corticosteroids                                      | 421,649                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 166,750                | 1.03 (0.85, 1.25)        | 0.769           |
| Inhaled Corticosteroids                                      | 166,750                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 166,750                | 1.07 (0.91, 1.25)        | 0.419           |
| Inhaled Corticosteroids                                      | 166,750                |                          |                 |

**Table 9a. Summary of Inpatient Depressive Disorder Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inhaled Corticosteroid 30-day Extension and Gap by Analysis Type and Sex**

| Medical Product  | Number of New Users | Person-Years at Risk | Average             | Average              | Number of Events | Incidence                   | Risk per        | Incidence                              | Difference in            | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|----------------------|---------------------|----------------------|------------------|-----------------------------|-----------------|--|--------------------------|-----------------------|--------------|
|  |                     |                      | Person-Days at Risk | Person-Years at Risk |                  | Rate per 1,000 Person-Years | 1,000 New Users | Rate Difference per 1,000 Person-Years | Risk per 1,000 New Users |                       |              |
| Male   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 191,582             | 40,834.60            | 77.85               | 0.21                 | 117              | 2.87                        | 0.61            | 0.67                                   | 0.16                     | 1.07 (0.84, 1.36)     | 0.579        |
| Inhaled Corticosteroids                                      | 542,631             | 110,591.65           | 74.44               | 0.20                 | 243              | 2.20                        | 0.45            |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 172,540             | 20,772.13            | 43.97               | 0.12                 | 68               | 3.27                        | 0.39            | 0.10                                   | 0.01                     | 1.03 (0.73, 1.45)     | 0.863        |
| Inhaled Corticosteroids                                      | 172,540             | 20,772.13            | 43.97               | 0.12                 | 66               | 3.18                        | 0.38            |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 172,540             | 36,793.88            | 77.89               | 0.21                 | 107              | 2.91                        | 0.62            | 0.32                                   | 0.11                     | 1.21 (0.90, 1.61)     | 0.205        |
| Inhaled Corticosteroids                                      | 172,540             | 33,954.87            | 71.88               | 0.20                 | 88               | 2.59                        | 0.51            |  |                          |                       |              |
| Female   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 321,937             | 73,583.86            | 83.48               | 0.23                 | 303              | 4.12                        | 0.94            | 0.07                                   | 0.12                     | 0.91 (0.78, 1.05)     | 0.189        |
| Inhaled Corticosteroids                                      | 789,900             | 159,403.51           | 73.71               | 0.20                 | 646              | 4.05                        | 0.82            |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 281,810             | 33,857.93            | 43.88               | 0.12                 | 165              | 4.87                        | 0.59            | -0.35                                  | -0.04                    | 0.93 (0.75, 1.15)     | 0.517        |
| Inhaled Corticosteroids                                      | 281,810             | 33,857.93            | 43.88               | 0.12                 | 177              | 5.23                        | 0.63            |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 281,810             | 64,512.63            | 83.61               | 0.23                 | 272              | 4.22                        | 0.97            | -0.36                                  | 0.06                     | 1.00 (0.84, 1.18)     | 0.959        |
| Inhaled Corticosteroids                                      | 281,810             | 55,929.93            | 72.49               | 0.20                 | 256              | 4.58                        | 0.91            |  |                          |                       |              |

**Table 9b. Summary of Inpatient Depressive Disorder Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inhaled Corticosteroid 30-day Extension and Gap by Analysis Type and Sex**

| Medical Product  | Number of New Users | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|-----------------------|--------------|
| Male   |                     |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 191,582             | 1.07 (0.84, 1.36)     | 0.605        |
| Inhaled Corticosteroids                                      | 542,631             |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 172,540             | 1.03 (0.73, 1.45)     | 0.863        |
| Inhaled Corticosteroids                                      | 172,540             |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 172,540             | 1.21 (0.90, 1.62)     | 0.2          |
| Inhaled Corticosteroids                                      | 172,540             |                       |              |
| Female   |                     |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 321,937             | 0.91 (0.79, 1.06)     | 0.237        |
| Inhaled Corticosteroids                                      | 789,900             |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 281,810             | 0.93 (0.75, 1.15)     | 0.517        |
| Inhaled Corticosteroids                                      | 281,810             |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 281,810             | 1.00 (0.84, 1.19)     | 0.993        |
| Inhaled Corticosteroids                                      | 281,810             |                       |              |



**Table 10a. Summary of Inpatient Depressive Disorder Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inhaled Corticosteroid 30-day Extension and Gap by Analysis Type and Age Group**

| Medical Product  | Number of New Users | Person-Years at Risk | Average Person-Days at Risk | Average Person-Years at Risk | Number of Events | Incidence Rate per 1,000 Person-Years | Risk per 1,000 New Users | Incidence Rate                    | Difference in            | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|----------------------|-----------------------------|------------------------------|------------------|---------------------------------------|--------------------------|-----------------------------------|--------------------------|-----------------------|--------------|
|  |                     |                      |                             |                              |                  |                                       |                          | Difference per 1,000 Person-Years | Risk per 1,000 New Users |                       |              |
| 6-11 years   |                     |                      |                             |                              |                  |                                       |                          |                                   |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                             |                              |                  |                                       |                          |                                   |                          |                       |              |
| Montelukast  | 92,294              | 17,293.63            | 68.44                       | 0.19                         | 11               | 0.64                                  | 0.12                     | -0.01                             | -0.01                    | 0.67 (0.32, 1.40)     | 0.289        |
| Inhaled Corticosteroids                                      | 269,772             | 52,223.91            | 70.71                       | 0.19                         | 34               | 0.65                                  | 0.13                     |                                   |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                             |                              |                  |                                       |                          |                                   |                          |                       |              |
| Montelukast  | 82,660              | 9,734.78             | 43.02                       | 0.12                         | 7                | 0.72                                  | 0.08                     | -0.51                             | -0.06                    | 0.58 (0.23, 1.48)     | 0.257        |
| Inhaled Corticosteroids                                      | 82,660              | 9,734.78             | 43.02                       | 0.12                         | 12               | 1.23                                  | 0.15                     |                                   |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                             |                              |                  |                                       |                          |                                   |                          |                       |              |
| Montelukast  | 82,660              | 15,522.96            | 68.59                       | 0.19                         | 10               | 0.64                                  | 0.12                     | -0.35                             | -0.06                    | 0.75 (0.33, 1.72)     | 0.501        |
| Inhaled Corticosteroids                                      | 82,660              | 15,027.24            | 66.40                       | 0.18                         | 15               | 1.00                                  | 0.18                     |                                   |                          |                       |              |
| 12-17 years  |                     |                      |                             |                              |                  |                                       |                          |                                   |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                             |                              |                  |                                       |                          |                                   |                          |                       |              |
| Montelukast  | 61,854              | 10,741.68            | 63.43                       | 0.17                         | 74               | 6.89                                  | 1.20                     | 0.36                              | -0.03                    | 0.98 (0.73, 1.33)     | 0.916        |
| Inhaled Corticosteroids                                      | 152,571             | 28,647.02            | 68.58                       | 0.19                         | 187              | 6.53                                  | 1.23                     |                                   |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                             |                              |                  |                                       |                          |                                   |                          |                       |              |
| Montelukast  | 50,191              | 5,768.37             | 41.98                       | 0.11                         | 42               | 7.28                                  | 0.84                     | -0.52                             | -0.06                    | 0.93 (0.61, 1.42)     | 0.748        |
| Inhaled Corticosteroids                                      | 50,191              | 5,768.37             | 41.98                       | 0.11                         | 45               | 7.80                                  | 0.90                     |                                   |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                             |                              |                  |                                       |                          |                                   |                          |                       |              |
| Montelukast  | 50,191              | 8,711.32             | 63.39                       | 0.17                         | 59               | 6.77                                  | 1.18                     | 0.16                              | 0.02                     | 1.08 (0.75, 1.57)     | 0.675        |
| Inhaled Corticosteroids                                      | 50,191              | 8,771.99             | 63.84                       | 0.17                         | 58               | 6.61                                  | 1.16                     |                                   |                          |                       |              |
| 18+ years  |                     |                      |                             |                              |                  |                                       |                          |                                   |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                             |                              |                  |                                       |                          |                                   |                          |                       |              |
| Montelukast  | 359,371             | 86,383.15            | 87.80                       | 0.24                         | 335              | 3.88                                  | 0.93                     | 0.35                              | 0.20                     | 1.00 (0.87, 1.15)     | 0.982        |
| Inhaled Corticosteroids                                      | 910,188             | 189,124.23           | 75.89                       | 0.21                         | 668              | 3.53                                  | 0.73                     |                                   |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                             |                              |                  |                                       |                          |                                   |                          |                       |              |
| Montelukast  | 308,196             | 37,700.76            | 44.68                       | 0.12                         | 174              | 4.62                                  | 0.56                     | -0.13                             | -0.02                    | 0.97 (0.79, 1.20)     | 0.79         |
| Inhaled Corticosteroids                                      | 308,196             | 37,700.76            | 44.68                       | 0.12                         | 179              | 4.75                                  | 0.58                     |                                   |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                             |                              |                  |                                       |                          |                                   |                          |                       |              |
| Montelukast  | 308,196             | 74,636.76            | 88.45                       | 0.24                         | 303              | 4.06                                  | 0.98                     | -0.11                             | 0.12                     | 1.05 (0.89, 1.25)     | 0.545        |
| Inhaled Corticosteroids                                      | 308,196             | 63,787.99            | 75.60                       | 0.21                         | 266              | 4.17                                  | 0.86                     |                                   |                          |                       |              |

**Table 10b. Summary of Inpatient Depressive Disorder Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inhaled Corticosteroid 30-day Extension and Gap by Analysis Type and Age Group**

| Medical Product  | Number of<br>New Users | Hazard Ratio<br>(95% CI) | Wald<br>P-Value |
|--|------------------------|--------------------------|-----------------|
| 6-11 years   |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 92,294                 | 0.63 (0.30, 1.34)        | 0.230           |
| Inhaled Corticosteroids                                      | 269,772                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 82,660                 | 0.58 (0.23, 1.48)        | 0.257           |
| Inhaled Corticosteroids                                      | 82,660                 |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 82,660                 | 0.71 (0.30, 1.65)        | 0.428           |
| Inhaled Corticosteroids                                      | 82,660                 |                          |                 |
| 12-17 years  |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 61,854                 | 0.99 (0.73, 1.34)        | 0.95            |
| Inhaled Corticosteroids                                      | 152,571                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 50,191                 | 0.93 (0.61, 1.42)        | 0.748           |
| Inhaled Corticosteroids                                      | 50,191                 |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 50,191                 | 1.08 (0.75, 1.57)        | 0.675           |
| Inhaled Corticosteroids                                      | 50,191                 |                          |                 |
| 18+ years  |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 359,371                | 1.01 (0.87, 1.16)        | 0.927           |
| Inhaled Corticosteroids                                      | 910,188                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 308,196                | 0.97 (0.79, 1.20)        | 0.790           |
| Inhaled Corticosteroids                                      | 308,196                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 308,196                | 1.06 (0.90, 1.26)        | 0.490           |
| Inhaled Corticosteroids                                      | 308,196                |                          |                 |

**Table 11a. Summary of Inpatient Depressive Disorder Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inhaled Corticosteroid 30-day Extension and Gap by Analysis Type and Year**

| Medical Product  | Number of New Users | Person-Years at Risk | Average             | Average              | Number of Events | Incidence                   | Risk per        | Incidence                              | Difference in            | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|----------------------|---------------------|----------------------|------------------|-----------------------------|-----------------|--|--------------------------|-----------------------|--------------|
|  |                     |                      | Person-Days at Risk | Person-Years at Risk |                  | Rate per 1,000 Person-Years | 1,000 New Users | Rate Difference per 1,000 Person-Years | Risk per 1,000 New Users |                       |              |
| 2000-2007  |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 53,082              | 12,027.03            | 82.76               | 0.23                 | 52               | 4.32                        | 0.98            | 0.98                                   | 0.32                     | 0.61 (0.44, 0.85)     | 0.003        |
| Inhaled Corticosteroids                                      | 380,780             | 75,274.95            | 72.20               | 0.20                 | 252              | 3.35                        | 0.66            |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 44,926              | 5,330.38             | 43.34               | 0.12                 | 33               | 6.19                        | 0.73            | -1.88                                  | -0.22                    | 0.77 (0.49, 1.21)     | 0.253        |
| Inhaled Corticosteroids                                      | 44,926              | 5,330.38             | 43.34               | 0.12                 | 43               | 8.07                        | 0.96            |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 44,926              | 10,334.11            | 84.02               | 0.23                 | 46               | 4.45                        | 1.02            | -2.03                                  | -0.16                    | 0.81 (0.54, 1.22)     | 0.318        |
| Inhaled Corticosteroids                                      | 44,926              | 8,172.94             | 66.45               | 0.18                 | 53               | 6.48                        | 1.18            |  |                          |                       |              |
| 2008-2015  |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 460,437             | 102,391.43           | 81.22               | 0.22                 | 368              | 3.59                        | 0.80            | 0.32                                   | 0.13                     | 1.05 (0.91, 1.20)     | 0.526        |
| Inhaled Corticosteroids                                      | 951,751             | 194,720.21           | 74.73               | 0.20                 | 637              | 3.27                        | 0.67            |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 410,335             | 49,457.77            | 44.02               | 0.12                 | 198              | 4.00                        | 0.48            | 0.10                                   | 0.01                     | 1.03 (0.84, 1.25)     | 0.800        |
| Inhaled Corticosteroids                                      | 410,335             | 49,457.77            | 44.02               | 0.12                 | 193              | 3.90                        | 0.47            |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 410,335             | 91,286.65            | 81.26               | 0.22                 | 334              | 3.66                        | 0.81            | 0.08                                   | 0.10                     | 1.08 (0.92, 1.27)     | 0.319        |
| Inhaled Corticosteroids                                      | 410,335             | 81,961.46            | 72.96               | 0.20                 | 293              | 3.57                        | 0.71            |  |                          |                       |              |

**Table 11b. Summary of Inpatient Depressive Disorder Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, Inhaled Corticosteroid 30-day Extension and Gap by Analysis Type and Year**

| Medical Product  | Number of New Users | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|-----------------------|--------------|
| 2000-2007  |                     |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 53,082              | 0.60 (0.43, 0.84)     | 0.003        |
| Inhaled Corticosteroids                                      | 380,780             |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 44,926              | 0.77 (0.49, 1.21)     | 0.253        |
| Inhaled Corticosteroids                                      | 44,926              |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 44,926              | 0.80 (0.53, 1.21)     | 0.293        |
| Inhaled Corticosteroids                                      | 44,926              |                       |              |
| 2008-2015  |                     |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 460,437             | 1.06 (0.92, 1.21)     | 0.428        |
| Inhaled Corticosteroids                                      | 951,751             |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 410,335             | 1.03 (0.84, 1.25)     | 0.800        |
| Inhaled Corticosteroids                                      | 410,335             |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 410,335             | 1.09 (0.93, 1.28)     | 0.280        |
| Inhaled Corticosteroids                                      | 410,335             |                       |              |

**Table 12a. Summary of Inpatient Depressive Disorder Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, No Episode Extension by Analysis Type**

| Medical Product  | Number of<br>New Users | Person-Years<br>at Risk | Average                | Average                 | Number of<br>Events | Incidence                         | Risk per           | Incidence                                       | Difference in                  | Hazard Ratio<br>(95% CI) | Wald<br>P-Value |
|--|------------------------|-------------------------|------------------------|-------------------------|---------------------|-----------------------------------|--------------------|---|--------------------------------|--------------------------|-----------------|
|  |                        |                         | Person-Days<br>at Risk | Person-Years<br>at Risk |                     | Rate per<br>1,000<br>Person-Years | 1,000<br>New Users | Rate<br>Difference<br>per 1,000<br>Person-Years | Risk per<br>1,000<br>New Users |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                         |                        |                         |                     |                                   |                    |   |                                |                          |                 |
| Montelukast  | 513,510                | 99,175.06               | 70.54                  | 0.19                    | 361                 | 3.64                              | 0.70               | 0.28  | 0.31                           | 0.97 (0.84, 1.13)        | 0.736           |
| Inhaled Corticosteroids                                      | 1,331,472              | 157,077.92              | 43.09                  | 0.12                    | 528                 | 3.36                              | 0.40               |   |                                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                         |                        |                         |                     |                                   |                    |   |                                |                          |                 |
| Montelukast  | 457,152                | 35,118.06               | 28.06                  | 0.08                    | 160                 | 4.56                              | 0.35               | 0.23  | 0.02                           | 1.05 (0.84, 1.31)        | 0.651           |
| Inhaled Corticosteroids                                      | 457,152                | 35,118.06               | 28.06                  | 0.08                    | 152                 | 4.33                              | 0.33               |   |                                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                         |                        |                         |                     |                                   |                    |   |                                |                          |                 |
| Montelukast  | 457,152                | 88,309.84               | 70.56                  | 0.19                    | 325                 | 3.68                              | 0.71               | -0.29   | 0.26                           | 1.07 (0.89, 1.28)        | 0.458           |
| Inhaled Corticosteroids                                      | 457,152                | 51,851.38               | 41.43                  | 0.11                    | 206                 | 3.97                              | 0.45               |   |                                |                          |                 |

**Table 12b. Summary of Inpatient Depressive Disorder Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, No Episode Extension by Analysis Type**

| Medical Product  | Number of New Users | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|-----------------------|--------------|
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 513,510             | 0.98 (0.85, 1.14)     | 0.816        |
| Inhaled Corticosteroids                                      | 1,331,472           |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 457,152             | 1.05 (0.84, 1.31)     | 0.691        |
| Inhaled Corticosteroids                                      | 457,152             |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 457,152             | 1.07 (0.89, 1.28)     | 0.485        |
| Inhaled Corticosteroids                                      | 457,152             |                       |              |

**Table 13a. Summary of Inpatient Depressive Disorder Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, No Episode Extension by Analysis Type and History of Psychiatric Disorder**

| Medical Product   | Number of New Users | Person-Years at Risk | Average Person-Days at Risk | Average Person-Years at Risk | Number of Events | Incidence Rate per 1,000 Person-Years | Risk per 1,000 New Users | Incidence Rate Difference per 1,000 Person-Years | Difference in Risk per 1,000 New Users | Hazard Ratio (95% CI) | Wald P-Value |
|---|---------------------|----------------------|-----------------------------|------------------------------|------------------|---------------------------------------|--------------------------|--|--|-----------------------|--------------|
| <b>No History of Psychiatric Disorder</b>                           |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 321,594             | 56,959.85            | 64.69                       | 0.18                         | 22               | 0.39                                  | 0.07                     | -0.16  | 0.00                                   | 0.79 (0.45, 1.38)     | 0.408        |
| Inhaled Corticosteroids   | 910,185             | 105,459.83           | 42.32                       | 0.12                         | 58               | 0.55                                  | 0.06                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 287,308             | 21,676.80            | 27.56                       | 0.08                         | 9                | 0.42                                  | 0.03                     | -0.37  | -0.03                                  | 0.53 (0.24, 1.19)     | 0.123        |
| Inhaled Corticosteroids   | 287,308             | 21,676.80            | 27.56                       | 0.08                         | 17               | 0.78                                  | 0.06                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 287,308             | 50,887.96            | 64.69                       | 0.18                         | 21               | 0.41                                  | 0.07                     | -0.23  | 0.00                                   | 0.77 (0.41, 1.45)     | 0.412        |
| Inhaled Corticosteroids   | 287,308             | 31,361.75            | 39.87                       | 0.11                         | 20               | 0.64                                  | 0.07                     |  |  |                       |              |
| <b>History of Psychiatric Disorder</b>                              |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 191,916             | 42,215.21            | 80.34                       | 0.22                         | 339              | 8.03                                  | 1.77                     | -1.08  | 0.65                                   | 0.98 (0.84, 1.15)     | 0.845        |
| Inhaled Corticosteroids   | 421,287             | 51,618.10            | 44.75                       | 0.12                         | 470              | 9.11                                  | 1.12                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 166,642             | 13,169.95            | 28.87                       | 0.08                         | 149              | 11.31                                 | 0.89                     | 1.14   | 0.09                                   | 1.11 (0.88, 1.40)     | 0.373        |
| Inhaled Corticosteroids   | 166,642             | 13,169.95            | 28.87                       | 0.08                         | 134              | 10.17                                 | 0.80                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 166,642             | 36,746.54            | 80.54                       | 0.22                         | 299              | 8.14                                  | 1.79                     | -1.02  | 0.69                                   | 1.08 (0.89, 1.30)     | 0.455        |
| Inhaled Corticosteroids   | 166,642             | 20,103.64            | 44.06                       | 0.12                         | 184              | 9.15                                  | 1.10                     |  |  |                       |              |

**Table 13b. Summary of Inpatient Depressive Disorder Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, No Episode Extension by Analysis Type and History of Psychiatric Disorder**

| Medical Product  | Number of<br>New Users | Hazard Ratio<br>(95% CI) | Wald<br>P-Value |
|--|------------------------|--------------------------|-----------------|
| No History of Psychiatric Disorder                           |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 321,594                | 0.77 (0.44, 1.37)        | 0.376           |
| Inhaled Corticosteroids                                      | 910,185                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 287,308                | 0.53 (0.24, 1.19)        | 0.123           |
| Inhaled Corticosteroids                                      | 287,308                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 287,308                | 0.74 (0.39, 1.41)        | 0.364           |
| Inhaled Corticosteroids                                      | 287,308                |                          |                 |
| History of Psychiatric Disorder                              |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 191,916                | 1.00 (0.85, 1.16)        | 0.961           |
| Inhaled Corticosteroids                                      | 421,287                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 166,642                | 1.11 (0.88, 1.40)        | 0.373           |
| Inhaled Corticosteroids                                      | 166,642                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 166,642                | 1.07 (0.89, 1.30)        | 0.461           |
| Inhaled Corticosteroids                                      | 166,642                |                          |                 |



**Table 14a. Summary of Inpatient Depressive Disorder Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, No Episode Extension by Analysis Type and Sex**

| Medical Product  | Number of New Users | Person-Years at Risk | Average             | Average              | Number of Events | Incidence                   | Risk per        | Incidence                              | Difference in            | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|----------------------|---------------------|----------------------|------------------|-----------------------------|-----------------|--|--------------------------|-----------------------|--------------|
|  |                     |                      | Person-Days at Risk | Person-Years at Risk |                  | Rate per 1,000 Person-Years | 1,000 New Users | Rate Difference per 1,000 Person-Years | Risk per 1,000 New Users |                       |              |
| Male   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 191,573             | 34,914.78            | 66.57               | 0.18                 | 101              | 2.89                        | 0.53            | 0.59                                   | 0.25                     | 1.03 (0.77, 1.36)     | 0.860        |
| Inhaled Corticosteroids                                      | 542,216             | 64,172.74            | 43.23               | 0.12                 | 148              | 2.31                        | 0.27            |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 172,413             | 13,177.65            | 27.92               | 0.08                 | 49               | 3.72                        | 0.28            | 0.83                                   | 0.06                     | 1.29 (0.84, 1.97)     | 0.240        |
| Inhaled Corticosteroids                                      | 172,413             | 13,177.65            | 27.92               | 0.08                 | 38               | 2.88                        | 0.22            |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 172,413             | 31,431.36            | 66.59               | 0.18                 | 92               | 2.93                        | 0.53            | 0.27                                   | 0.24                     | 1.29 (0.91, 1.83)     | 0.158        |
| Inhaled Corticosteroids                                      | 172,413             | 19,177.72            | 40.63               | 0.11                 | 51               | 2.66                        | 0.30            |  |                          |                       |              |
| Female   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 321,937             | 64,260.27            | 72.91               | 0.20                 | 260              | 4.05                        | 0.81            | -0.04                                  | 0.33                     | 0.95 (0.79, 1.13)     | 0.535        |
| Inhaled Corticosteroids                                      | 789,256             | 92,905.18            | 42.99               | 0.12                 | 380              | 4.09                        | 0.48            |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 281,625             | 21,713.58            | 28.16               | 0.08                 | 115              | 5.30                        | 0.41            | 0.00                                   | 0.00                     | 1.00 (0.77, 1.29)     | 1.000        |
| Inhaled Corticosteroids                                      | 281,625             | 21,713.58            | 28.16               | 0.08                 | 115              | 5.30                        | 0.41            |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 281,625             | 56,232.17            | 72.93               | 0.20                 | 230              | 4.09                        | 0.82            | -0.65                                  | 0.27                     | 1.00 (0.81, 1.24)     | 0.984        |
| Inhaled Corticosteroids                                      | 281,625             | 32,293.79            | 41.88               | 0.11                 | 153              | 4.74                        | 0.54            |  |                          |                       |              |

**Table 14b. Summary of Inpatient Depressive Disorder Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, No Episode Extension by Analysis Type and Sex**

| Medical Product  | Number of New Users | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|-----------------------|--------------|
| Male   |                     |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 191,573             | 1.01 (0.76, 1.35)     | 0.920        |
| Inhaled Corticosteroids                                      | 542,216             |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 172,413             | 1.29 (0.84, 1.97)     | 0.240        |
| Inhaled Corticosteroids                                      | 172,413             |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 172,413             | 1.27 (0.90, 1.81)     | 0.177        |
| Inhaled Corticosteroids                                      | 172,413             |                       |              |
| Female   |                     |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 321,937             | 0.96 (0.80, 1.15)     | 0.652        |
| Inhaled Corticosteroids                                      | 789,256             |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 281,625             | 0.99 (0.77, 1.28)     | 0.947        |
| Inhaled Corticosteroids                                      | 281,625             |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 281,625             | 1.00 (0.81, 1.24)     | 0.987        |
| Inhaled Corticosteroids                                      | 281,625             |                       |              |

**Table 15a. Summary of Inpatient Depressive Disorder Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, No Episode Extension by Analysis Type and Age Group**

| Medical Product   | Number of New Users | Person-Years at Risk | Average Person-Days at Risk | Average Person-Years at Risk | Number of Events | Incidence Rate per 1,000 Person-Years | Risk per 1,000 New Users | Incidence Rate Difference per 1,000 Person-Years | Difference in Risk per 1,000 New Users | Hazard Ratio (95% CI) | Wald P-Value |
|---|---------------------|----------------------|-----------------------------|------------------------------|------------------|---------------------------------------|--------------------------|--|--|-----------------------|--------------|
| <b>6-11 years</b>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 92,286              | 14,246.60            | 56.39                       | 0.15                         | 10               | 0.70                                  | 0.11                     | -0.04  | 0.03                                   | 0.75 (0.32, 1.75)     | 0.502        |
| Inhaled Corticosteroids   | 269,565             | 29,813.73            | 40.40                       | 0.11                         | 22               | 0.74                                  | 0.08                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 82,677              | 6,061.03             | 26.78                       | 0.07                         | 4                | 0.66                                  | 0.05                     | -0.16  | -0.01                                  | 0.80 (0.21, 2.98)     | 0.739        |
| Inhaled Corticosteroids   | 82,677              | 6,061.03             | 26.78                       | 0.07                         | 5                | 0.82                                  | 0.06                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 82,677              | 12,814.71            | 56.61                       | 0.15                         | 9                | 0.70                                  | 0.11                     | -0.04  | 0.04                                   | 0.96 (0.33, 2.81)     | 0.942        |
| Inhaled Corticosteroids   | 82,677              | 8,053.48             | 35.58                       | 0.10                         | 6                | 0.75                                  | 0.07                     |  |  |                       |              |
| <b>12-17 years</b>  |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 61,863              | 8,667.05             | 51.17                       | 0.14                         | 61               | 7.04                                  | 0.99                     | 0.62   | 0.30                                   | 0.98 (0.69, 1.39)     | 0.899        |
| Inhaled Corticosteroids   | 152,438             | 16,359.00            | 39.20                       | 0.11                         | 105              | 6.42                                  | 0.69                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 50,266              | 3,641.66             | 26.46                       | 0.07                         | 34               | 9.34                                  | 0.68                     | 2.20   | 0.16                                   | 1.31 (0.78, 2.18)     | 0.303        |
| Inhaled Corticosteroids   | 50,266              | 3,641.66             | 26.46                       | 0.07                         | 26               | 7.14                                  | 0.52                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 50,266              | 7,058.62             | 51.29                       | 0.14                         | 51               | 7.23                                  | 1.01                     | -0.10  | 0.32                                   | 1.09 (0.70, 1.70)     | 0.702        |
| Inhaled Corticosteroids   | 50,266              | 4,775.09             | 34.70                       | 0.09                         | 35               | 7.33                                  | 0.70                     |  |  |                       |              |
| <b>18+ years</b>  |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 359,361             | 76,261.41            | 77.51                       | 0.21                         | 290              | 3.80                                  | 0.81                     | 0.19   | 0.37                                   | 1.01 (0.86, 1.20)     | 0.889        |
| Inhaled Corticosteroids   | 909,469             | 110,905.20           | 44.54                       | 0.12                         | 401              | 3.62                                  | 0.44                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 308,205             | 24,333.97            | 28.84                       | 0.08                         | 119              | 4.89                                  | 0.39                     | 0.04   | 0.00                                   | 1.01 (0.78, 1.30)     | 0.948        |
| Inhaled Corticosteroids   | 308,205             | 24,333.97            | 28.84                       | 0.08                         | 118              | 4.85                                  | 0.38                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 308,205             | 65,861.23            | 78.05                       | 0.21                         | 260              | 3.95                                  | 0.84                     | -0.27  | 0.33                                   | 1.09 (0.89, 1.34)     | 0.393        |
| Inhaled Corticosteroids   | 308,205             | 37,448.91            | 44.38                       | 0.12                         | 158              | 4.22                                  | 0.51                     |  |  |                       |              |

**Table 15b. Summary of Inpatient Depressive Disorder Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, No Episode Extension by Analysis Type and Age Group**

| Medical Product  | Number of<br>New Users | Hazard Ratio<br>(95% CI) | Wald<br>P-Value |
|--|------------------------|--------------------------|-----------------|
| 6-11 years   |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 92,286                 | 0.72 (0.30, 1.70)        | 0.451           |
| Inhaled Corticosteroids                                      | 269,565                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 82,677                 | 0.80 (0.21, 2.98)        | 0.739           |
| Inhaled Corticosteroids                                      | 82,677                 |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 82,677                 | 0.93 (0.31, 2.75)        | 0.893           |
| Inhaled Corticosteroids                                      | 82,677                 |                          |                 |
| 12-17 years  |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 61,863                 | 1.00 (0.70, 1.42)        | 0.984           |
| Inhaled Corticosteroids                                      | 152,438                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 50,266                 | 1.31 (0.78, 2.18)        | 0.303           |
| Inhaled Corticosteroids                                      | 50,266                 |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 50,266                 | 1.09 (0.70, 1.70)        | 0.702           |
| Inhaled Corticosteroids                                      | 50,266                 |                          |                 |
| 18+ years  |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 359,361                | 1.02 (0.86, 1.21)        | 0.816           |
| Inhaled Corticosteroids                                      | 909,469                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 308,205                | 1.00 (0.77, 1.29)        | 1.000           |
| Inhaled Corticosteroids                                      | 308,205                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 308,205                | 1.09 (0.89, 1.34)        | 0.411           |
| Inhaled Corticosteroids                                      | 308,205                |                          |                 |

**Table 16a. Summary of Inpatient Depressive Disorder Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, No Episode Extension by Analysis Type and Year**

| Medical Product  | Number of New Users | Person-Years at Risk | Average             | Average              | Number of Events | Incidence                   | Risk per        | Incidence                              | Difference in            | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|----------------------|---------------------|----------------------|------------------|-----------------------------|-----------------|--|--------------------------|-----------------------|--------------|
|  |                     |                      | Person-Days at Risk | Person-Years at Risk |                  | Rate per 1,000 Person-Years | 1,000 New Users | Rate Difference per 1,000 Person-Years | Risk per 1,000 New Users |                       |              |
| 2000-2007  |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 53,078              | 10,320.08            | 71.02               | 0.19                 | 43               | 4.17                        | 0.81            | 1.15                                   | 0.47                     | 0.65 (0.43, 0.97)     | 0.036        |
| Inhaled Corticosteroids                                      | 380,356             | 42,450.78            | 40.76               | 0.11                 | 128              | 3.02                        | 0.34            |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 44,784              | 3,162.57             | 25.79               | 0.07                 | 18               | 5.69                        | 0.40            | -1.58                                  | -0.11                    | 0.78 (0.42, 1.45)     | 0.436        |
| Inhaled Corticosteroids                                      | 44,784              | 3,162.57             | 25.79               | 0.07                 | 23               | 7.27                        | 0.51            |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 44,784              | 8,864.93             | 72.30               | 0.20                 | 35               | 3.95                        | 0.78            | -2.52                                  | 0.16                     | 0.79 (0.47, 1.33)     | 0.381        |
| Inhaled Corticosteroids                                      | 44,784              | 4,329.91             | 35.31               | 0.10                 | 28               | 6.47                        | 0.63            |  |                          |                       |              |
| 2008-2015  |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 460,432             | 88,854.97            | 70.49               | 0.19                 | 318              | 3.58                        | 0.69            | 0.09                                   | 0.27                     | 1.04 (0.89, 1.23)     | 0.596        |
| Inhaled Corticosteroids                                      | 951,116             | 114,627.15           | 44.02               | 0.12                 | 400              | 3.49                        | 0.42            |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 410,322             | 31,815.76            | 28.32               | 0.08                 | 143              | 4.49                        | 0.35            | 0.38                                   | 0.03                     | 1.09 (0.86, 1.38)     | 0.469        |
| Inhaled Corticosteroids                                      | 410,322             | 31,815.76            | 28.32               | 0.08                 | 131              | 4.12                        | 0.32            |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 410,322             | 79,091.79            | 70.40               | 0.19                 | 288              | 3.64                        | 0.70            | -0.12                                  | 0.27                     | 1.11 (0.91, 1.34)     | 0.303        |
| Inhaled Corticosteroids                                      | 410,322             | 47,298.10            | 42.10               | 0.12                 | 178              | 3.76                        | 0.43            |  |                          |                       |              |

**Table 16b. Summary of Inpatient Depressive Disorder Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, No Episode Extension by Analysis Type and Year**

| Medical Product  | Number of New Users | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|-----------------------|--------------|
| 2000-2007  |                     |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 53,078              | 0.64 (0.43, 0.96)     | 0.032        |
| Inhaled Corticosteroids                                      | 380,356             |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 44,784              | 0.78 (0.42, 1.45)     | 0.436        |
| Inhaled Corticosteroids                                      | 44,784              |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 44,784              | 0.78 (0.47, 1.32)     | 0.360        |
| Inhaled Corticosteroids                                      | 44,784              |                       |              |
| 2008-2015  |                     |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 460,432             | 1.06 (0.90, 1.24)     | 0.498        |
| Inhaled Corticosteroids                                      | 951,116             |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 410,322             | 1.08 (0.85, 1.37)     | 0.506        |
| Inhaled Corticosteroids                                      | 410,322             |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 410,322             | 1.10 (0.91, 1.34)     | 0.317        |
| Inhaled Corticosteroids                                      | 410,322             |                       |              |

**Table 17a. Summary of Outpatient Depressive Disorder Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type**

| Medical Product   | Number of New Users | Person-Years at Risk | Average Person-Days at Risk | Average Person-Years at Risk | Number of Events | Incidence Rate per 1,000 Person-Years | Risk per 1,000 New Users | Incidence Rate Difference per 1,000 Person-Years | Difference in Risk per 1,000 New Users | Hazard Ratio (95% CI) | Wald P-Value |
|---|---------------------|----------------------|-----------------------------|------------------------------|------------------|---------------------------------------|--------------------------|--|--|-----------------------|--------------|
| <b>Unmatched Analysis (Site-adjusted only)</b>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 513,519             | 140,202.21           | 99.72                       | 0.27                         | 22,212           | 158.43                                | 43.25                    | -3.63  | 11.33                                  | 0.92 (0.90, 0.94)     | <0.001       |
| Inhaled Corticosteroids   | 1,332,531           | 262,524.51           | 71.96                       | 0.20                         | 42,544           | 162.06                                | 31.93                    |  |  |                       |              |
| <b>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</b>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 457,377             | 60,518.08            | 48.33                       | 0.13                         | 12,625           | 208.62                                | 27.60                    | -28.36   | -3.75                                  | 0.88 (0.86, 0.90)     | <0.001       |
| Inhaled Corticosteroids   | 457,377             | 60,518.08            | 48.33                       | 0.13                         | 14,341           | 236.97                                | 31.35                    |  |  |                       |              |
| <b>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</b> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 457,377             | 125,161.31           | 99.95                       | 0.27                         | 19,598           | 156.58                                | 42.85                    | -51.21   | 3.18                                   | 0.91 (0.89, 0.93)     | <0.001       |
| Inhaled Corticosteroids   | 457,377             | 87,307.63            | 69.72                       | 0.19                         | 18,142           | 207.79                                | 39.67                    |  |  |                       |              |

**Table 17b. Summary of Outpatient Depressive Disorder Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type**

| Medical Product  | Number of New Users | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|-----------------------|--------------|
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 513,519             | 0.92 (0.90, 0.93)     | <0.001       |
| Inhaled Corticosteroids                                      | 1,332,531           |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 457,377             | 0.88 (0.86, 0.90)     | <0.001       |
| Inhaled Corticosteroids                                      | 457,377             |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 457,377             | 0.91 (0.89, 0.93)     | <0.001       |
| Inhaled Corticosteroids                                      | 457,377             |                       |              |



**Table 18a. Summary of Outpatient Depressive Disorder Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and History of Psychiatric Disorder**

| Medical Product  | Number of New Users | Person-Years at Risk | Average Person-Days at Risk | Average Person-Years at Risk | Number of Events | Incidence                   | Risk per        | Incidence                              | Difference in            | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|----------------------|-----------------------------|------------------------------|------------------|-----------------------------|-----------------|--|--------------------------|-----------------------|--------------|
|  |                     |                      |                             |                              |                  | Rate per 1,000 Person-Years | 1,000 New Users | Rate Difference per 1,000 Person-Years | Risk per 1,000 New Users |                       |              |
| No History of Psychiatric Disorder                           |                     |                      |                             |                              |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                             |                              |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 321,597             | 87,666.73            | 99.57                       | 0.27                         | 1,492            | 17.02                       | 4.64            | 0.85                                   | 1.41                     | 1.04 (0.97, 1.12)     | 0.262        |
| Inhaled Corticosteroids                                      | 910,882             | 182,070.13           | 73.01                       | 0.20                         | 2,943            | 16.16                       | 3.23            |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                             |                              |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 287,233             | 39,689.29            | 50.47                       | 0.14                         | 624              | 15.72                       | 2.17            | 0.63                                   | 0.09                     | 1.04 (0.93, 1.17)     | 0.475        |
| Inhaled Corticosteroids                                      | 287,233             | 39,689.29            | 50.47                       | 0.14                         | 599              | 15.09                       | 2.09            |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                             |                              |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 287,233             | 78,390.17            | 99.68                       | 0.27                         | 1,325            | 16.90                       | 4.61            | 1.54                                   | 1.64                     | 1.07 (0.98, 1.17)     | 0.159        |
| Inhaled Corticosteroids                                      | 287,233             | 55,539.57            | 70.62                       | 0.19                         | 853              | 15.36                       | 2.97            |  |                          |                       |              |
| History of Psychiatric Disorder                              |                     |                      |                             |                              |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                             |                              |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 191,922             | 52,535.48            | 99.98                       | 0.27                         | 20,720           | 394.40                      | 107.96          | -97.82                                 | 14.04                    | 0.89 (0.87, 0.91)     | <0.001       |
| Inhaled Corticosteroids                                      | 421,649             | 80,454.38            | 69.69                       | 0.19                         | 39,601           | 492.22                      | 93.92           |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                             |                              |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 166,750             | 20,467.39            | 44.83                       | 0.12                         | 11,546           | 564.12                      | 69.24           | -81.35                                 | -9.99                    | 0.87 (0.85, 0.90)     | <0.001       |
| Inhaled Corticosteroids                                      | 166,750             | 20,467.39            | 44.83                       | 0.12                         | 13,211           | 645.47                      | 79.23           |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                             |                              |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 166,750             | 45,788.91            | 100.30                      | 0.27                         | 18,077           | 394.79                      | 108.41          | -155.14                                | 5.83                     | 0.89 (0.88, 0.91)     | <0.001       |
| Inhaled Corticosteroids                                      | 166,750             | 31,103.99            | 68.13                       | 0.19                         | 17,105           | 549.93                      | 102.58          |  |                          |                       |              |

**Table 18b. Summary of Outpatient Depressive Disorder Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and History of Psychiatric Disorder**

| Medical Product  | Number of New Users | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|-----------------------|--------------|
| No History of Psychiatric Disorder                           |                     |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 321,597             | 1.05 (0.98, 1.13)     | 0.176        |
| Inhaled Corticosteroids                                      | 910,882             |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 287,233             | 1.04 (0.93, 1.17)     | 0.475        |
| Inhaled Corticosteroids                                      | 287,233             |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 287,233             | 1.07 (0.98, 1.18)     | 0.125        |
| Inhaled Corticosteroids                                      | 287,233             |                       |              |
| History of Psychiatric Disorder                              |                     |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 191,922             | 0.89 (0.87, 0.90)     | <0.001       |
| Inhaled Corticosteroids                                      | 421,649             |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 166,750             | 0.87 (0.85, 0.90)     | <0.001       |
| Inhaled Corticosteroids                                      | 166,750             |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 166,750             | 0.89 (0.87, 0.91)     | <0.001       |
| Inhaled Corticosteroids                                      | 166,750             |                       |              |

**Table 19a. Summary of Outpatient Depressive Disorder Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Sex**

| Medical Product  | Number of New Users | Person-Years at Risk | Average             | Average              | Number of Events | Incidence                   | Risk per        | Incidence                              | Difference in            | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|----------------------|---------------------|----------------------|------------------|-----------------------------|-----------------|--|--------------------------|-----------------------|--------------|
|  |                     |                      | Person-Days at Risk | Person-Years at Risk |                  | Rate per 1,000 Person-Years | 1,000 New Users | Rate Difference per 1,000 Person-Years | Risk per 1,000 New Users |                       |              |
| Male   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 191,582             | 52,116.91            | 99.36               | 0.27                 | 4,359            | 83.64                       | 22.75           | -1.10                                  | 5.75                     | 0.91 (0.87, 0.94)     | <0.001       |
| Inhaled Corticosteroids                                      | 542,631             | 108,880.37           | 73.29               | 0.20                 | 9,226            | 84.74                       | 17.00           |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 172,540             | 23,544.01            | 49.84               | 0.14                 | 2,592            | 110.09                      | 15.02           | -9.17                                  | -1.25                    | 0.92 (0.88, 0.97)     | 0.003        |
| Inhaled Corticosteroids                                      | 172,540             | 23,544.01            | 49.84               | 0.14                 | 2,808            | 119.27                      | 16.27           |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 172,540             | 47,003.97            | 99.50               | 0.27                 | 3,905            | 83.08                       | 22.63           | -23.39                                 | 2.09                     | 0.93 (0.89, 0.97)     | 0.002        |
| Inhaled Corticosteroids                                      | 172,540             | 33,285.70            | 70.46               | 0.19                 | 3,544            | 106.47                      | 20.54           |  |                          |                       |              |
| Female   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 321,937             | 88,085.30            | 99.94               | 0.27                 | 17,853           | 202.68                      | 55.45           | -14.17                                 | 13.27                    | 0.90 (0.89, 0.92)     | <0.001       |
| Inhaled Corticosteroids                                      | 789,900             | 153,644.14           | 71.05               | 0.19                 | 33,318           | 216.85                      | 42.18           |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 281,810             | 36,598.93            | 47.44               | 0.13                 | 9,926            | 271.21                      | 35.22           | -39.15                                 | -5.08                    | 0.87 (0.85, 0.90)     | <0.001       |
| Inhaled Corticosteroids                                      | 281,810             | 36,598.93            | 47.44               | 0.13                 | 11,359           | 310.36                      | 40.31           |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 281,810             | 77,267.76            | 100.15              | 0.27                 | 15,549           | 201.24                      | 55.18           | -69.89                                 | 3.80                     | 0.90 (0.88, 0.93)     | <0.001       |
| Inhaled Corticosteroids                                      | 281,810             | 53,400.22            | 69.21               | 0.19                 | 14,478           | 271.12                      | 51.38           |  |                          |                       |              |

**Table 19b. Summary of Outpatient Depressive Disorder Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Sex**

| Medical Product  | Number of<br>New Users | Hazard Ratio<br>(95% CI) | Wald<br>P-Value |
|--|------------------------|--------------------------|-----------------|
| Male   |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 191,582                | 0.91 (0.87, 0.94)        | <0.001          |
| Inhaled Corticosteroids                                      | 542,631                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 172,540                | 0.92 (0.88, 0.97)        | 0.003           |
| Inhaled Corticosteroids                                      | 172,540                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 172,540                | 0.93 (0.89, 0.97)        | 0.002           |
| Inhaled Corticosteroids                                      | 172,540                |                          |                 |
| Female   |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 321,937                | 0.90 (0.88, 0.92)        | <0.001          |
| Inhaled Corticosteroids                                      | 789,900                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 281,810                | 0.87 (0.85, 0.90)        | <0.001          |
| Inhaled Corticosteroids                                      | 281,810                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 281,810                | 0.90 (0.88, 0.92)        | <0.001          |
| Inhaled Corticosteroids                                      | 281,810                |                          |                 |

**Table 20a. Summary of Outpatient Depressive Disorder Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Age Group**

| Medical Product  | Number of New Users | Person-Years at Risk | Average Person-Days at Risk | Average Person-Years at Risk | Number of Events | Incidence Rate per 1,000 Person-Years | Risk per 1,000 New Users | Incidence Rate Difference per 1,000 Person-Years | Difference in Risk per 1,000 New Users | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|----------------------|-----------------------------|------------------------------|------------------|---------------------------------------|--------------------------|--|--|-----------------------|--------------|
| 6-11 years   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast  | 92,294              | 23,623.53            | 93.49                       | 0.26                         | 434              | 18.37                                 | 4.70                     | 2.61   | 1.66                                   | 1.05 (0.92, 1.19)     | 0.449        |
| Inhaled Corticosteroids                                      | 269,772             | 52,101.52            | 70.54                       | 0.19                         | 821              | 15.76                                 | 3.04                     |  |  |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast  | 82,660              | 11,369.28            | 50.24                       | 0.14                         | 254              | 22.34                                 | 3.07                     | 0.70   | 0.10                                   | 1.03 (0.87, 1.23)     | 0.721        |
| Inhaled Corticosteroids                                      | 82,660              | 11,369.28            | 50.24                       | 0.14                         | 246              | 21.64                                 | 2.98                     |  |  |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast  | 82,660              | 21,168.83            | 93.54                       | 0.26                         | 384              | 18.14                                 | 4.65                     | -2.02  | 0.99                                   | 1.02 (0.87, 1.19)     | 0.843        |
| Inhaled Corticosteroids                                      | 82,660              | 14,980.87            | 66.20                       | 0.18                         | 302              | 20.16                                 | 3.65                     |  |  |                       |              |
| 12-17 years  |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast  | 61,854              | 14,181.32            | 83.74                       | 0.23                         | 1,353            | 95.41                                 | 21.87                    | -9.61  | 2.42                                   | 0.86 (0.81, 0.93)     | <0.001       |
| Inhaled Corticosteroids                                      | 152,571             | 28,260.78            | 67.66                       | 0.19                         | 2,968            | 105.02                                | 19.45                    |  |  |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast  | 50,191              | 6,647.23             | 48.37                       | 0.13                         | 789              | 118.70                                | 15.72                    | -35.35   | -4.68                                  | 0.77 (0.70, 0.85)     | <0.001       |
| Inhaled Corticosteroids                                      | 50,191              | 6,647.23             | 48.37                       | 0.13                         | 1,024            | 154.05                                | 20.40                    |  |  |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast  | 50,191              | 11,497.94            | 83.67                       | 0.23                         | 1,103            | 95.93                                 | 21.98                    | -39.10   | -1.22                                  | 0.82 (0.76, 0.89)     | <0.001       |
| Inhaled Corticosteroids                                      | 50,191              | 8,620.33             | 62.73                       | 0.17                         | 1,164            | 135.03                                | 23.19                    |  |  |                       |              |
| 18+ years  |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast  | 359,371             | 102,397.36           | 104.07                      | 0.28                         | 20,425           | 199.47                                | 56.84                    | -13.28   | 14.26                                  | 0.91 (0.90, 0.93)     | <0.001       |
| Inhaled Corticosteroids                                      | 910,188             | 182,162.20           | 73.10                       | 0.20                         | 38,755           | 212.75                                | 42.58                    |  |  |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast  | 308,196             | 40,400.34            | 47.88                       | 0.13                         | 11,278           | 279.16                                | 36.59                    | -39.26   | -5.15                                  | 0.88 (0.85, 0.90)     | <0.001       |
| Inhaled Corticosteroids                                      | 308,196             | 40,400.34            | 47.88                       | 0.13                         | 12,864           | 318.41                                | 41.74                    |  |  |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast  | 308,196             | 88,442.04            | 104.81                      | 0.29                         | 17,595           | 198.94                                | 57.09                    | -72.72   | 3.51                                   | 0.90 (0.88, 0.92)     | <0.001       |
| Inhaled Corticosteroids                                      | 308,196             | 60,787.83            | 72.04                       | 0.20                         | 16,514           | 271.67                                | 53.58                    |  |  |                       |              |

**Table 20b. Summary of Outpatient Depressive Disorder Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Age Group**

| Medical Product  | Number of New Users | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|-----------------------|--------------|
| 6-11 years   |                     |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 92,294              | 1.06 (0.93, 1.20)     | 0.410        |
| Inhaled Corticosteroids                                      | 269,772             |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 82,660              | 1.03 (0.87, 1.23)     | 0.721        |
| Inhaled Corticosteroids                                      | 82,660              |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 82,660              | 1.02 (0.87, 1.19)     | 0.813        |
| Inhaled Corticosteroids                                      | 82,660              |                       |              |
| 12-17 years  |                     |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 61,854              | 0.86 (0.80, 0.93)     | <0.001       |
| Inhaled Corticosteroids                                      | 152,571             |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 50,191              | 0.77 (0.70, 0.85)     | <0.001       |
| Inhaled Corticosteroids                                      | 50,191              |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 50,191              | 0.82 (0.76, 0.89)     | <0.001       |
| Inhaled Corticosteroids                                      | 50,191              |                       |              |
| Age Group: 18+   |                     |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 359,371             | 0.91 (0.89, 0.93)     | <0.001       |
| Inhaled Corticosteroids                                      | 910,188             |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 308,196             | 0.88 (0.85, 0.90)     | <0.001       |
| Inhaled Corticosteroids                                      | 308,196             |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 308,196             | 0.90 (0.88, 0.92)     | <0.001       |
| Inhaled Corticosteroids                                      | 308,196             |                       |              |

**Table 21a. Summary of Outpatient Depressive Disorder Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Year**

| Medical Product  | Number of New Users | Person-Years at Risk | Average             | Average              | Number of Events | Incidence                   | Risk per        | Incidence                              | Difference in            | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|----------------------|---------------------|----------------------|------------------|-----------------------------|-----------------|--|--------------------------|-----------------------|--------------|
|  |                     |                      | Person-Days at Risk | Person-Years at Risk |                  | Rate per 1,000 Person-Years | 1,000 New Users | Rate Difference per 1,000 Person-Years | Risk per 1,000 New Users |                       |              |
| 2000-2007  |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 53,082              | 15,665.03            | 107.79              | 0.30                 | 1,570            | 100.22                      | 29.58           | -14.31                                 | 7.34                     | 0.75 (0.70, 0.80)     | <0.001       |
| Inhaled Corticosteroids                                      | 380,780             | 73,937.36            | 70.92               | 0.19                 | 8,468            | 114.53                      | 22.24           |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 44,926              | 5,950.36             | 48.38               | 0.13                 | 880              | 147.89                      | 19.59           | -18.49                                 | -2.45                    | 0.89 (0.81, 0.97)     | 0.011        |
| Inhaled Corticosteroids                                      | 44,926              | 5,950.36             | 48.38               | 0.13                 | 990              | 166.38                      | 22.04           |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 44,926              | 13,410.23            | 109.03              | 0.30                 | 1,364            | 101.71                      | 30.36           | -45.79                                 | 4.10                     | 0.90 (0.83, 0.98)     | 0.015        |
| Inhaled Corticosteroids                                      | 44,926              | 8,000.05             | 65.04               | 0.18                 | 1,180            | 147.50                      | 26.27           |  |                          |                       |              |
| 2008-2015  |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 460,437             | 124,537.18           | 98.79               | 0.27                 | 20,642           | 165.75                      | 44.83           | -14.94                                 | 9.03                     | 0.94 (0.92, 0.96)     | <0.001       |
| Inhaled Corticosteroids                                      | 951,751             | 188,587.14           | 72.37               | 0.20                 | 34,076           | 180.69                      | 35.80           |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 410,335             | 54,305.67            | 48.34               | 0.13                 | 11,687           | 215.21                      | 28.48           | -29.94                                 | -3.96                    | 0.88 (0.86, 0.90)     | <0.001       |
| Inhaled Corticosteroids                                      | 410,335             | 54,305.67            | 48.34               | 0.13                 | 13,313           | 245.15                      | 32.44           |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 410,335             | 111,197.33           | 98.98               | 0.27                 | 18,153           | 163.25                      | 44.24           | -51.01                                 | 3.03                     | 0.91 (0.89, 0.93)     | <0.001       |
| Inhaled Corticosteroids                                      | 410,335             | 78,922.77            | 70.25               | 0.19                 | 16,910           | 214.26                      | 41.21           |  |                          |                       |              |

**Table 21b. Summary of Outpatient Depressive Disorder Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Year**

| Medical Product  | Number of<br>New Users | Hazard Ratio<br>(95% CI) | Wald<br>P-Value |
|--|------------------------|--------------------------|-----------------|
| 2000-2007  |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 53,082                 | 0.75 (0.70, 0.80)        | <0.001          |
| Inhaled Corticosteroids                                      | 380,780                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 44,926                 | 0.89 (0.81, 0.97)        | 0.011           |
| Inhaled Corticosteroids                                      | 44,926                 |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 44,926                 | 0.90 (0.83, 0.98)        | 0.013           |
| Inhaled Corticosteroids                                      | 44,926                 |                          |                 |
| 2008-2015  |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 460,437                | 0.94 (0.92, 0.95)        | <0.001          |
| Inhaled Corticosteroids                                      | 951,751                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 410,335                | 0.88 (0.86, 0.90)        | <0.001          |
| Inhaled Corticosteroids                                      | 410,335                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 410,335                | 0.91 (0.89, 0.93)        | <0.001          |
| Inhaled Corticosteroids                                      | 410,335                |                          |                 |



**Table 22a. Summary of Self-Harm Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type**

| Medical Product  | Number of New Users | Person-Years at Risk | Average             | Average              | Number of Events | Incidence                   | Risk per        | Incidence                              | Difference in            | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|----------------------|---------------------|----------------------|------------------|-----------------------------|-----------------|--|--------------------------|-----------------------|--------------|
|  |                     |                      | Person-Days at Risk | Person-Years at Risk |                  | Rate per 1,000 Person-Years | 1,000 New Users | Rate Difference per 1,000 Person-Years | Risk per 1,000 New Users |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 513,519             | 114,492.95           | 81.44               | 0.22                 | 138              | 1.21                        | 0.27            | 0.05                                   | 0.09                     | 0.82 (0.65, 1.04)     | 0.099        |
| Inhaled Corticosteroids                                      | 1,332,531           | 204,895.75           | 56.16               | 0.15                 | 236              | 1.15                        | 0.18            |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 457,377             | 48,749.94            | 38.93               | 0.11                 | 61               | 1.25                        | 0.13            | -0.14                                  | -0.02                    | 0.90 (0.63, 1.27)     | 0.538        |
| Inhaled Corticosteroids                                      | 457,377             | 48,749.94            | 38.93               | 0.11                 | 68               | 1.39                        | 0.15            |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 457,377             | 102,109.93           | 81.54               | 0.22                 | 124              | 1.21                        | 0.27            | -0.19                                  | 0.06                     | 0.92 (0.69, 1.21)     | 0.533        |
| Inhaled Corticosteroids                                      | 457,377             | 67,686.16            | 54.05               | 0.15                 | 95               | 1.40                        | 0.21            |  |                          |                       |              |

**Table 22b. Summary of Self-Harm Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type**

| Medical Product  | Number of<br>New Users | Hazard Ratio<br>(95% CI) | Wald<br>P-Value |
|--|------------------------|--------------------------|-----------------|
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 513,519                | 0.85 (0.67, 1.08)        | 0.178           |
| Inhaled Corticosteroids                                      | 1,332,531              |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 457,377                | 0.90 (0.63, 1.27)        | 0.538           |
| Inhaled Corticosteroids                                      | 457,377                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 457,377                | 0.96 (0.72, 1.26)        | 0.747           |
| Inhaled Corticosteroids                                      | 457,377                |                          |                 |

**Table 23a. Summary of Self-Harm Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and History of Psychiatric Disorder**

| Medical Product   | Number of New Users | Person-Years at Risk | Average Person-Days at Risk | Average Person-Years at Risk | Number of Events | Incidence Rate per 1,000 Person-Years | Risk per 1,000 New Users | Incidence Rate Difference per 1,000 Person-Years | Difference in Risk per 1,000 New Users | Hazard Ratio (95% CI) | Wald P-Value |
|---|---------------------|----------------------|-----------------------------|------------------------------|------------------|---------------------------------------|--------------------------|--|--|-----------------------|--------------|
| <b>No History of Psychiatric Disorder</b>                           |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 321,597             | 66,932.55            | 76.02                       | 0.21                         | 8                | 0.12                                  | 0.02                     | -0.01  | 0.01                                   | 0.85 (0.33, 2.15)     | 0.728        |
| Inhaled Corticosteroids   | 910,882             | 138,642.41           | 55.59                       | 0.15                         | 18               | 0.13                                  | 0.02                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 287,233             | 30,490.92            | 38.77                       | 0.11                         | 4                | 0.13                                  | 0.01                     | 0.03   | 0.00                                   | 1.33 (0.30, 5.96)     | 0.706        |
| Inhaled Corticosteroids   | 287,233             | 30,490.92            | 38.77                       | 0.11                         | 3                | 0.10                                  | 0.01                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 287,233             | 59,796.79            | 76.04                       | 0.21                         | 7                | 0.12                                  | 0.02                     | 0.02   | 0.01                                   | 1.34 (0.38, 4.71)     | 0.649        |
| Inhaled Corticosteroids   | 287,233             | 41,418.43            | 52.67                       | 0.14                         | 4                | 0.10                                  | 0.01                     |  |  |                       |              |
| <b>History of Psychiatric Disorder</b>                              |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 191,922             | 47,560.40            | 90.51                       | 0.25                         | 130              | 2.73                                  | 0.68                     | -0.56  | 0.16                                   | 0.81 (0.64, 1.03)     | 0.080        |
| Inhaled Corticosteroids   | 421,649             | 66,253.34            | 57.39                       | 0.16                         | 218              | 3.29                                  | 0.52                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 166,750             | 17,917.36            | 39.25                       | 0.11                         | 52               | 2.90                                  | 0.31                     | -1.00  | -0.11                                  | 0.74 (0.52, 1.06)     | 0.104        |
| Inhaled Corticosteroids   | 166,750             | 17,917.36            | 39.25                       | 0.11                         | 70               | 3.91                                  | 0.42                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 166,750             | 41,499.51            | 90.90                       | 0.25                         | 115              | 2.77                                  | 0.69                     | -0.72  | 0.15                                   | 0.89 (0.66, 1.18)     | 0.405        |
| Inhaled Corticosteroids   | 166,750             | 25,743.21            | 56.39                       | 0.15                         | 90               | 3.50                                  | 0.54                     |  |  |                       |              |

**Table 23b. Summary of Self-Harm Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and History of Psychiatric Disorder**

| Medical Product  | Number of<br>New Users | Hazard Ratio<br>(95% CI) | Wald<br>P-Value |
|--|------------------------|--------------------------|-----------------|
| No History of Psychiatric Disorder                           |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 321,597                | 0.81 (0.31, 2.09)        | 0.657           |
| Inhaled Corticosteroids                                      | 910,882                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 287,233                | 1.33 (0.30, 5.96)        | 0.706           |
| Inhaled Corticosteroids                                      | 287,233                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 287,233                | 1.29 (0.36, 4.62)        | 0.693           |
| Inhaled Corticosteroids                                      | 287,233                |                          |                 |
| History of Psychiatric Disorder                              |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 191,922                | 0.84 (0.66, 1.07)        | 0.168           |
| Inhaled Corticosteroids                                      | 421,649                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 166,750                | 0.75 (0.53, 1.08)        | 0.123           |
| Inhaled Corticosteroids                                      | 166,750                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 166,750                | 0.93 (0.70, 1.24)        | 0.617           |
| Inhaled Corticosteroids                                      | 166,750                |                          |                 |

**Table 24a. Summary of Self-Harm Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Sex**

| Medical Product  | Number of New Users | Person-Years at Risk | Average             | Average              | Number of Events | Incidence                   | Risk per        | Incidence                              | Difference in            | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|----------------------|---------------------|----------------------|------------------|-----------------------------|-----------------|--|--------------------------|-----------------------|--------------|
|  |                     |                      | Person-Days at Risk | Person-Years at Risk |                  | Rate per 1,000 Person-Years | 1,000 New Users | Rate Difference per 1,000 Person-Years | Risk per 1,000 New Users |                       |              |
| Male   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 191,582             | 40,864.59            | 77.91               | 0.21                 | 24               | 0.59                        | 0.13            | 0.04                                   | 0.04                     | 0.75 (0.43, 1.29)     | 0.302        |
| Inhaled Corticosteroids                                      | 542,631             | 83,892.88            | 56.47               | 0.15                 | 46               | 0.55                        | 0.08            |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 172,540             | 18,462.11            | 39.08               | 0.11                 | 9                | 0.49                        | 0.05            | 0.05                                   | 0.01                     | 1.12 (0.43, 2.92)     | 0.808        |
| Inhaled Corticosteroids                                      | 172,540             | 18,462.11            | 39.08               | 0.11                 | 8                | 0.43                        | 0.05            |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 172,540             | 36,821.74            | 77.95               | 0.21                 | 23               | 0.62                        | 0.13            | 0.11                                   | 0.06                     | 1.16 (0.58, 2.36)     | 0.671        |
| Inhaled Corticosteroids                                      | 172,540             | 25,254.25            | 53.46               | 0.15                 | 13               | 0.51                        | 0.08            |  |                          |                       |              |
| Female   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 321,937             | 73,628.36            | 83.53               | 0.23                 | 114              | 1.55                        | 0.35            | -0.02                                  | 0.11                     | 0.83 (0.64, 1.07)     | 0.140        |
| Inhaled Corticosteroids                                      | 789,900             | 121,002.87           | 55.95               | 0.15                 | 190              | 1.57                        | 0.24            |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 281,810             | 29,943.72            | 38.81               | 0.11                 | 51               | 1.70                        | 0.18            | -0.30                                  | -0.03                    | 0.85 (0.59, 1.23)     | 0.393        |
| Inhaled Corticosteroids                                      | 281,810             | 29,943.72            | 38.81               | 0.11                 | 60               | 2.00                        | 0.21            |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 281,810             | 64,551.93            | 83.66               | 0.23                 | 100              | 1.55                        | 0.35            | -0.38                                  | 0.07                     | 0.87 (0.65, 1.18)     | 0.386        |
| Inhaled Corticosteroids                                      | 281,810             | 41,950.38            | 54.37               | 0.15                 | 81               | 1.93                        | 0.29            |  |                          |                       |              |

**Table 24b. Summary of Self-Harm Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Sex**

| Medical Product  | Number of<br>New Users | Hazard Ratio<br>(95% CI) | Wald<br>P-Value |
|--|------------------------|--------------------------|-----------------|
| Male   |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 191,582                | 0.80 (0.46, 1.39)        | 0.429           |
| Inhaled Corticosteroids                                      | 542,631                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 172,540                | 1.12 (0.43, 2.92)        | 0.808           |
| Inhaled Corticosteroids                                      | 172,540                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 172,540                | 1.32 (0.64, 2.70)        | 0.454           |
| Inhaled Corticosteroids                                      | 172,540                |                          |                 |
| Female   |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 321,937                | 0.85 (0.66, 1.10)        | 0.211           |
| Inhaled Corticosteroids                                      | 789,900                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 281,810                | 0.85 (0.59, 1.23)        | 0.393           |
| Inhaled Corticosteroids                                      | 281,810                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 281,810                | 0.90 (0.66, 1.22)        | 0.498           |
| Inhaled Corticosteroids                                      | 281,810                |                          |                 |

**Table 25a. Summary of Self-Harm Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Age Group**

| Medical Product   | Number of New Users | Person-Years at Risk | Average Person-Days at Risk | Average Person-Years at Risk | Number of Events | Incidence Rate per 1,000 Person-Years | Risk per 1,000 New Users | Incidence Rate Difference per 1,000 Person-Years | Difference in Risk per 1,000 New Users | Hazard Ratio (95% CI) | Wald P-Value |
|---|---------------------|----------------------|-----------------------------|------------------------------|------------------|---------------------------------------|--------------------------|--|--|-----------------------|--------------|
| <b>6-11 years</b>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 92,294              | 17,300.21            | 68.46                       | 0.19                         | 2                | 0.12                                  | 0.02                     | 0.12   | 0.02                                   | -                     | -            |
| Inhaled Corticosteroids   | 269,772             | 39,754.20            | 53.82                       | 0.15                         | 0                | 0.00                                  | 0.00                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 82,660              | 8,681.02             | 38.36                       | 0.11                         | 1                | 0.12                                  | 0.01                     | 0.12   | 0.01                                   | -                     | -            |
| Inhaled Corticosteroids   | 82,660              | 8,681.02             | 38.36                       | 0.11                         | 0                | 0.00                                  | 0.00                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 82,660              | 15,529.47            | 68.62                       | 0.19                         | 1                | 0.06                                  | 0.01                     | 0.06   | 0.01                                   | -                     | -            |
| Inhaled Corticosteroids   | 82,660              | 11,038.21            | 48.77                       | 0.13                         | 0                | 0.00                                  | 0.00                     |  |  |                       |              |
| <b>12-17 years</b>  |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 61,854              | 10,749.60            | 63.48                       | 0.17                         | 14               | 1.30                                  | 0.23                     | 0.12   | 0.06                                   | 0.89 (0.43, 1.85)     | 0.749        |
| Inhaled Corticosteroids   | 152,571             | 22,000.27            | 52.67                       | 0.14                         | 26               | 1.18                                  | 0.17                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 50,191              | 5,223.21             | 38.01                       | 0.10                         | 6                | 1.15                                  | 0.12                     | -0.19  | -0.02                                  | 0.86 (0.29, 2.55)     | 0.782        |
| Inhaled Corticosteroids   | 50,191              | 5,223.21             | 38.01                       | 0.10                         | 7                | 1.34                                  | 0.14                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 50,191              | 8,718.21             | 63.44                       | 0.17                         | 11               | 1.26                                  | 0.22                     | 0.04   | 0.06                                   | 1.04 (0.41, 2.66)     | 0.931        |
| Inhaled Corticosteroids   | 50,191              | 6,537.89             | 47.58                       | 0.13                         | 8                | 1.22                                  | 0.16                     |  |  |                       |              |
| <b>18+ years</b>  |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 359,371             | 86,443.13            | 87.86                       | 0.24                         | 122              | 1.41                                  | 0.34                     | -0.06  | 0.11                                   | 0.82 (0.64, 1.05)     | 0.115        |
| Inhaled Corticosteroids   | 910,188             | 143,141.28           | 57.44                       | 0.16                         | 210              | 1.47                                  | 0.23                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 308,196             | 33,221.87            | 39.37                       | 0.11                         | 56               | 1.69                                  | 0.18                     | -0.18  | -0.02                                  | 0.90 (0.63, 1.30)     | 0.581        |
| Inhaled Corticosteroids   | 308,196             | 33,221.87            | 39.37                       | 0.11                         | 62               | 1.87                                  | 0.20                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 308,196             | 74,690.00            | 88.52                       | 0.24                         | 109              | 1.46                                  | 0.35                     | -0.29  | 0.08                                   | 0.91 (0.68, 1.22)     | 0.521        |
| Inhaled Corticosteroids   | 308,196             | 47,945.46            | 56.82                       | 0.16                         | 84               | 1.75                                  | 0.27                     |  |  |                       |              |

**Table 25b. Summary of Self-Harm Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Age Group**

| Medical Product   | Number of New Users | Hazard Ratio (95% CI) | Wald P-Value |
|---|---------------------|-----------------------|--------------|
| <b>6-11 years</b>   |                     |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                       |              |
| Montelukast   | 92,294              | -                     | -            |
| Inhaled Corticosteroids   | 269,772             |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                       |              |
| Montelukast   | 82,660              | -                     | -            |
| Inhaled Corticosteroids   | 82,660              |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                       |              |
| Montelukast   | 82,660              | -                     | -            |
| Inhaled Corticosteroids   | 82,660              |                       |              |
| <b>12-17 years</b>  |                     |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                       |              |
| Montelukast   | 61,854              | 0.89 (0.43, 1.85)     | 0.749        |
| Inhaled Corticosteroids   | 152,571             |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                       |              |
| Montelukast   | 50,191              | 0.86 (0.29, 2.55)     | 0.782        |
| Inhaled Corticosteroids   | 50,191              |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                       |              |
| Montelukast   | 50,191              | 1.04 (0.41, 2.66)     | 0.931        |
| Inhaled Corticosteroids   | 50,191              |                       |              |
| <b>18+ years</b>  |                     |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                       |              |
| Montelukast   | 359,371             | 0.85 (0.67, 1.09)     | 0.209        |
| Inhaled Corticosteroids   | 910,188             |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                       |              |
| Montelukast   | 308,196             | 0.90 (0.63, 1.30)     | 0.581        |
| Inhaled Corticosteroids   | 308,196             |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                       |              |
| Montelukast   | 308,196             | 0.95 (0.71, 1.28)     | 0.749        |
| Inhaled Corticosteroids   | 308,196             |                       |              |



**Table 26a. Summary of Self-Harm Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Year**

| Medical Product  | Number of New Users | Person-Years at Risk | Average             | Average              | Number of Events | Incidence                   | Risk per        | Incidence                              | Difference in            | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|----------------------|---------------------|----------------------|------------------|-----------------------------|-----------------|--|--------------------------|-----------------------|--------------|
|  |                     |                      | Person-Days at Risk | Person-Years at Risk |                  | Rate per 1,000 Person-Years | 1,000 New Users | Rate Difference per 1,000 Person-Years | Risk per 1,000 New Users |                       |              |
| 2000-2007  |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 53,082              | 12,031.63            | 82.79               | 0.23                 | 20               | 1.66                        | 0.38            | 0.69                                   | 0.23                     | 0.77 (0.41, 1.45)     | 0.419        |
| Inhaled Corticosteroids                                      | 380,780             | 56,651.39            | 54.34               | 0.15                 | 55               | 0.97                        | 0.14            |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 44,926              | 4,597.79             | 37.38               | 0.10                 | 10               | 2.17                        | 0.22            | 0.65                                   | 0.07                     | 1.43 (0.54, 3.75)     | 0.469        |
| Inhaled Corticosteroids                                      | 44,926              | 4,597.79             | 37.38               | 0.10                 | 7                | 1.52                        | 0.16            |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 44,926              | 10,337.92            | 84.05               | 0.23                 | 17               | 1.64                        | 0.38            | 0.13                                   | 0.18                     | 1.16 (0.49, 2.74)     | 0.728        |
| Inhaled Corticosteroids                                      | 44,926              | 5,950.57             | 48.38               | 0.13                 | 9                | 1.51                        | 0.20            |  |                          |                       |              |
| 2008-2015  |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 460,437             | 102,461.33           | 81.28               | 0.22                 | 118              | 1.15                        | 0.26            | -0.07                                  | 0.07                     | 0.83 (0.65, 1.07)     | 0.145        |
| Inhaled Corticosteroids                                      | 951,751             | 148,244.36           | 56.89               | 0.16                 | 181              | 1.22                        | 0.19            |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 410,335             | 43,940.54            | 39.11               | 0.11                 | 53               | 1.21                        | 0.13            | -0.11                                  | -0.01                    | 0.91 (0.63, 1.33)     | 0.635        |
| Inhaled Corticosteroids                                      | 410,335             | 43,940.54            | 39.11               | 0.11                 | 58               | 1.32                        | 0.14            |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                     |                      |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 410,335             | 91,349.89            | 81.31               | 0.22                 | 107              | 1.17                        | 0.26            | -0.20                                  | 0.06                     | 0.90 (0.67, 1.21)     | 0.497        |
| Inhaled Corticosteroids                                      | 410,335             | 61,447.98            | 54.70               | 0.15                 | 84               | 1.37                        | 0.20            |  |                          |                       |              |

**Table 26b. Summary of Self-Harm Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Year**

| Medical Product  | Number of<br>New Users | Hazard Ratio<br>(95% CI) | Wald<br>P-Value |
|--|------------------------|--------------------------|-----------------|
| 2000-2007  |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 53,082                 | 0.78 (0.41, 1.48)        | 0.444           |
| Inhaled Corticosteroids                                      | 380,780                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 44,926                 | 1.43 (0.54, 3.75)        | 0.469           |
| Inhaled Corticosteroids                                      | 44,926                 |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 44,926                 | 1.16 (0.49, 2.74)        | 0.737           |
| Inhaled Corticosteroids                                      | 44,926                 |                          |                 |
| 2008-2015  |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 460,437                | 0.86 (0.67, 1.11)        | 0.245           |
| Inhaled Corticosteroids                                      | 951,751                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 410,335                | 0.91 (0.63, 1.33)        | 0.635           |
| Inhaled Corticosteroids                                      | 410,335                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 410,335                | 0.95 (0.70, 1.28)        | 0.725           |
| Inhaled Corticosteroids                                      | 410,335                |                          |                 |

**Table 27a. Summary of Self-Harm Through All Available Follow-Up with E-Code after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type**

| Medical Product   | Number of New Users | Person-Years at Risk | Average Person-Days at Risk | Average Person-Years at Risk | Number of Events | Incidence Rate per 1,000 Person-Years | Risk per 1,000 New Users | Incidence Rate Difference per 1,000 Person-Years | Difference in Risk per 1,000 New Users | Hazard Ratio (95% CI) | Wald P-Value |
|---|---------------------|----------------------|-----------------------------|------------------------------|------------------|---------------------------------------|--------------------------|--|--|-----------------------|--------------|
| <b>Unmatched Analysis (Site-adjusted only)</b>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 513,519             | 114,489.36           | 81.43                       | 0.22                         | 157              | 1.37                                  | 0.31                     | -0.15  | 0.07                                   | 0.72 (0.59, 0.89)     | 0.003        |
| Inhaled Corticosteroids   | 1,332,531           | 204,884.70           | 56.16                       | 0.15                         | 312              | 1.52                                  | 0.23                     |  |  |                       |              |
| <b>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</b>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 457,377             | 48,748.44            | 38.93                       | 0.11                         | 69               | 1.42                                  | 0.15                     | -0.31  | -0.03                                  | 0.82 (0.60, 1.13)     | 0.226        |
| Inhaled Corticosteroids   | 457,377             | 48,748.44            | 38.93                       | 0.11                         | 84               | 1.72                                  | 0.18                     |  |  |                       |              |
| <b>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</b> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 457,377             | 102,106.39           | 81.54                       | 0.22                         | 142              | 1.39                                  | 0.31                     | -0.41  | 0.04                                   | 0.81 (0.63, 1.05)     | 0.107        |
| Inhaled Corticosteroids   | 457,377             | 67,682.54            | 54.05                       | 0.15                         | 122              | 1.80                                  | 0.27                     |  |  |                       |              |

**Table 27b. Summary of Self-Harm Through 365 Days with E-Code after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type**

| Medical Product  | Number of<br>New Users | Hazard Ratio<br>(95% CI) | Wald<br>P-Value |
|--|------------------------|--------------------------|-----------------|
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 513,519                | 0.75 (0.61, 0.93)        | 0.009           |
| Inhaled Corticosteroids                                      | 1,332,531              |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 457,377                | 0.82 (0.60, 1.13)        | 0.226           |
| Inhaled Corticosteroids                                      | 457,377                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 457,377                | 0.86 (0.67, 1.11)        | 0.255           |
| Inhaled Corticosteroids                                      | 457,377                |                          |                 |

**Table 28a. Summary of Self-Harm Through All Available Follow-Up with E-Code after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and History of Psychiatric Disorder**

| Medical Product   | Number of New Users | Person-Years at Risk | Average Person-Days at Risk | Average Person-Years at Risk | Number of Events | Incidence Rate per 1,000 Person-Years | Risk per 1,000 New Users | Incidence Rate Difference per 1,000 Person-Years | Difference in Risk per 1,000 New Users | Hazard Ratio (95% CI) | Wald P-Value |
|---|---------------------|----------------------|-----------------------------|------------------------------|------------------|---------------------------------------|--------------------------|--|--|-----------------------|--------------|
| <b>No History of Psychiatric Disorder</b>                           |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 321,597             | 66,932.30            | 76.02                       | 0.21                         | 12               | 0.18                                  | 0.04                     | -0.01  | 0.01                                   | 0.89 (0.41, 1.93)     | 0.762        |
| Inhaled Corticosteroids   | 910,882             | 138,641.31           | 55.59                       | 0.15                         | 26               | 0.19                                  | 0.03                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 287,233             | 30,490.52            | 38.77                       | 0.11                         | 6                | 0.20                                  | 0.02                     | -0.03  | 0.00                                   | 0.86 (0.29, 2.55)     | 0.782        |
| Inhaled Corticosteroids   | 287,233             | 30,490.52            | 38.77                       | 0.11                         | 7                | 0.23                                  | 0.02                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 287,233             | 59,796.59            | 76.04                       | 0.21                         | 10               | 0.17                                  | 0.03                     | -0.05  | 0.00                                   | 0.84 (0.33, 2.13)     | 0.713        |
| Inhaled Corticosteroids   | 287,233             | 41,418.06            | 52.67                       | 0.14                         | 9                | 0.22                                  | 0.03                     |  |  |                       |              |
| <b>History of Psychiatric Disorder</b>                              |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 191,922             | 47,557.06            | 90.51                       | 0.25                         | 145              | 3.05                                  | 0.76                     | -1.27  | 0.08                                   | 0.70 (0.56, 0.88)     | 0.002        |
| Inhaled Corticosteroids   | 421,649             | 66,243.40            | 57.38                       | 0.16                         | 286              | 4.32                                  | 0.68                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 166,750             | 17,916.35            | 39.24                       | 0.11                         | 59               | 3.29                                  | 0.35                     | -1.23  | -0.13                                  | 0.73 (0.52, 1.02)     | 0.064        |
| Inhaled Corticosteroids   | 166,750             | 17,916.35            | 39.24                       | 0.11                         | 81               | 4.52                                  | 0.49                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 166,750             | 41,496.17            | 90.89                       | 0.25                         | 130              | 3.13                                  | 0.78                     | -1.22  | 0.11                                   | 0.80 (0.61, 1.04)     | 0.094        |
| Inhaled Corticosteroids   | 166,750             | 25,739.96            | 56.38                       | 0.15                         | 112              | 4.35                                  | 0.67                     |  |  |                       |              |

**Table 28b. Summary of Self-Harm Through 365 Days with E-Code after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and History of Psychiatric Disorder**

| Medical Product  | Number of New Users | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|-----------------------|--------------|
| No History of Psychiatric Disorder                           |                     |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 321,597             | 0.83 (0.37, 1.85)     | 0.645        |
| Inhaled Corticosteroids                                      | 910,882             |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 287,233             | 0.86 (0.29, 2.55)     | 0.782        |
| Inhaled Corticosteroids                                      | 287,233             |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 287,233             | 0.79 (0.30, 2.06)     | 0.631        |
| Inhaled Corticosteroids                                      | 287,233             |                       |              |
| History of Psychiatric Disorder                              |                     |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 191,922             | 0.74 (0.59, 0.93)     | 0.008        |
| Inhaled Corticosteroids                                      | 421,649             |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 166,750             | 0.74 (0.53, 1.03)     | 0.076        |
| Inhaled Corticosteroids                                      | 166,750             |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 166,750             | 0.86 (0.66, 1.12)     | 0.254        |
| Inhaled Corticosteroids                                      | 166,750             |                       |              |

**Table 29a. Summary of Self-Harm Through All Available Follow-Up with E-Code after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Sex**

| Medical Product   | Number of New Users | Person-Years at Risk | Average Person-Days at Risk | Average Person-Years at Risk | Number of Events | Incidence Rate per 1,000 Person-Years | Risk per 1,000 New Users | Incidence Rate Difference per 1,000 Person-Years | Difference in Risk per 1,000 New Users | Hazard Ratio (95% CI) | Wald P-Value |
|---|---------------------|----------------------|-----------------------------|------------------------------|------------------|---------------------------------------|--------------------------|--|--|-----------------------|--------------|
| <b>Male</b>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 191,582             | 40,863.40            | 77.91                       | 0.21                         | 32               | 0.78                                  | 0.17                     | -0.04  | 0.04                                   | 0.67 (0.42, 1.06)     | 0.086        |
| Inhaled Corticosteroids   | 542,631             | 83,890.02            | 56.47                       | 0.15                         | 69               | 0.82                                  | 0.13                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 172,540             | 18,461.45            | 39.08                       | 0.11                         | 13               | 0.70                                  | 0.08                     | -0.05  | -0.01                                  | 0.93 (0.44, 1.98)     | 0.847        |
| Inhaled Corticosteroids   | 172,540             | 18,461.45            | 39.08                       | 0.11                         | 14               | 0.76                                  | 0.08                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 172,540             | 36,820.61            | 77.95                       | 0.21                         | 30               | 0.81                                  | 0.17                     | 0.02   | 0.06                                   | 1.00 (0.55, 1.80)     | 0.998        |
| Inhaled Corticosteroids   | 172,540             | 25,252.81            | 53.46                       | 0.15                         | 20               | 0.79                                  | 0.12                     |  |  |                       |              |
| <b>Female</b>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 321,937             | 73,625.95            | 83.53                       | 0.23                         | 125              | 1.70                                  | 0.39                     | -0.31  | 0.08                                   | 0.72 (0.57, 0.92)     | 0.008        |
| Inhaled Corticosteroids   | 789,900             | 120,994.68           | 55.95                       | 0.15                         | 243              | 2.01                                  | 0.31                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 281,810             | 29,942.70            | 38.81                       | 0.11                         | 55               | 1.84                                  | 0.20                     | -0.60  | -0.06                                  | 0.75 (0.53, 1.07)     | 0.113        |
| Inhaled Corticosteroids   | 281,810             | 29,942.70            | 38.81                       | 0.11                         | 73               | 2.44                                  | 0.26                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 281,810             | 64,549.52            | 83.66                       | 0.23                         | 111              | 1.72                                  | 0.39                     | -0.69  | 0.04                                   | 0.77 (0.59, 1.02)     | 0.074        |
| Inhaled Corticosteroids   | 281,810             | 41,948.20            | 54.37                       | 0.15                         | 101              | 2.41                                  | 0.36                     |  |  |                       |              |

**Table 29b. Summary of Self-Harm Through 365 Days with E-Code after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Sex**

| Medical Product  | Number of New Users | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|-----------------------|--------------|
| Male   |                     |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 191,582             | 0.72 (0.45, 1.15)     | 0.17         |
| Inhaled Corticosteroids                                      | 542,631             |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 172,540             | 0.93 (0.44, 1.98)     | 0.847        |
| Inhaled Corticosteroids                                      | 172,540             |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 172,540             | 1.17 (0.64, 2.15)     | 0.603        |
| Inhaled Corticosteroids                                      | 172,540             |                       |              |
| Female   |                     |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                       |              |
| Montelukast  | 321,937             | 0.75 (0.59, 0.95)     | 0.018        |
| Inhaled Corticosteroids                                      | 789,900             |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                       |              |
| Montelukast  | 281,810             | 0.75 (0.53, 1.07)     | 0.113        |
| Inhaled Corticosteroids                                      | 281,810             |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                       |              |
| Montelukast  | 281,810             | 0.80 (0.61, 1.07)     | 0.131        |
| Inhaled Corticosteroids                                      | 281,810             |                       |              |



**Table 30a. Summary of Self-Harm with E-Code Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Age Group**

| Medical Product   | Number of New Users | Person-Years at Risk | Average Person-Days at Risk | Average Person-Years at Risk | Number of Events | Incidence Rate per 1,000 Person-Years | Risk per 1,000 New Users | Incidence Rate Difference per 1,000 Person-Years | Difference in Risk per 1,000 New Users | Hazard Ratio (95% CI) | Wald P-Value |
|---|---------------------|----------------------|-----------------------------|------------------------------|------------------|---------------------------------------|--------------------------|--|--|-----------------------|--------------|
| <b>6-11 years</b>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 92,294              | 17,300.21            | 68.46                       | 0.19                         | 2                | 0.12                                  | 0.02                     | 0.12   | 0.02                                   | -                     | -            |
| Inhaled Corticosteroids   | 269,772             | 39,754.20            | 53.82                       | 0.15                         | 0                | 0.00                                  | 0.00                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 82,660              | 8,681.02             | 38.36                       | 0.11                         | 1                | 0.12                                  | 0.01                     | 0.12   | 0.01                                   | -                     | -            |
| Inhaled Corticosteroids   | 82,660              | 8,681.02             | 38.36                       | 0.11                         | 0                | 0.00                                  | 0.00                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 82,660              | 15,529.47            | 68.62                       | 0.19                         | 1                | 0.06                                  | 0.01                     | 0.06   | 0.01                                   | -                     | -            |
| Inhaled Corticosteroids   | 82,660              | 11,038.21            | 48.77                       | 0.13                         | 0                | 0.00                                  | 0.00                     |  |  |                       |              |
| <b>12-17 years</b>  |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 61,854              | 10,747.85            | 63.47                       | 0.17                         | 21               | 1.95                                  | 0.34                     | -0.27  | 0.02                                   | 0.86 (0.48, 1.54)     | 0.609        |
| Inhaled Corticosteroids   | 152,571             | 21,995.68            | 52.66                       | 0.14                         | 49               | 2.23                                  | 0.32                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 50,191              | 5,223.03             | 38.01                       | 0.10                         | 11               | 2.11                                  | 0.22                     | 0.57   | 0.06                                   | 1.37 (0.55, 3.42)     | 0.493        |
| Inhaled Corticosteroids   | 50,191              | 5,223.03             | 38.01                       | 0.10                         | 8                | 1.53                                  | 0.16                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 50,191              | 8,716.52             | 63.43                       | 0.17                         | 17               | 1.95                                  | 0.34                     | 0.27   | 0.12                                   | 1.23 (0.57, 2.68)     | 0.594        |
| Inhaled Corticosteroids   | 50,191              | 6,537.82             | 47.58                       | 0.13                         | 11               | 1.68                                  | 0.22                     |  |  |                       |              |
| <b>18+ years</b>  |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 359,371             | 86,441.29            | 87.86                       | 0.24                         | 134              | 1.55                                  | 0.37                     | -0.29  | 0.08                                   | 0.72 (0.57, 0.90)     | 0.004        |
| Inhaled Corticosteroids   | 910,188             | 143,134.83           | 57.44                       | 0.16                         | 263              | 1.84                                  | 0.29                     |  |  |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 308,196             | 33,220.84            | 39.37                       | 0.11                         | 60               | 1.81                                  | 0.19                     | -0.48  | -0.05                                  | 0.79 (0.56, 1.11)     | 0.171        |
| Inhaled Corticosteroids   | 308,196             | 33,220.84            | 39.37                       | 0.11                         | 76               | 2.29                                  | 0.25                     |  |  |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                      |                             |                              |                  |                                       |                          |  |  |                       |              |
| Montelukast   | 308,196             | 74,688.16            | 88.51                       | 0.24                         | 121              | 1.62                                  | 0.39                     | -0.61  | 0.05                                   | 0.78 (0.60, 1.03)     | 0.079        |
| Inhaled Corticosteroids   | 308,196             | 47,942.90            | 56.82                       | 0.16                         | 107              | 2.23                                  | 0.35                     |  |  |                       |              |

**Table 30b. Summary of Self-Harm with E-Code Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Age Group**

| Medical Product   | Number of New Users | Hazard Ratio (95% CI) | Wald P-Value |
|---|---------------------|-----------------------|--------------|
| <b>6-11 years</b>   |                     |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                       |              |
| Montelukast   | 92,294              | -                     | -            |
| Inhaled Corticosteroids   | 269,772             |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                       |              |
| Montelukast   | 82,660              | -                     | -            |
| Inhaled Corticosteroids   | 82,660              |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                       |              |
| Montelukast   | 82,660              | -                     | -            |
| Inhaled Corticosteroids   | 82,660              |                       |              |
| <b>12-17 years</b>  |                     |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                       |              |
| Montelukast   | 61,854              | 0.88 (0.49, 1.58)     | 0.669        |
| Inhaled Corticosteroids   | 152,571             |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                       |              |
| Montelukast   | 50,191              | 1.37 (0.55, 3.42)     | 0.493        |
| Inhaled Corticosteroids   | 50,191              |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                       |              |
| Montelukast   | 50,191              | 1.23 (0.57, 2.68)     | 0.594        |
| Inhaled Corticosteroids   | 50,191              |                       |              |
| <b>18+ years</b>  |                     |                       |              |
| <i>Unmatched Analysis (Site-adjusted only)</i>                      |                     |                       |              |
| Montelukast   | 359,371             | 0.75 (0.59, 0.94)     | 0.014        |
| Inhaled Corticosteroids   | 910,188             |                       |              |
| <i>1:1 Matched Conditional Predefined Analysis; Caliper= 0.05</i>   |                     |                       |              |
| Montelukast   | 308,196             | 0.79 (0.56, 1.11)     | 0.171        |
| Inhaled Corticosteroids   | 308,196             |                       |              |
| <i>1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05</i> |                     |                       |              |
| Montelukast   | 308,196             | 0.83 (0.63, 1.09)     | 0.169        |
| Inhaled Corticosteroids   | 308,196             |                       |              |

**Table 31a. Summary of Self-Harm with E-Code Through All Available Follow-Up after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Year**

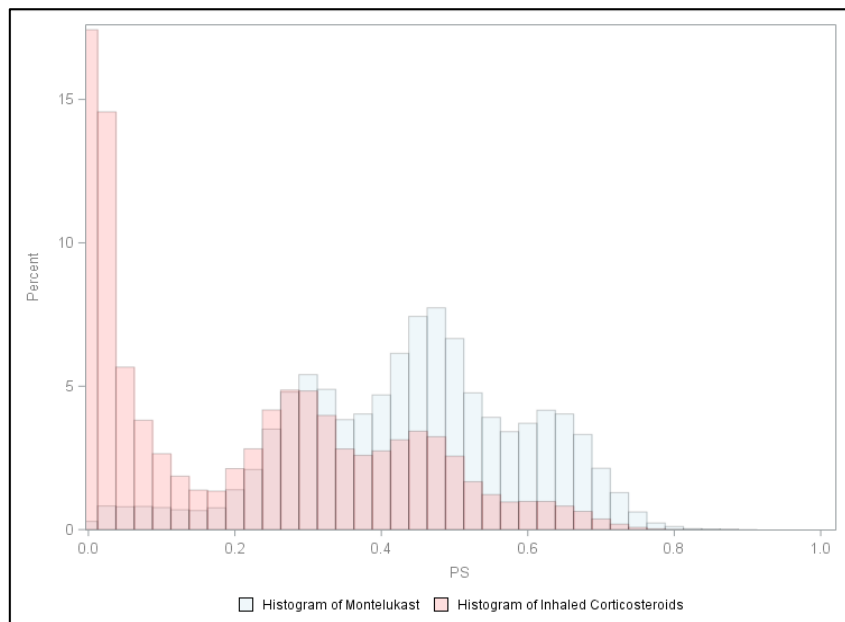
| Medical Product  | Number of New Users | Person-Years at Risk | Average Person-Days at Risk | Average Person-Years at Risk | Number of Events | Incidence                   | Risk per        | Incidence                              | Difference in            | Hazard Ratio (95% CI) | Wald P-Value |
|--|---------------------|----------------------|-----------------------------|------------------------------|------------------|-----------------------------|-----------------|--|--------------------------|-----------------------|--------------|
|  |                     |                      |                             |                              |                  | Rate per 1,000 Person-Years | 1,000 New Users | Rate Difference per 1,000 Person-Years | Risk per 1,000 New Users |                       |              |
| 2000-2007  |                     |                      |                             |                              |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                             |                              |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 53,082              | 12,030.98            | 82.78                       | 0.23                         | 27               | 2.24                        | 0.51            | 0.94                                   | 0.31                     | 0.78 (0.46, 1.32)     | 0.350        |
| Inhaled Corticosteroids                                      | 380,780             | 56,649.72            | 54.34                       | 0.15                         | 74               | 1.31                        | 0.19            |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                             |                              |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 44,926              | 4,597.44             | 37.38                       | 0.10                         | 12               | 2.61                        | 0.27            | 0.00                                   | 0.00                     | 1.00 (0.45, 2.23)     | 1.000        |
| Inhaled Corticosteroids                                      | 44,926              | 4,597.44             | 37.38                       | 0.10                         | 12               | 2.61                        | 0.27            |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                             |                              |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 44,926              | 10,337.45            | 84.04                       | 0.23                         | 22               | 2.13                        | 0.49            | -0.22                                  | 0.18                     | 1.06 (0.53, 2.15)     | 0.866        |
| Inhaled Corticosteroids                                      | 44,926              | 5,950.29             | 48.38                       | 0.13                         | 14               | 2.35                        | 0.31            |  |                          |                       |              |
| 2008-2015  |                     |                      |                             |                              |                  |                             |                 |  |                          |                       |              |
| Unmatched Analysis (Site-adjusted only)                      |                     |                      |                             |                              |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 460,437             | 102,458.37           | 81.28                       | 0.22                         | 130              | 1.27                        | 0.28            | -0.34                                  | 0.03                     | 0.71 (0.57, 0.90)     | 0.004        |
| Inhaled Corticosteroids                                      | 951,751             | 148,234.98           | 56.89                       | 0.16                         | 238              | 1.61                        | 0.25            |  |                          |                       |              |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                     |                      |                             |                              |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 410,335             | 43,939.69            | 39.11                       | 0.11                         | 58               | 1.32                        | 0.14            | -0.23                                  | -0.02                    | 0.85 (0.60, 1.21)     | 0.374        |
| Inhaled Corticosteroids                                      | 410,335             | 43,939.69            | 39.11                       | 0.11                         | 68               | 1.55                        | 0.17            |  |                          |                       |              |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                     |                      |                             |                              |                  |                             |                 |  |                          |                       |              |
| Montelukast  | 410,335             | 91,346.94            | 81.31                       | 0.22                         | 119              | 1.30                        | 0.29            | -0.42                                  | 0.03                     | 0.78 (0.60, 1.03)     | 0.075        |
| Inhaled Corticosteroids                                      | 410,335             | 61,444.64            | 54.69                       | 0.15                         | 106              | 1.73                        | 0.26            |  |                          |                       |              |

**Table 31b. Summary of Self-Harm with E-Code Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Year**

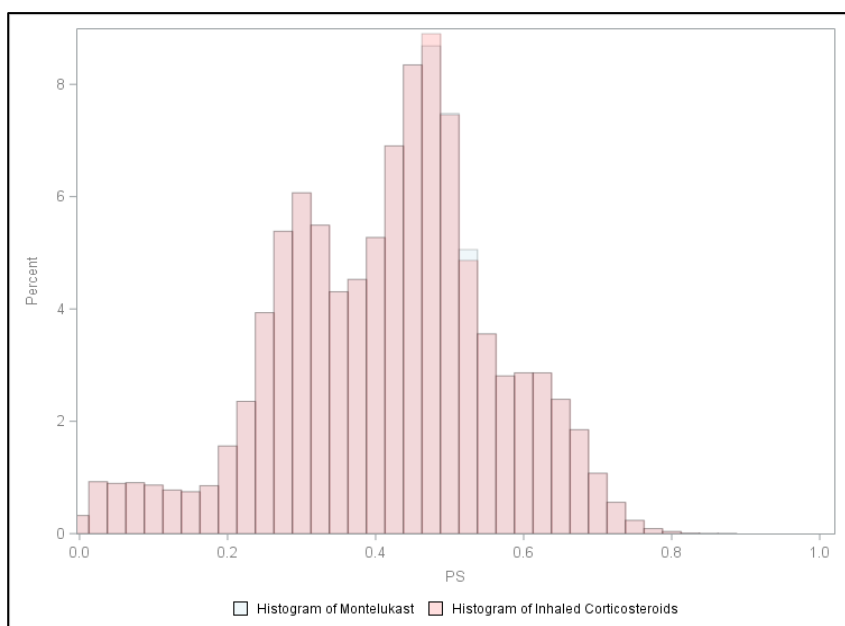
| Medical Product  | Number of<br>New Users | Hazard Ratio<br>(95% CI) | Wald<br>P-Value |
|--|------------------------|--------------------------|-----------------|
| 2000-2007  |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 53,082                 | 0.78 (0.46, 1.33)        | 0.369           |
| Inhaled Corticosteroids                                      | 380,780                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 44,926                 | 1.00 (0.45, 2.23)        | 1.000           |
| Inhaled Corticosteroids                                      | 44,926                 |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 44,926                 | 1.06 (0.52, 2.14)        | 0.874           |
| Inhaled Corticosteroids                                      | 44,926                 |                          |                 |
| 2008-2015  |                        |                          |                 |
| Unmatched Analysis (Site-adjusted only)                      |                        |                          |                 |
| Montelukast  | 460,437                | 0.75 (0.59, 0.94)        | 0.014           |
| Inhaled Corticosteroids                                      | 951,751                |                          |                 |
| 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05   |                        |                          |                 |
| Montelukast  | 410,335                | 0.85 (0.60, 1.21)        | 0.374           |
| Inhaled Corticosteroids                                      | 410,335                |                          |                 |
| 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05 |                        |                          |                 |
| Montelukast  | 410,335                | 0.84 (0.64, 1.10)        | 0.204           |
| Inhaled Corticosteroids                                      | 410,335                |                          |                 |

**Figure 1a. Propensity Score Distribution of Inpatient Depressive Disorder Before and After Matching among Montelukast and Inhaled Corticosteroid Users**

**Propensity Score Distribution Before Matching**

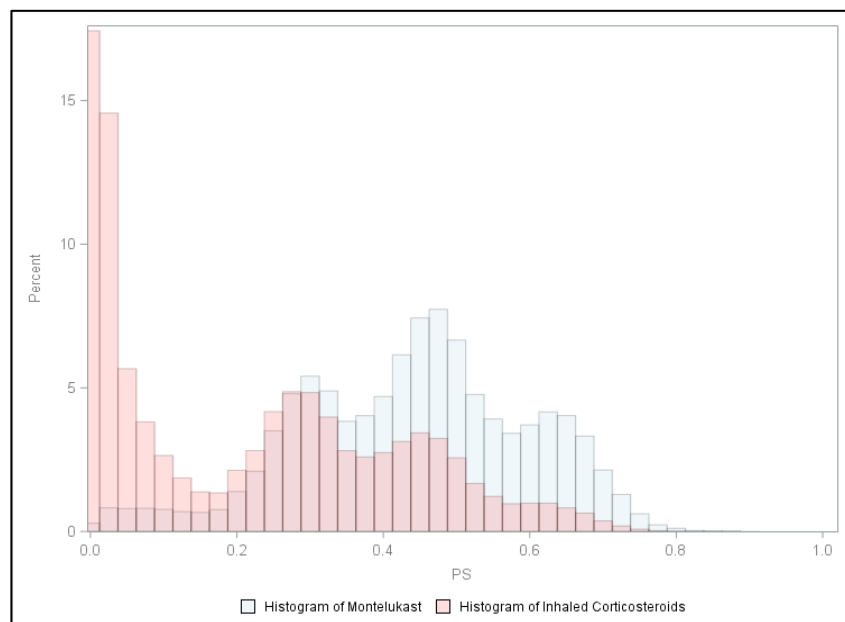


**Propensity Score 1:1 Aggregated Matched Cohort, Matched Caliper = 0.05**

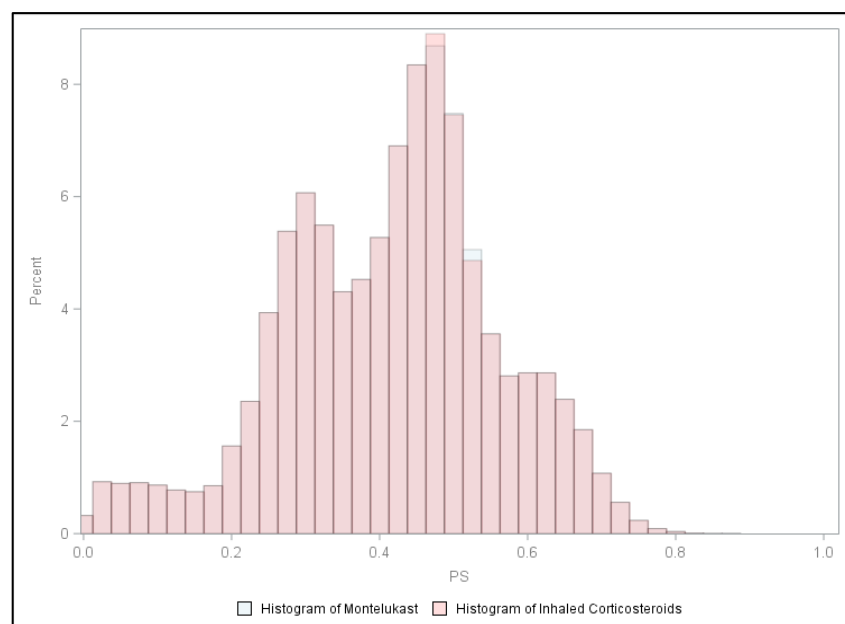


**Figure 1b. Propensity Score Distribution of Inpatient Depressive Disorder, Inhaled Corticosteroid 30-Day Extension and Gap Before and After Matching among Montelukast and Inhaled Corticosteroid Users**

**Propensity Score Distribution Before Matching**

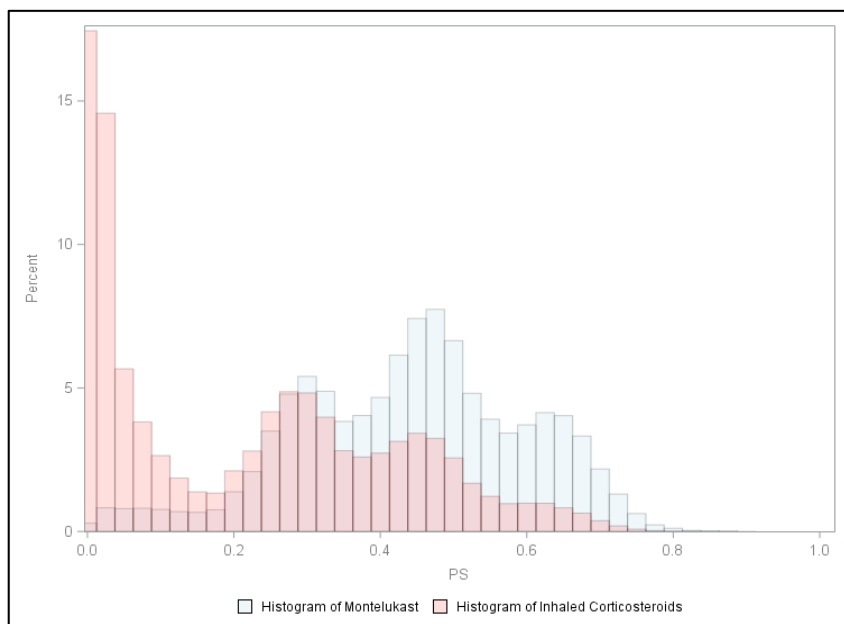


**Propensity Score 1:1 Aggregated Matched Cohort, Matched Caliper = 0.05**

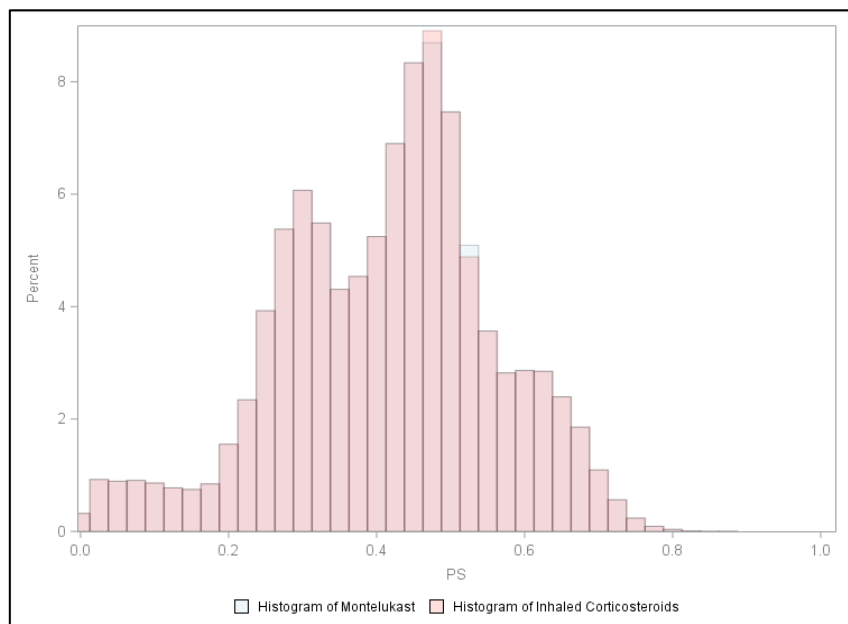


**Figure 1c. Propensity Score Distribution of Inpatient Depressive Disorder, No Episode Extension and Gap Before and After Matching among Montelukast and Inhaled Corticosteroid Users**

**Propensity Score Distribution Before Matching**

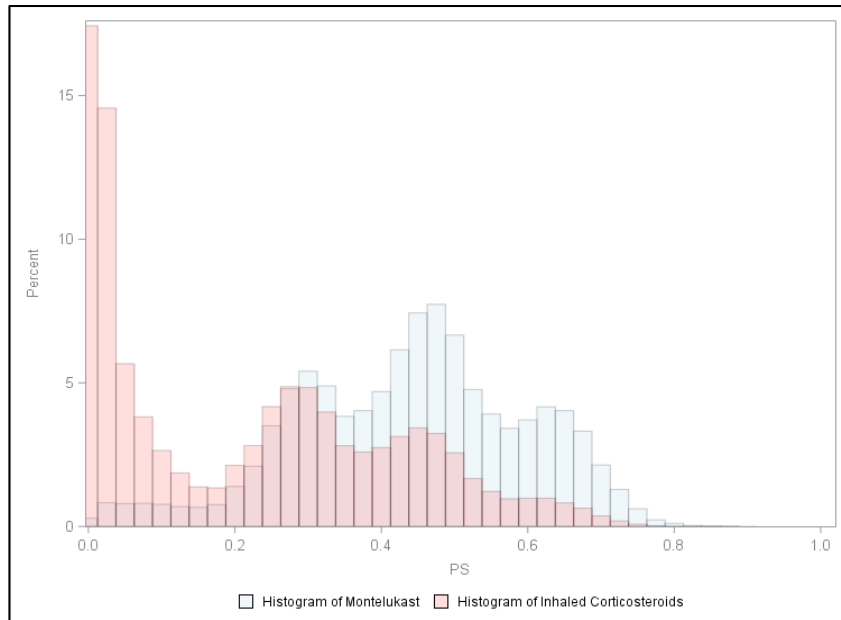


**Propensity Score 1:1 Aggregated Matched Cohort, Matched Caliper = 0.05**

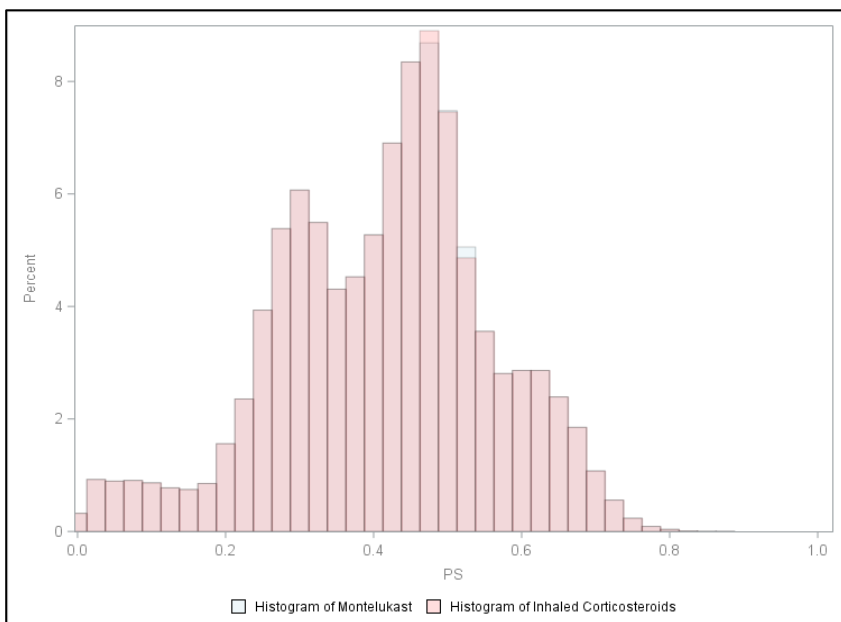


**Figure 1d. Propensity Score Distribution of Outpatient Depressive Disorder Before and After Matching among Montelukast and Inhaled Corticosteroid Users**

**Propensity Score Distribution Before Matching**



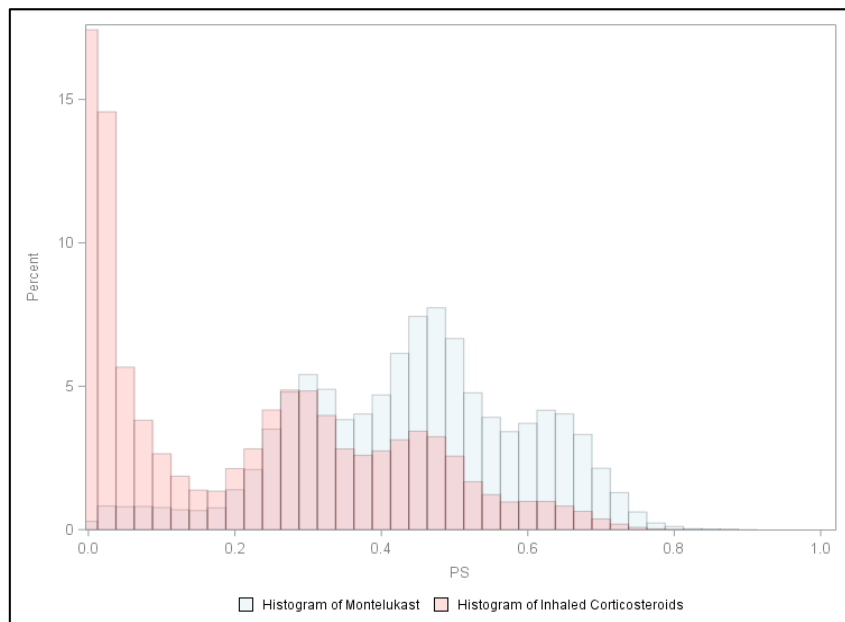
**Propensity Score 1:1 Aggregated Matched Cohort, Matched Caliper = 0.05**



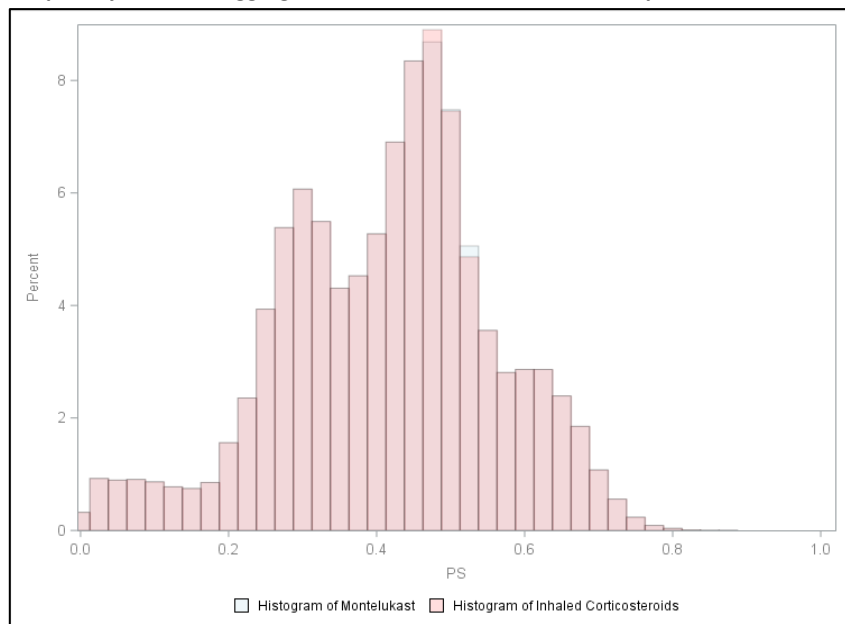


**Figure 1e. Propensity Score Distribution of Self-Harm Before and After Matching among Montelukast and Inhaled Corticosteroid Users**

**Propensity Score Distribution Before Matching**

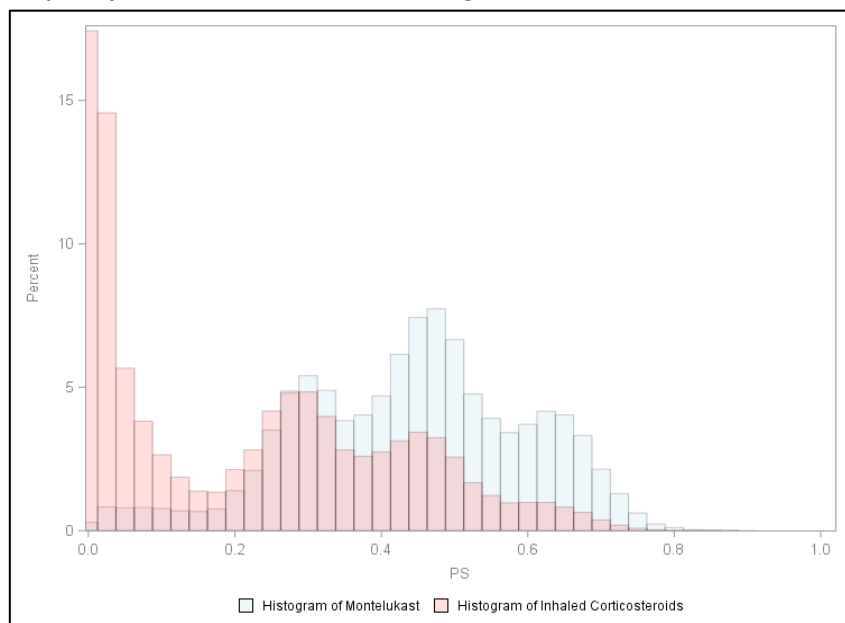


**Propensity Score 1:1 Aggregated Matched Cohort, Matched Caliper = 0.05**

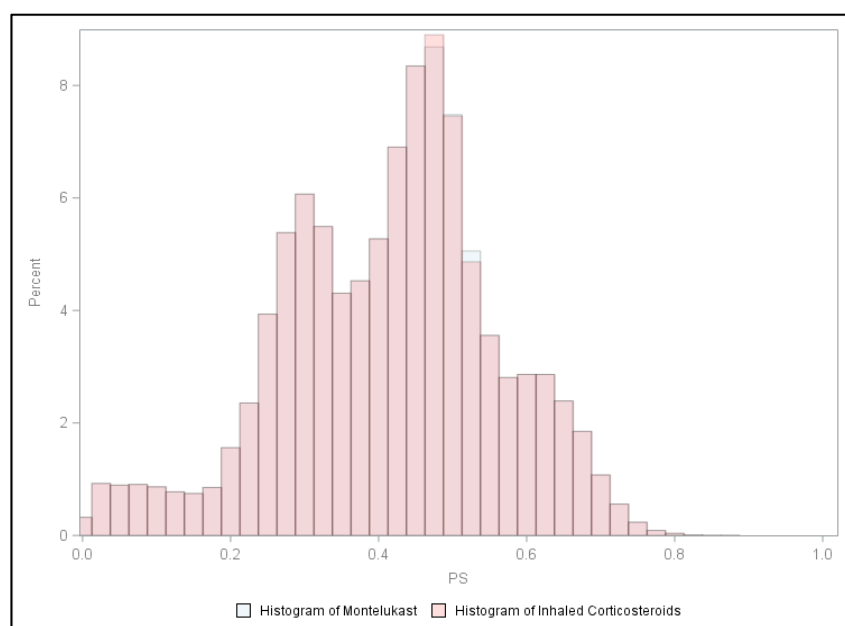


**Figure 1f. Propensity Score Distribution of Self-Harm with E-Code Before and After Matching among Montelukast and Inhaled Corticosteroid Users**

**Propensity Score Distribution Before Matching**

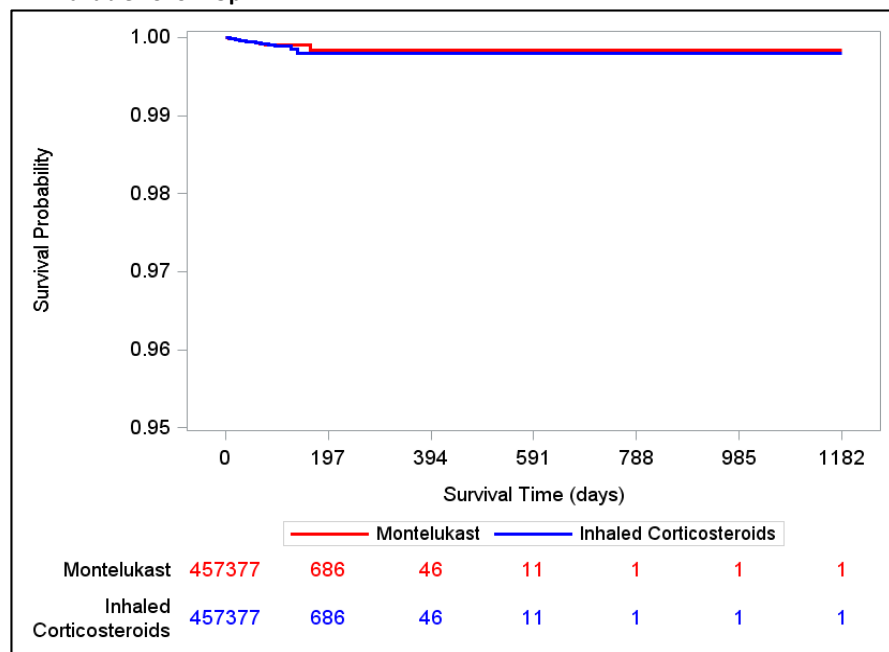


**Propensity Score 1:1 Aggregated Matched Cohort, Matched Caliper = 0.05**

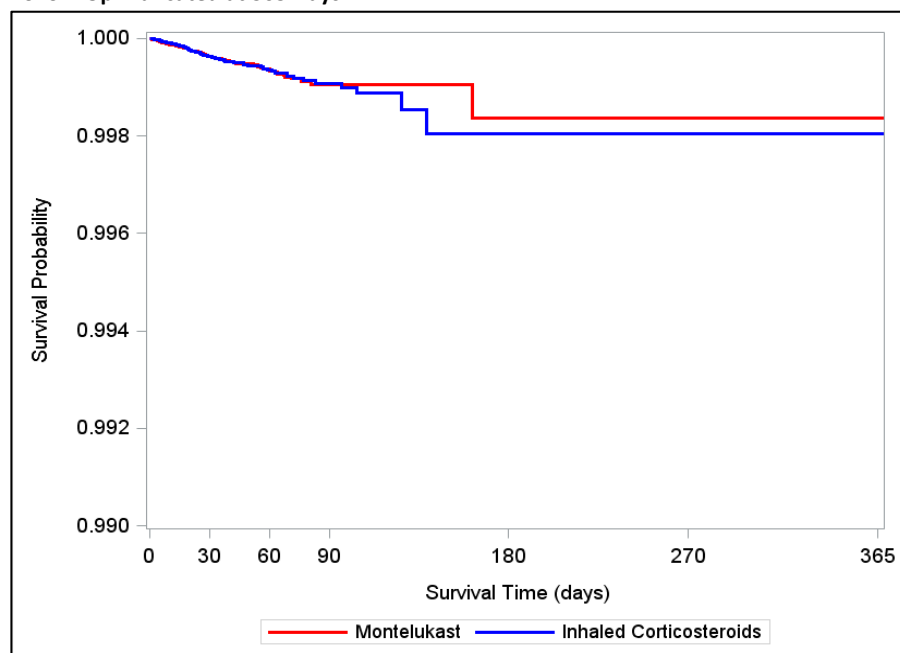


**Figure 2a. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, Conditional Matched Cohort**

**All Available Follow-Up**



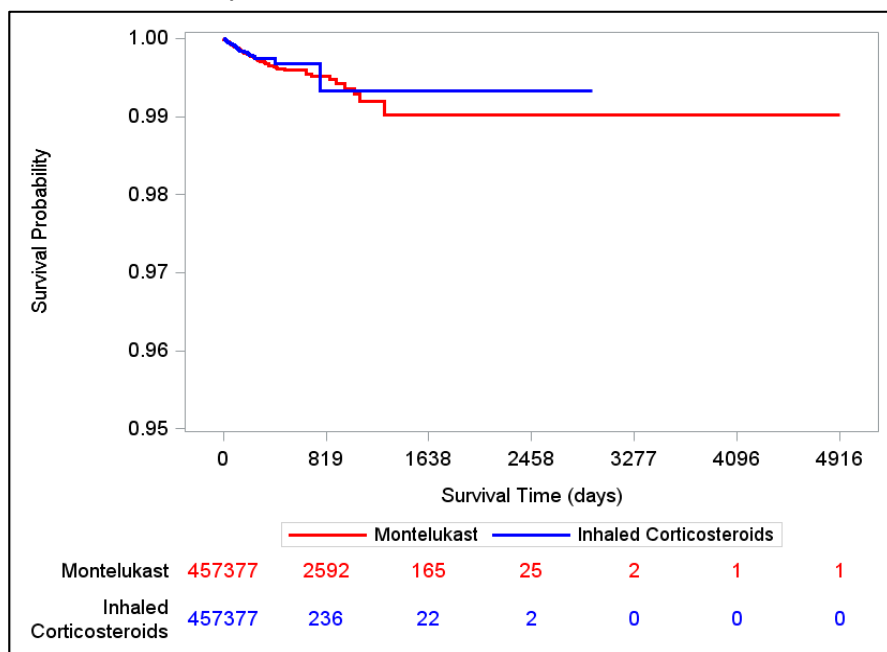
**Follow-Up Truncated at 365 Days**



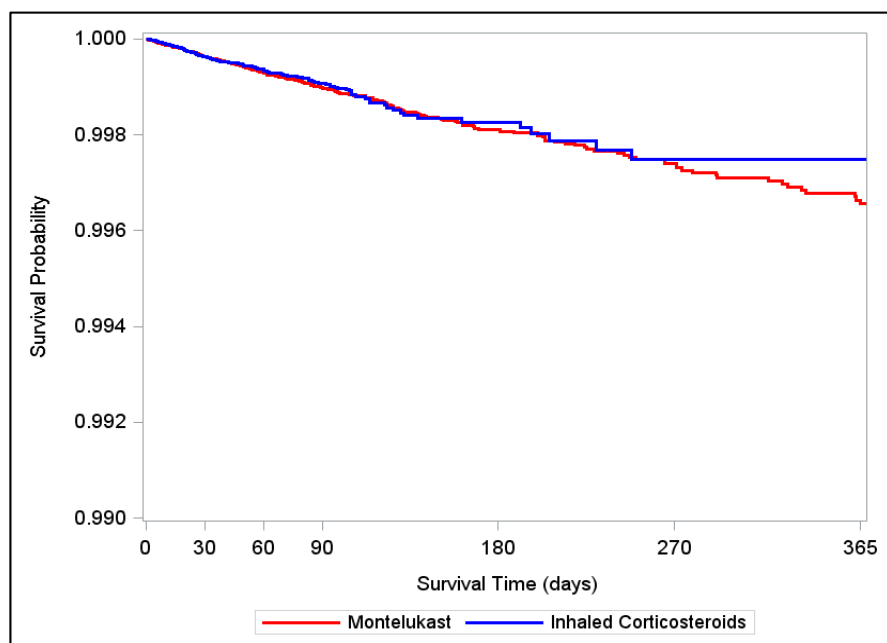
|                         | 0       | 30      | 60     | 90     | 180   | 270 | 365 |
|-------------------------|---------|---------|--------|--------|-------|-----|-----|
| Montelukast             | 457,377 | 336,729 | 33,109 | 12,257 | 1,074 | 252 | 88  |
| Inhaled Corticosteroids | 457,377 | 336,729 | 33,109 | 12,257 | 1,074 | 252 | 88  |

**Figure 2b. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, Unconditional Matched Cohort**

**All Available Follow-Up**



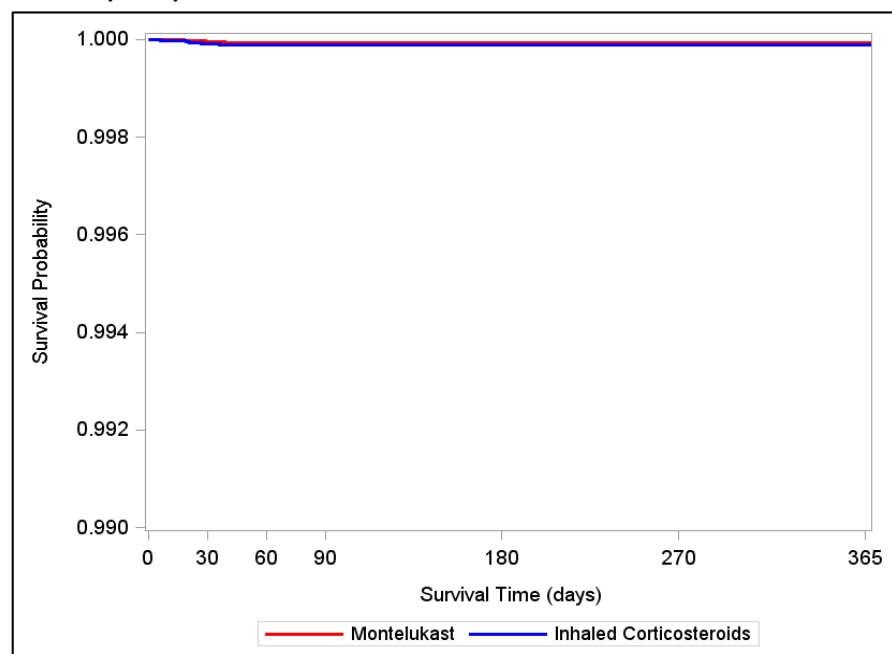
**Follow-Up Truncated at 365 Days**



|                         | 0       | 30      | 60      | 90      | 180    | 270    | 365    |
|-------------------------|---------|---------|---------|---------|--------|--------|--------|
| Montelukast             | 457,377 | 391,416 | 150,977 | 103,182 | 37,880 | 20,887 | 13,339 |
| Inhaled Corticosteroids | 457,377 | 393,367 | 91,081  | 46,392  | 10,103 | 4,168  | 2,248  |

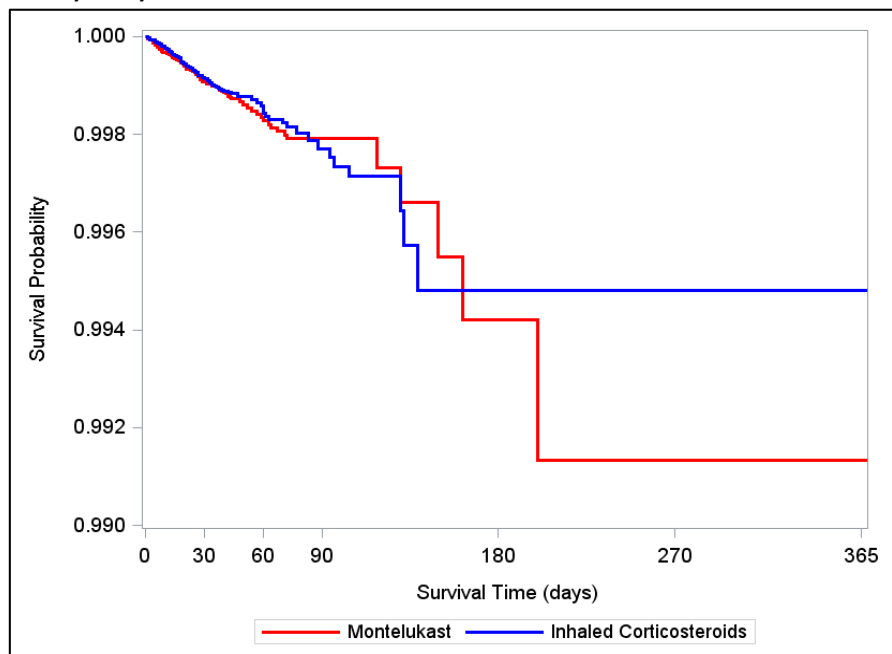
**Figure 2c. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by History of Psychiatric Disorder, Conditional Matched Cohort, Follow-Up Truncated to 365 Days**

**No History of Psychiatric Disorder**



|                         | 0       | 30      | 60     | 90    | 180 | 270 | 365 |
|-------------------------|---------|---------|--------|-------|-----|-----|-----|
| Montelukast             | 287,233 | 215,047 | 18,080 | 6,467 | 486 | 123 | 44  |
| Inhaled Corticosteroids | 287,233 | 215,047 | 18,080 | 6,467 | 486 | 123 | 44  |

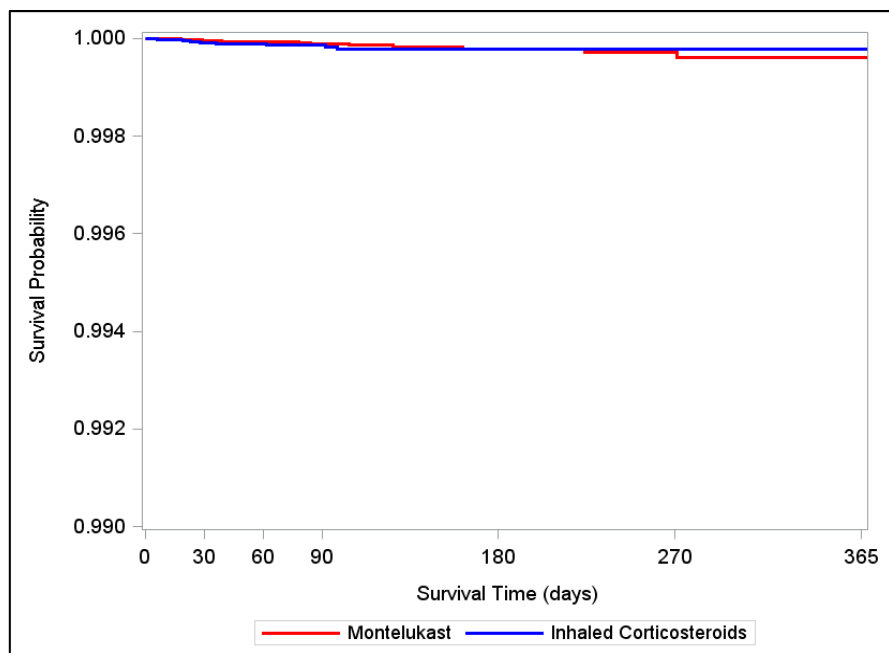
**History of Psychiatric Disorder**



|                         | 0       | 30      | 60     | 90    | 180 | 270 | 365 |
|-------------------------|---------|---------|--------|-------|-----|-----|-----|
| Montelukast             | 166,750 | 119,293 | 14,886 | 5,637 | 582 | 155 | 54  |
| Inhaled Corticosteroids | 166,750 | 119,293 | 14,886 | 5,637 | 582 | 155 | 54  |

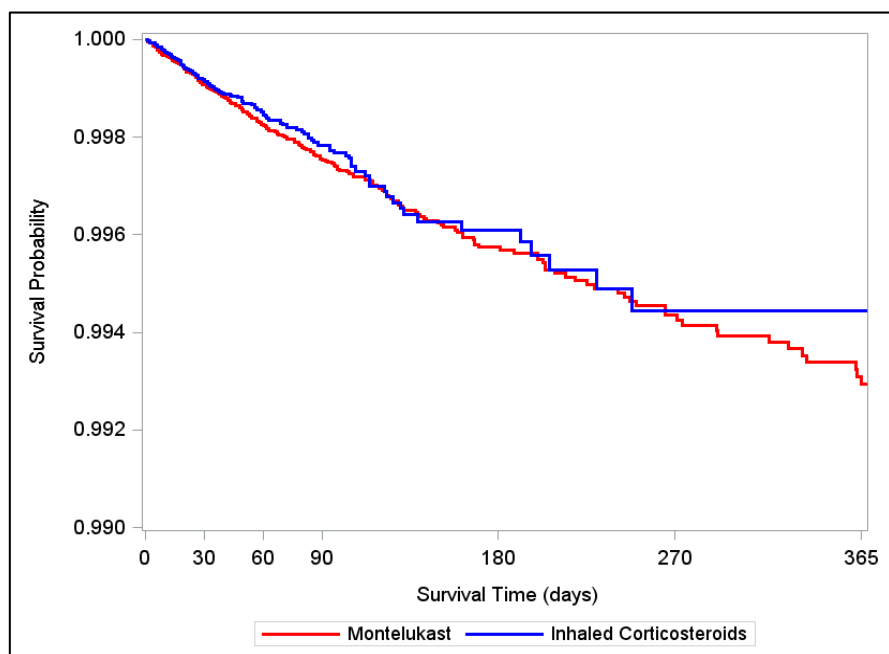
**Figure 2d. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by History of Psychiatric Disorder, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days**

**No History of Psychiatric Disorder**



|                         | 0       | 30      | 60     | 90     | 180    | 270    | 365   |
|-------------------------|---------|---------|--------|--------|--------|--------|-------|
| Montelukast             | 287,233 | 248,272 | 87,673 | 58,219 | 19,916 | 10,696 | 6,778 |
| Inhaled Corticosteroids | 287,233 | 248,621 | 52,573 | 26,401 | 5,364  | 2,216  | 1,180 |

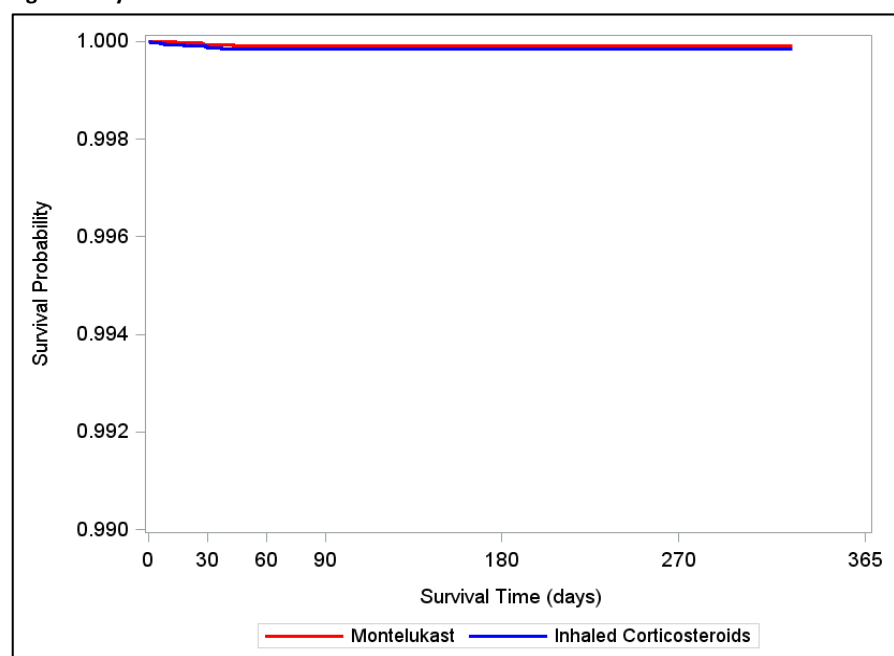
**History of Psychiatric Disorder**



|                         | 0       | 30      | 60     | 90     | 180    | 270   | 365   |
|-------------------------|---------|---------|--------|--------|--------|-------|-------|
| Montelukast             | 166,750 | 140,246 | 62,083 | 44,118 | 17,645 | 9,991 | 6,433 |
| Inhaled Corticosteroids | 166,750 | 141,794 | 37,694 | 19,607 | 4,663  | 1,919 | 1,054 |

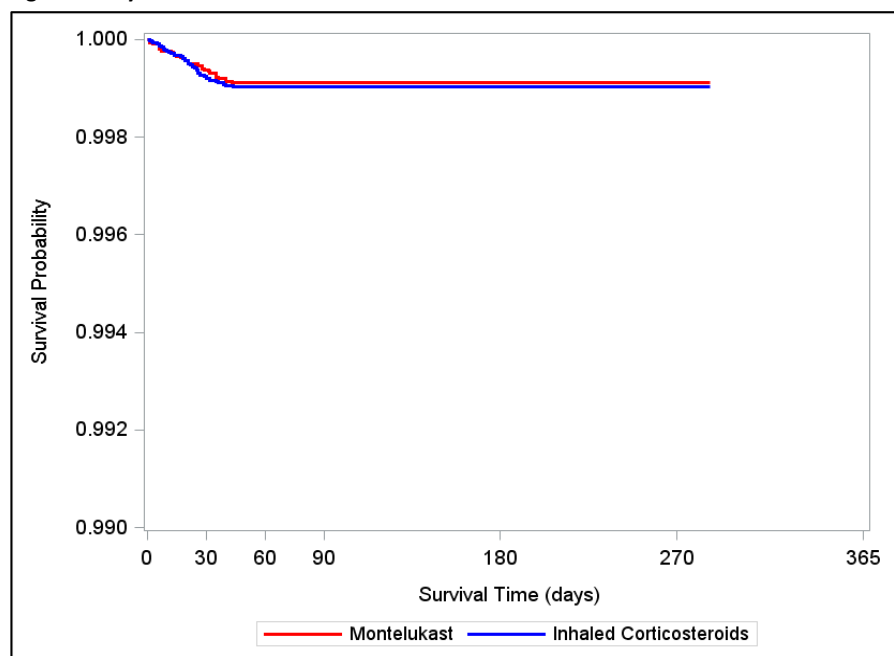
**Figure 2e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, Conditional Matched Cohort, Follow-Up Truncated to 365 Days**

**Ages 6-11 years**



|                         | 0      | 30     | 60    | 90    | 180 | 270 | 365 |
|-------------------------|--------|--------|-------|-------|-----|-----|-----|
| Montelukast             | 82,660 | 62,440 | 4,137 | 1,156 | 49  | 4   | 0   |
| Inhaled Corticosteroids | 82,660 | 62,440 | 4,137 | 1,156 | 49  | 4   | 0   |

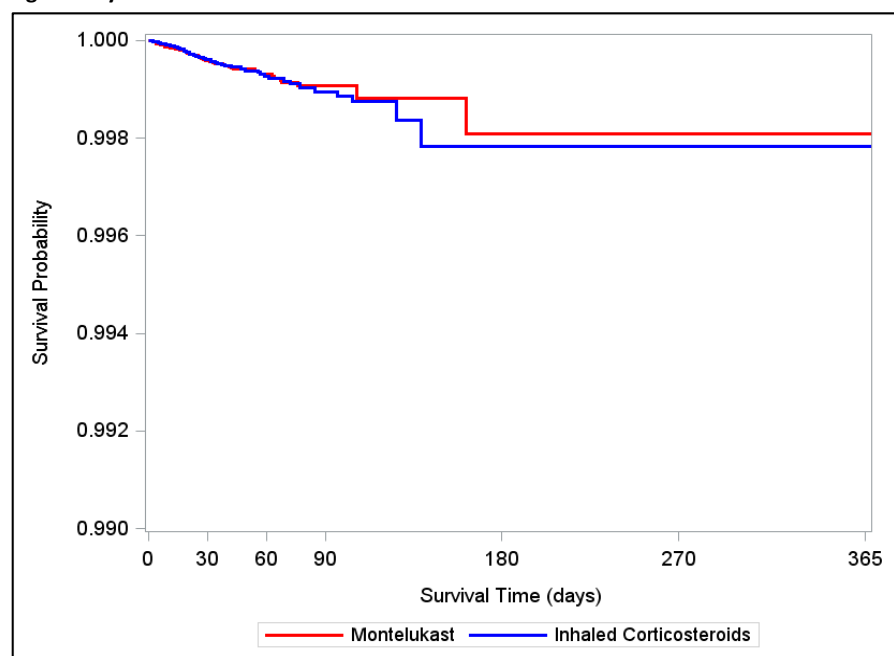
**Ages 12-17 years**



|                         | 0      | 30     | 60    | 90  | 180 | 270 | 365 |
|-------------------------|--------|--------|-------|-----|-----|-----|-----|
| Montelukast             | 50,191 | 38,485 | 2,079 | 604 | 19  | 2   | 0   |
| Inhaled Corticosteroids | 50,191 | 38,485 | 2,079 | 604 | 19  | 2   | 0   |

**Figure 2e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, Conditional Matched Cohort, Follow-Up Truncated to 365 Days**

**Ages 18+ years**

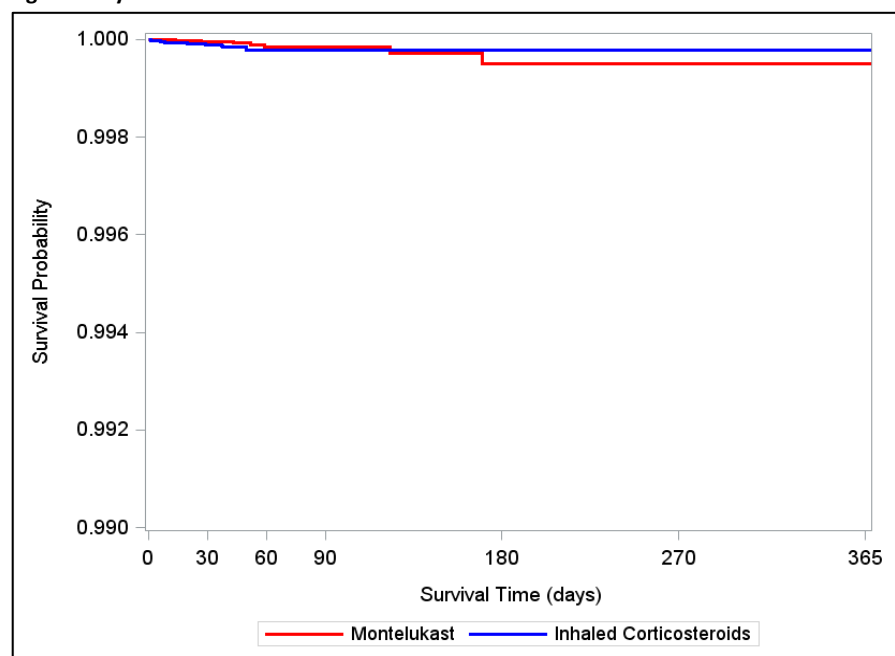


|                         | 0       | 30      | 60     | 90     | 180   | 270 | 365 |
|-------------------------|---------|---------|--------|--------|-------|-----|-----|
| Montelukast             | 308,196 | 223,996 | 26,393 | 10,404 | 1,017 | 258 | 90  |
| Inhaled Corticosteroids | 308,196 | 223,996 | 26,393 | 10,404 | 1,017 | 258 | 90  |



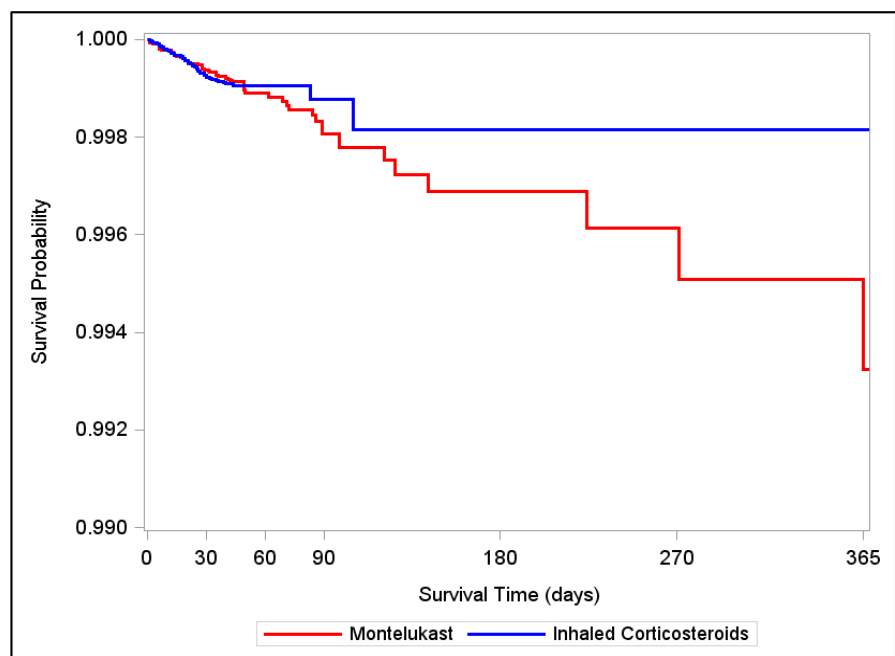
**Figure 2f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days**

**Ages 6-11 years**



|                         | 0      | 30     | 60     | 90     | 180   | 270   | 365   |
|-------------------------|--------|--------|--------|--------|-------|-------|-------|
| Montelukast             | 82,660 | 72,922 | 23,345 | 13,905 | 4,305 | 2,101 | 1,212 |
| Inhaled Corticosteroids | 82,660 | 70,761 | 12,369 | 5,187  | 859   | 308   | 154   |

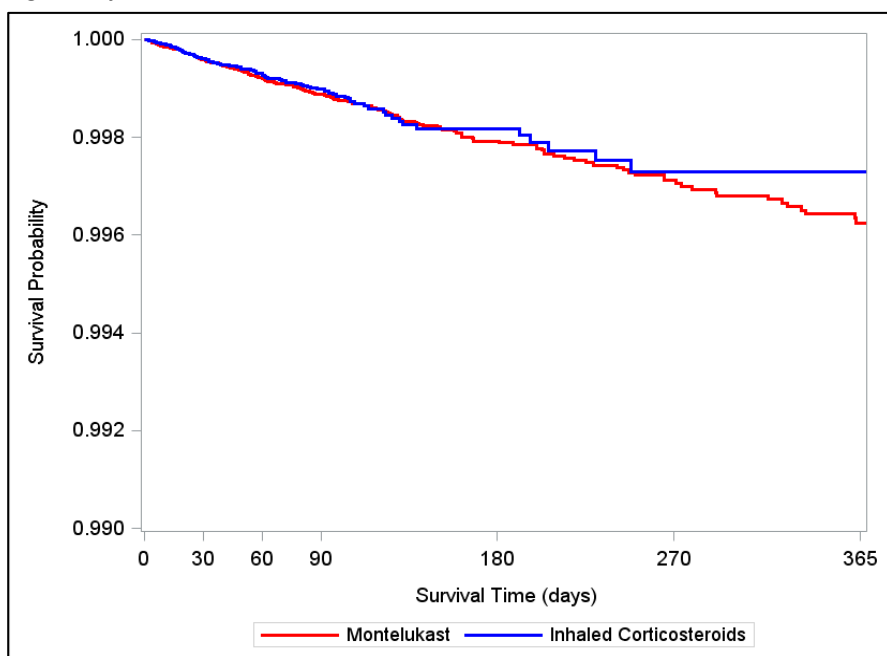
**Ages 12-17 years**



|                         | 0      | 30     | 60     | 90    | 180   | 270 | 365 |
|-------------------------|--------|--------|--------|-------|-------|-----|-----|
| Montelukast             | 50,191 | 44,366 | 12,462 | 7,508 | 1,986 | 941 | 540 |
| Inhaled Corticosteroids | 50,191 | 43,570 | 6,789  | 2,871 | 427   | 148 | 65  |

**Figure 2f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days**

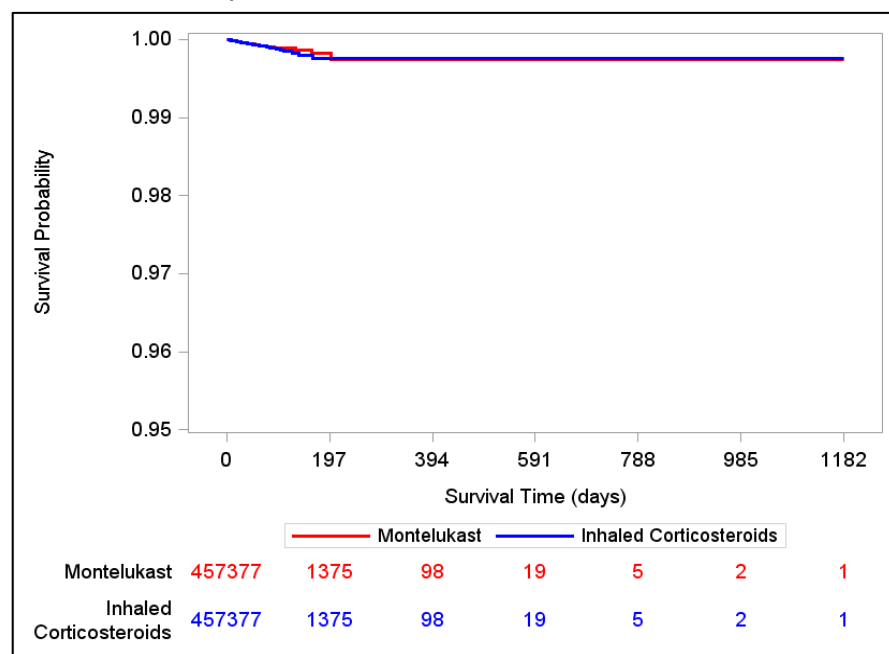
**Ages 18+ years**



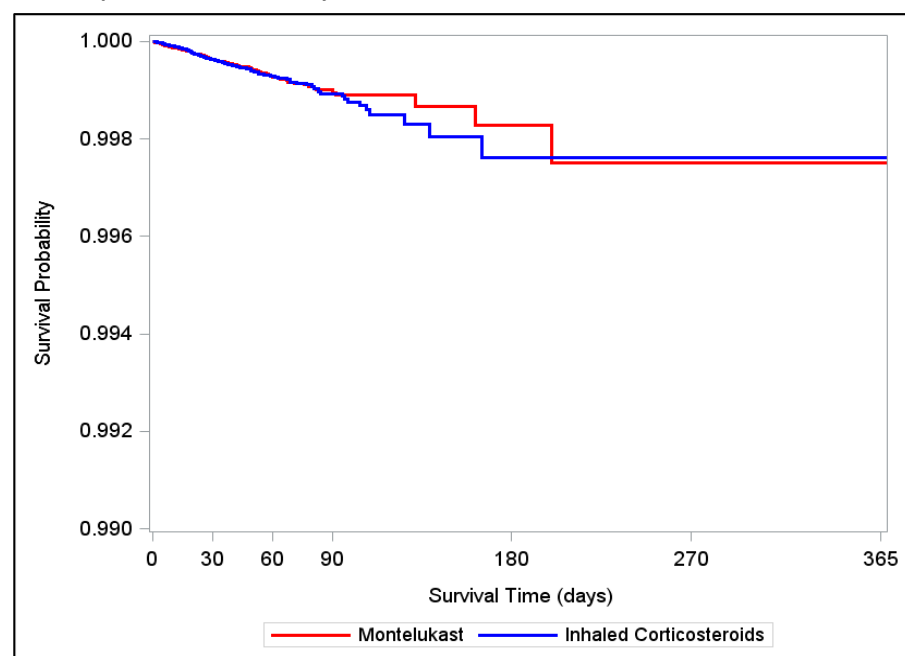
|                         | 0       | 30      | 60      | 90     | 180    | 270    | 365    |
|-------------------------|---------|---------|---------|--------|--------|--------|--------|
| Montelukast             | 308,196 | 260,080 | 110,588 | 78,756 | 30,638 | 17,354 | 11,292 |
| Inhaled Corticosteroids | 308,196 | 265,191 | 69,632  | 37,351 | 8,641  | 3,648  | 1,998  |

**Figure 3a. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, Inhaled Corticosteroids 30-day Extension and Gap, Conditional Matched Cohort**

**All Available Follow-Up**



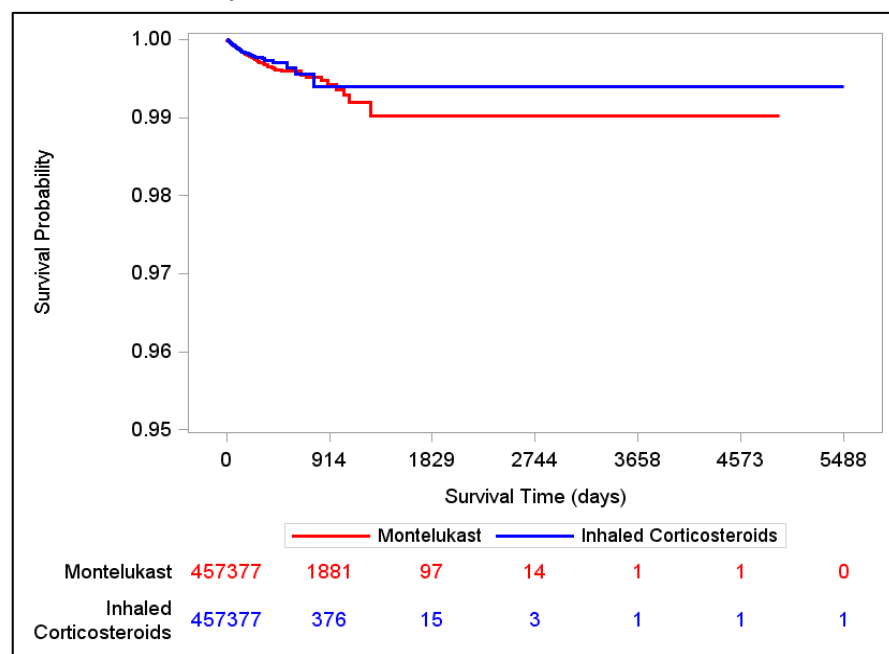
**Follow-Up Truncated at 365 Days**



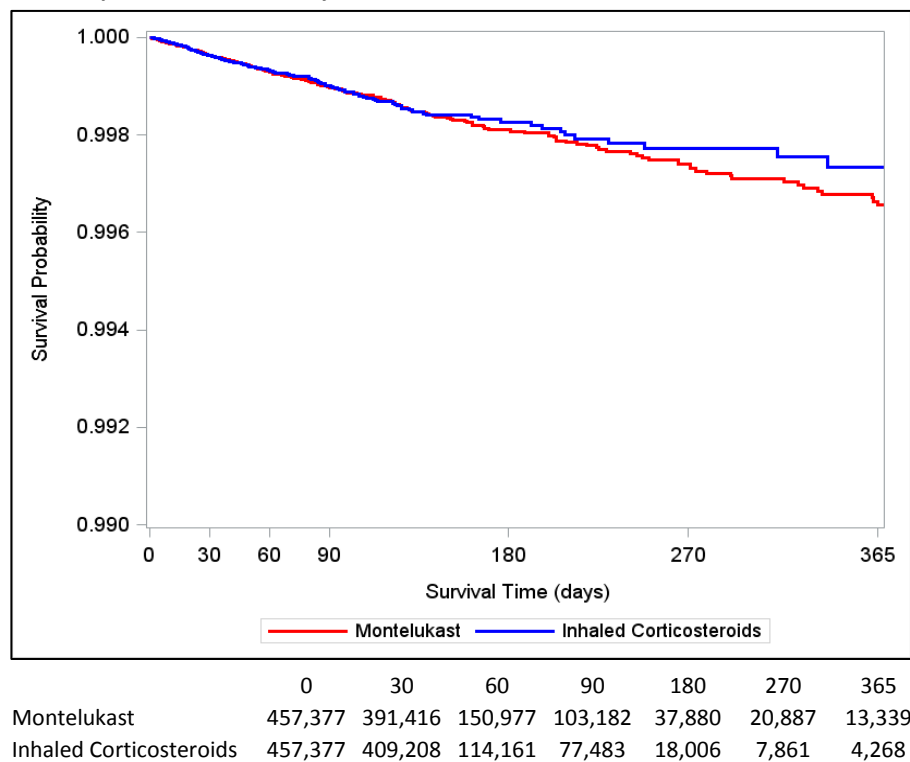
|                         | 0       | 30      | 60     | 90     | 180   | 270 | 365 |
|-------------------------|---------|---------|--------|--------|-------|-----|-----|
| Montelukast             | 457,377 | 350,351 | 40,558 | 19,259 | 1,838 | 460 | 156 |
| Inhaled Corticosteroids | 457,377 | 350,351 | 40,558 | 19,259 | 1,838 | 460 | 156 |

**Figure 3b. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, Inhaled Corticosteroids 30-day Extension and Gap, Unconditional Matched Cohort**

**All Available Follow-Up**

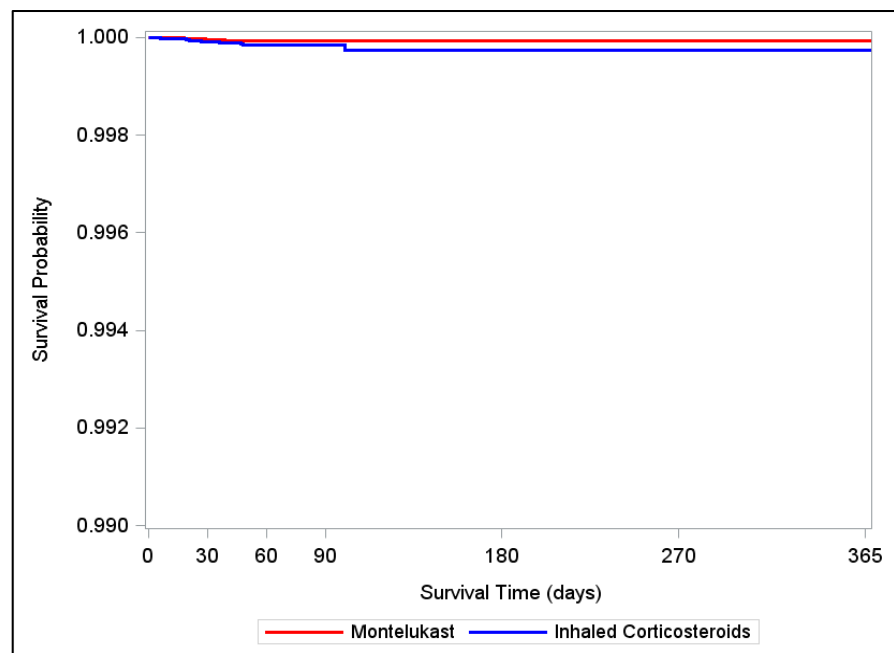


**Follow-Up Truncated at 365 Days**



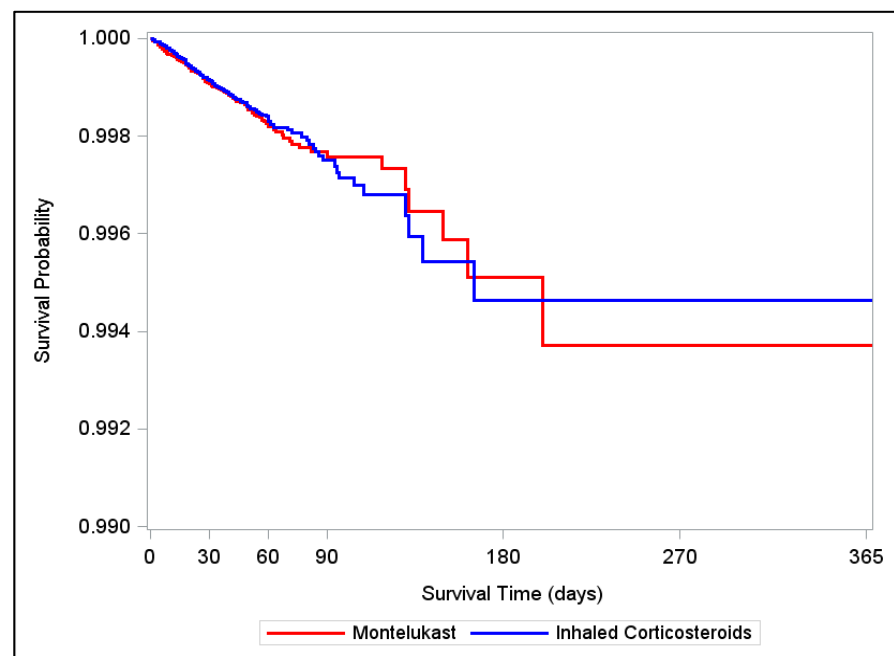
**Figure 3c. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by History of Psychiatric Disorder, ICS 30 day Extension and Gap, Conditional Matched Cohort, Follow-Up Truncated to 365 Days**

**No History of Psychiatric Disorder**



|                         | 0       | 30      | 60     | 90     | 180 | 270 | 365 |
|-------------------------|---------|---------|--------|--------|-----|-----|-----|
| Montelukast             | 287,233 | 224,285 | 22,222 | 10,208 | 829 | 223 | 79  |
| Inhaled Corticosteroids | 287,233 | 224,285 | 22,222 | 10,208 | 829 | 223 | 79  |

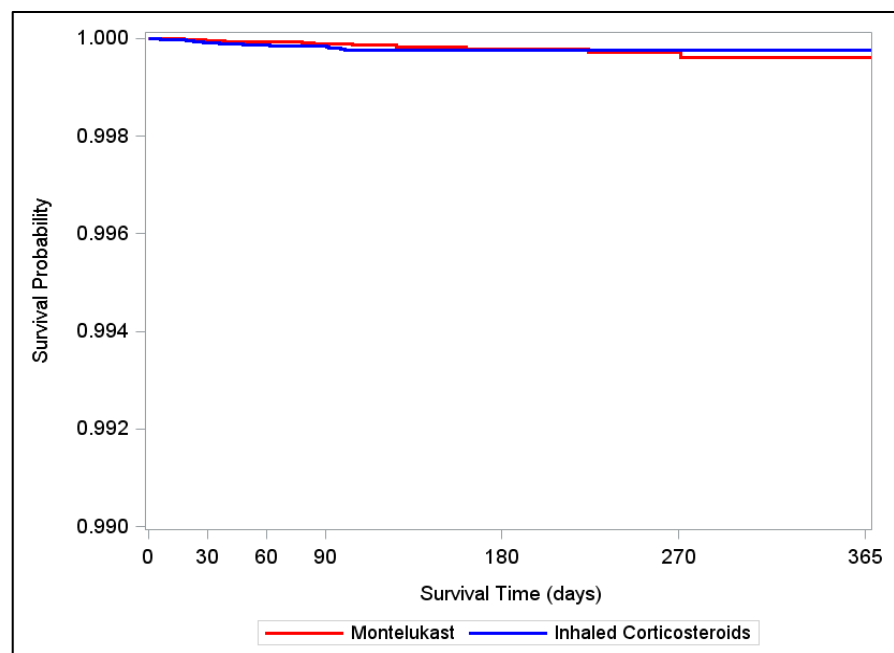
**History of Psychiatric Disorder**



|                         | 0       | 30      | 60     | 90    | 180 | 270 | 365 |
|-------------------------|---------|---------|--------|-------|-----|-----|-----|
| Montelukast             | 166,750 | 123,579 | 18,091 | 8,949 | 991 | 266 | 91  |
| Inhaled Corticosteroids | 166,750 | 123,579 | 18,091 | 8,949 | 991 | 266 | 91  |

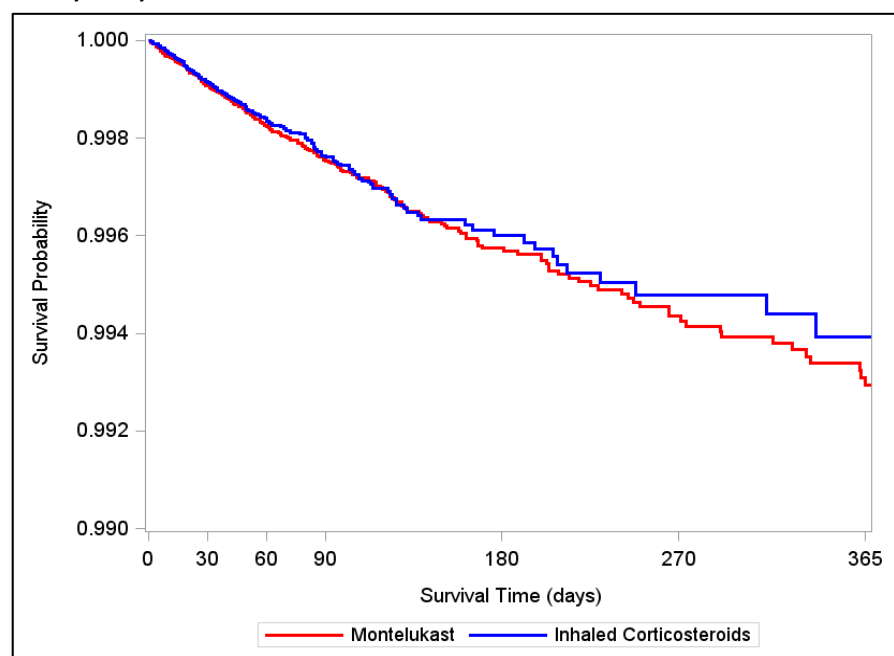
**Figure 3d. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by History of Psychiatric Disorder, ICS 30 day Extension and Gap, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days**

**No History of Psychiatric Disorder**



|                         | 0       | 30      | 60     | 90     | 180    | 270    | 365   |
|-------------------------|---------|---------|--------|--------|--------|--------|-------|
| Montelukast             | 287,233 | 248,272 | 87,673 | 58,219 | 19,916 | 10,696 | 6,778 |
| Inhaled Corticosteroids | 287,233 | 248,621 | 52,573 | 26,401 | 5,364  | 2,216  | 1,180 |

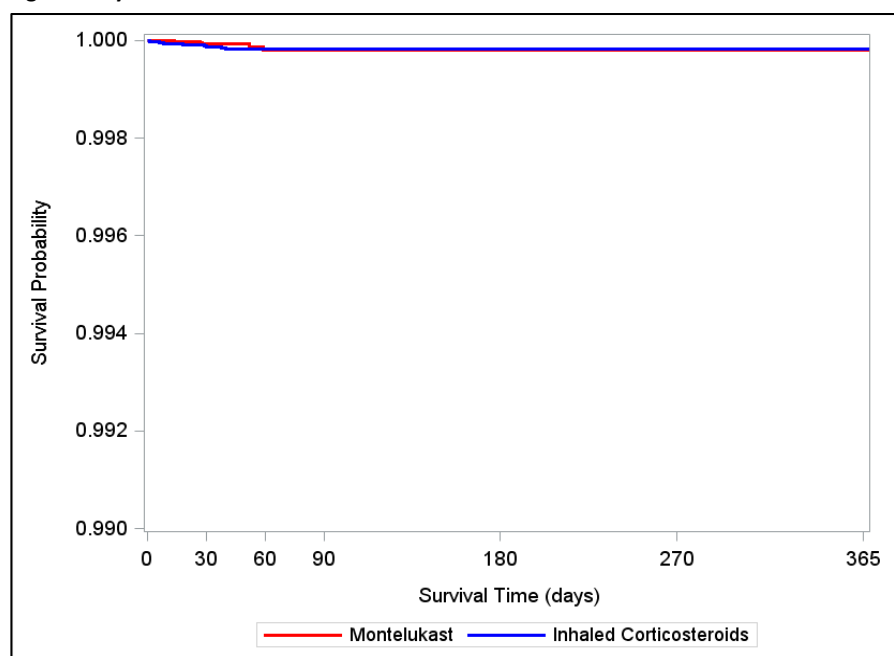
**History of Psychiatric Disorder**



|                         | 0       | 30      | 60     | 90     | 180    | 270   | 365   |
|-------------------------|---------|---------|--------|--------|--------|-------|-------|
| Montelukast             | 166,750 | 140,246 | 62,083 | 44,118 | 17,645 | 9,991 | 6,433 |
| Inhaled Corticosteroids | 166,750 | 146,868 | 46,444 | 31,555 | 7,958  | 3,463 | 1,897 |

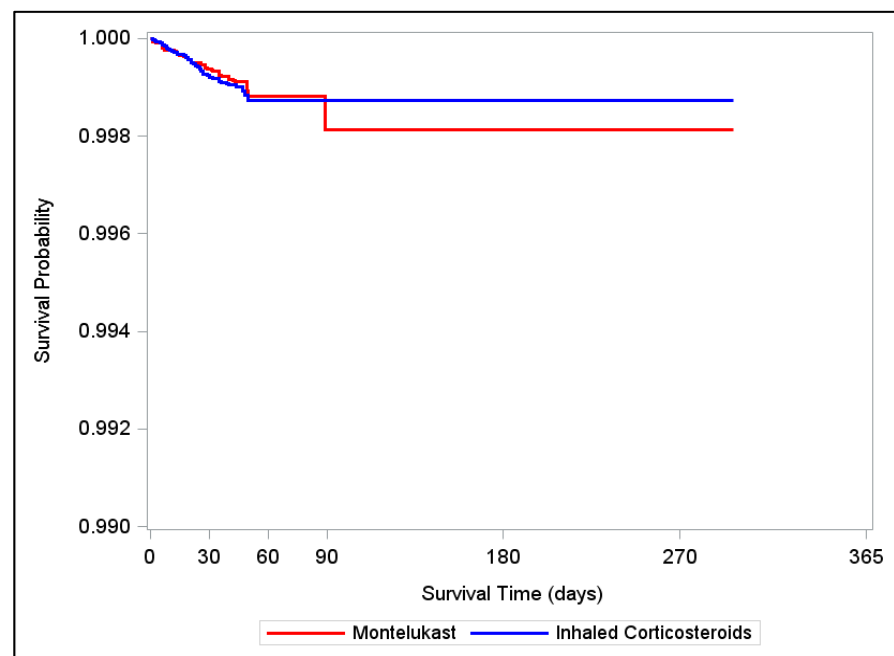
**Figure 3e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, ICS 30 day Extension and Gap, Conditional Matched Cohort, Follow-Up Truncated to 365 Days**

**Ages 6-11 years**



|                         | 0      | 30     | 60    | 90    | 180 | 270 | 365 |
|-------------------------|--------|--------|-------|-------|-----|-----|-----|
| Montelukast             | 82,660 | 66,586 | 5,234 | 2,003 | 115 | 19  | 3   |
| Inhaled Corticosteroids | 82,660 | 66,586 | 5,234 | 2,003 | 115 | 19  | 3   |

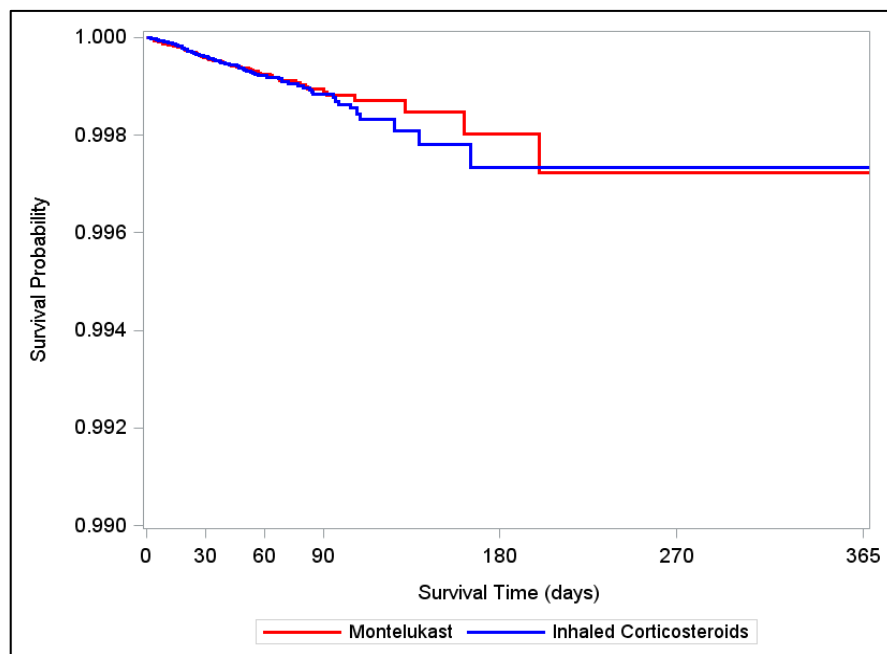
**Ages 12-17 years**



|                         | 0      | 30     | 60    | 90    | 180 | 270 | 365 |
|-------------------------|--------|--------|-------|-------|-----|-----|-----|
| Montelukast             | 50,191 | 40,194 | 2,612 | 1,001 | 33  | 8   | 0   |
| Inhaled Corticosteroids | 50,191 | 40,194 | 2,612 | 1,001 | 33  | 8   | 0   |

**Figure 3e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, ICS 30 day Extension and Gap, Conditional Matched Cohort, Follow-Up Truncated to 365 Days**

Ages 18+ years

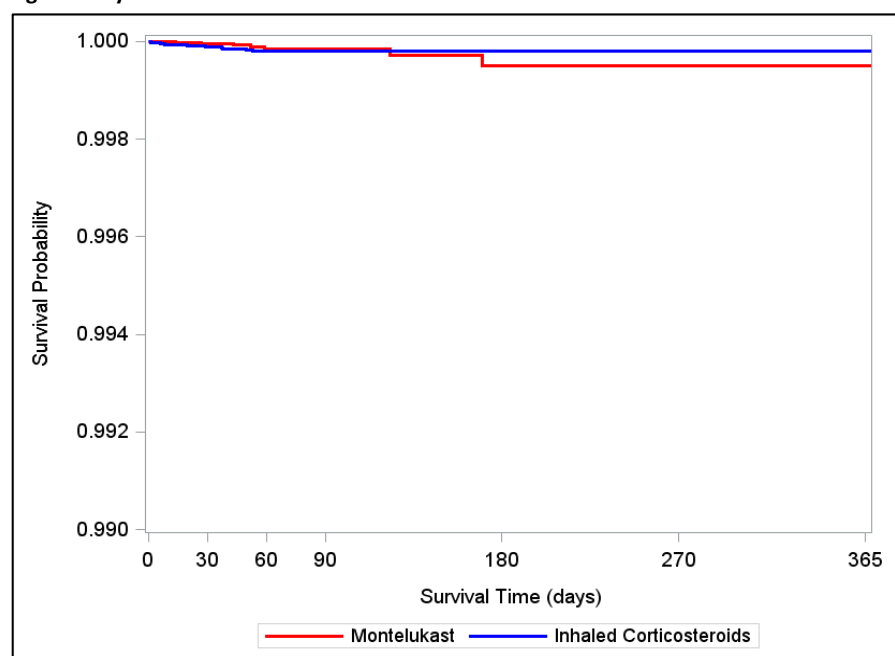


|                         | 0       | 30      | 60     | 90     | 180   | 270 | 365 |
|-------------------------|---------|---------|--------|--------|-------|-----|-----|
| Montelukast             | 308,196 | 230,986 | 32,041 | 16,074 | 1,720 | 460 | 161 |
| Inhaled Corticosteroids | 308,196 | 230,986 | 32,041 | 16,074 | 1,720 | 460 | 161 |



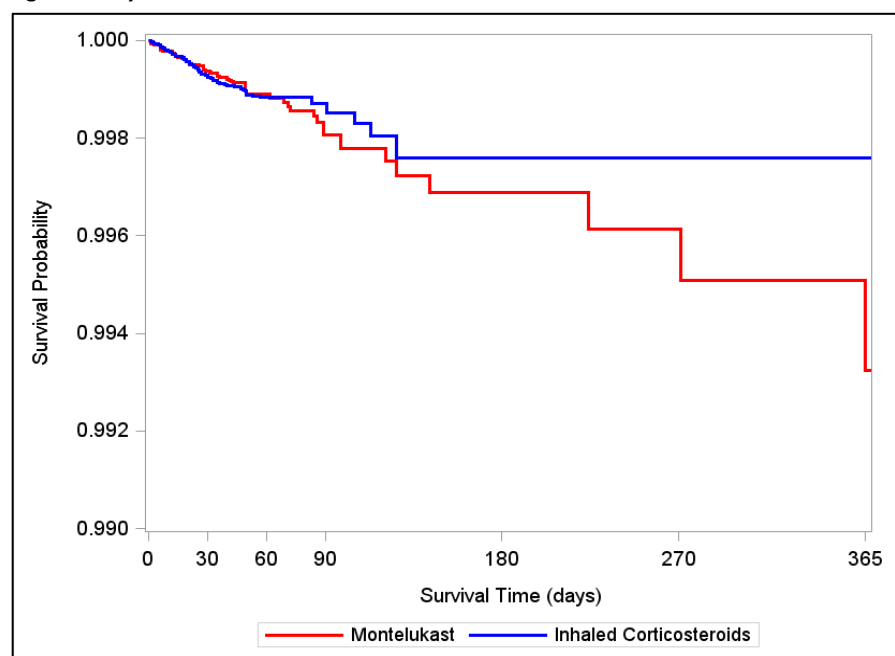
**Figure 3f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, ICS 30 day Extension and Gap, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days**

**Ages 6-11 years**



|                         | 0      | 30     | 60     | 90     | 180   | 270   | 365   |
|-------------------------|--------|--------|--------|--------|-------|-------|-------|
| Montelukast             | 82,660 | 72,922 | 23,345 | 13,905 | 4,305 | 2,101 | 1,212 |
| Inhaled Corticosteroids | 82,660 | 75,412 | 16,618 | 10,716 | 1,981 | 767   | 386   |

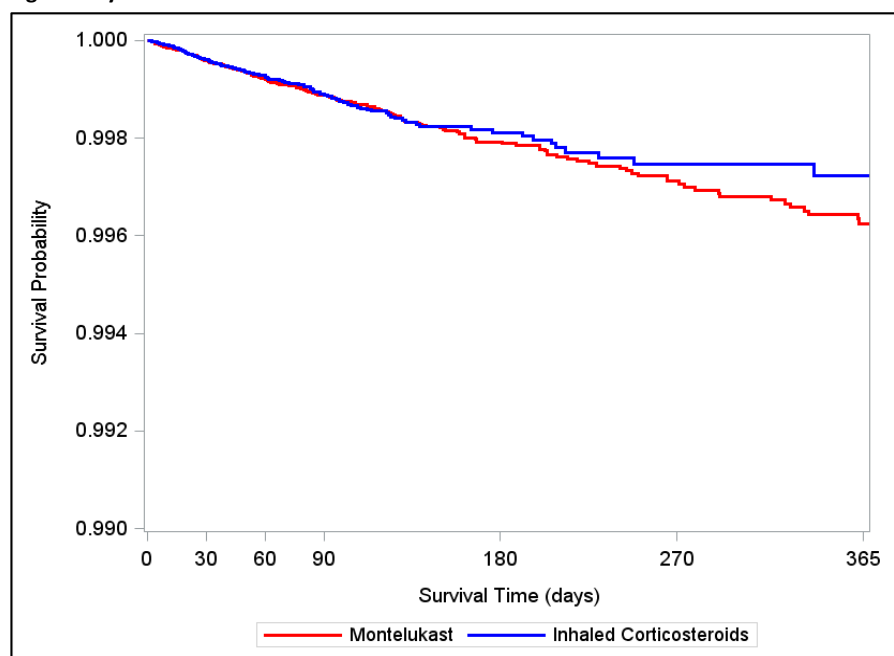
**Ages 12-17 years**



|                         | 0      | 30     | 60     | 90    | 180   | 270 | 365 |
|-------------------------|--------|--------|--------|-------|-------|-----|-----|
| Montelukast             | 50,191 | 44,366 | 12,462 | 7,508 | 1,986 | 941 | 540 |
| Inhaled Corticosteroids | 50,191 | 45,504 | 9,032  | 5,658 | 904   | 326 | 150 |

**Figure 3f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, ICS 30 day Extension and Gap, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days**

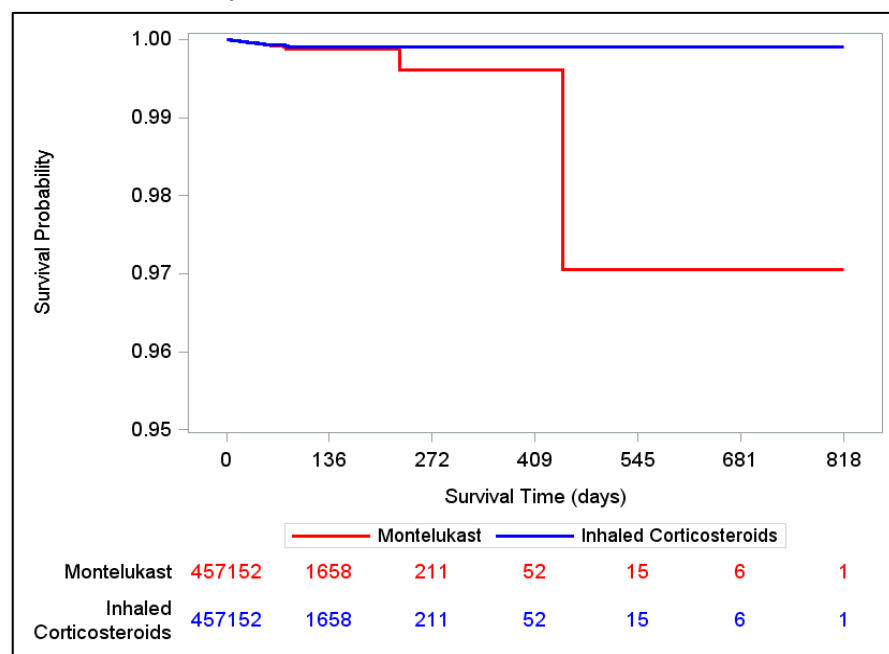
**Ages 18+ years**



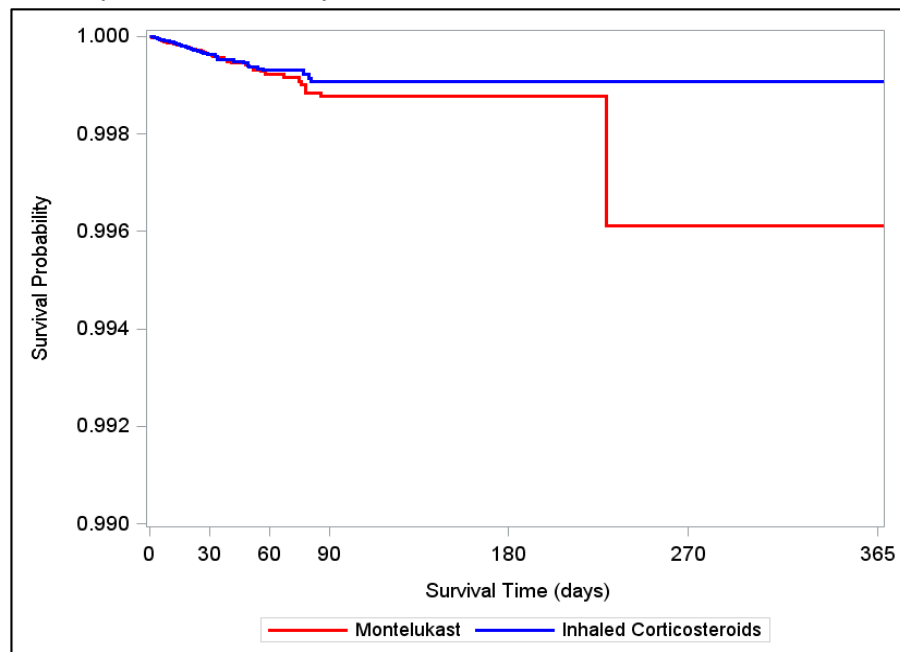
|                         | 0       | 30      | 60      | 90     | 180    | 270    | 365    |
|-------------------------|---------|---------|---------|--------|--------|--------|--------|
| Montelukast             | 308,196 | 260,080 | 110,588 | 78,756 | 30,638 | 17,354 | 11,292 |
| Inhaled Corticosteroids | 308,196 | 273,498 | 85,403  | 59,033 | 14,732 | 6,626  | 3,666  |

**Figure 4a. Kaplan Meier Survival Curves of Informative Events and Followup Time for Inpatient Depressive Disorder, No Episode Extension, Conditional Matched Cohort**

**All Available Follow-Up**



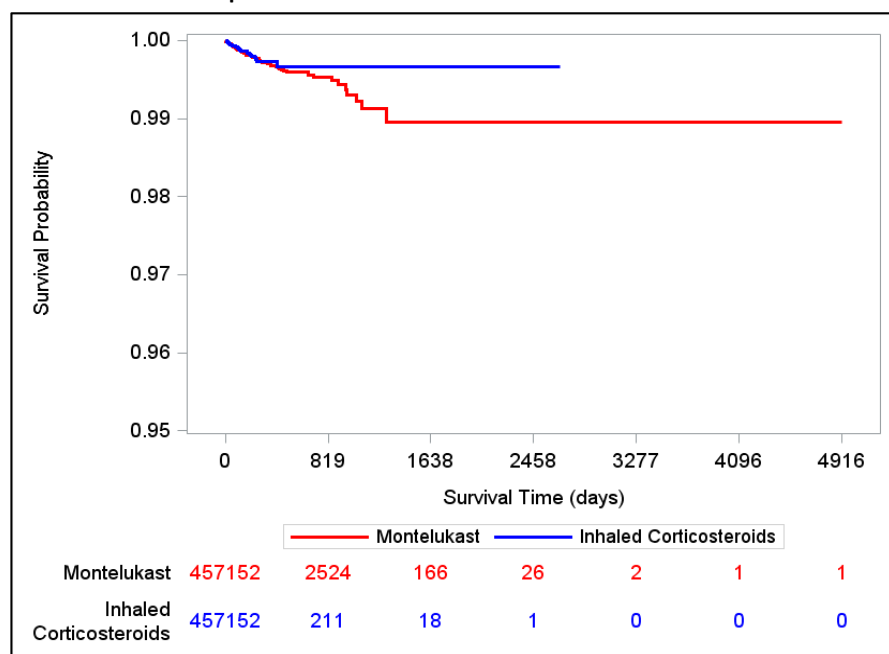
**Follow-Up Truncated at 365 Days**



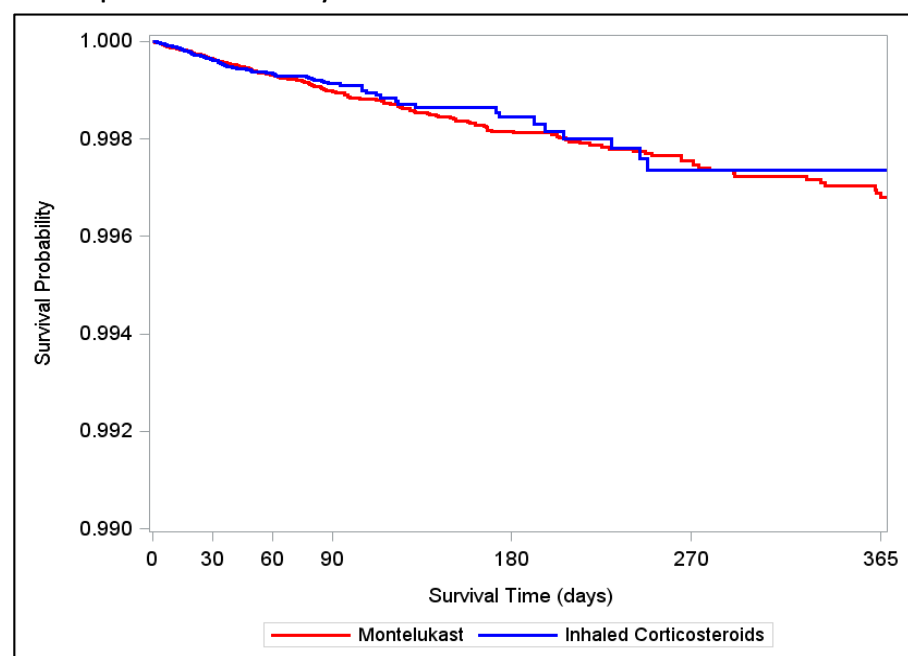
|                         | 0       | 30     | 60     | 90    | 180 | 270 | 365 |
|-------------------------|---------|--------|--------|-------|-----|-----|-----|
| Montelukast             | 457,152 | 42,463 | 20,610 | 4,958 | 764 | 219 | 83  |
| Inhaled Corticosteroids | 457,152 | 42,463 | 20,610 | 4,958 | 764 | 219 | 83  |

**Figure 4b. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, No Episode Extension, Unconditional Matched Cohort**

**All Available Follow-Up**



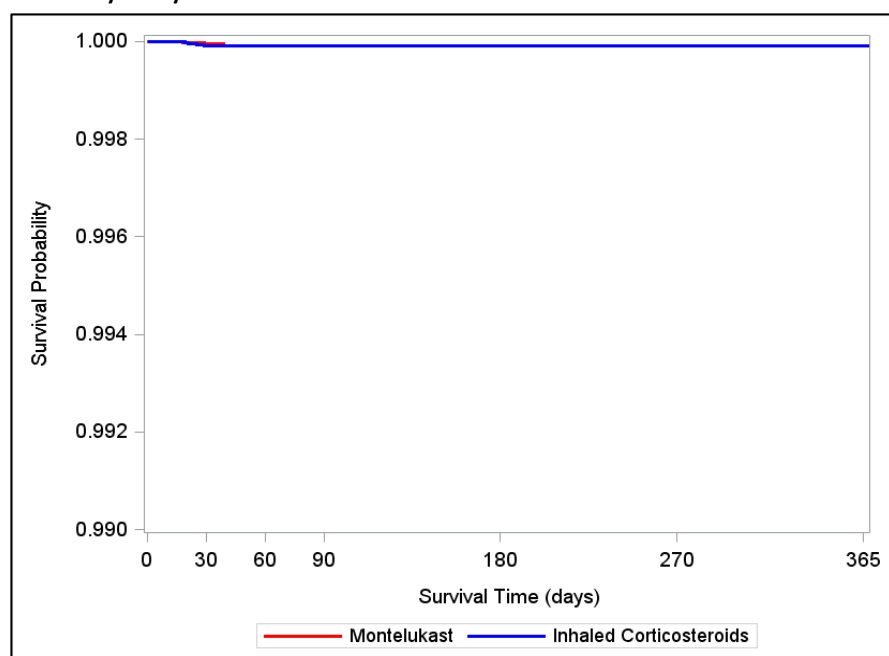
**Follow-Up Truncated at 365 Days**



|                         | 0       | 30      | 60      | 90     | 180    | 270    | 365    |
|-------------------------|---------|---------|---------|--------|--------|--------|--------|
| Montelukast             | 457,152 | 169,528 | 134,848 | 76,357 | 34,419 | 19,789 | 12,560 |
| Inhaled Corticosteroids | 457,152 | 105,073 | 63,625  | 26,580 | 8,160  | 3,711  | 1,953  |

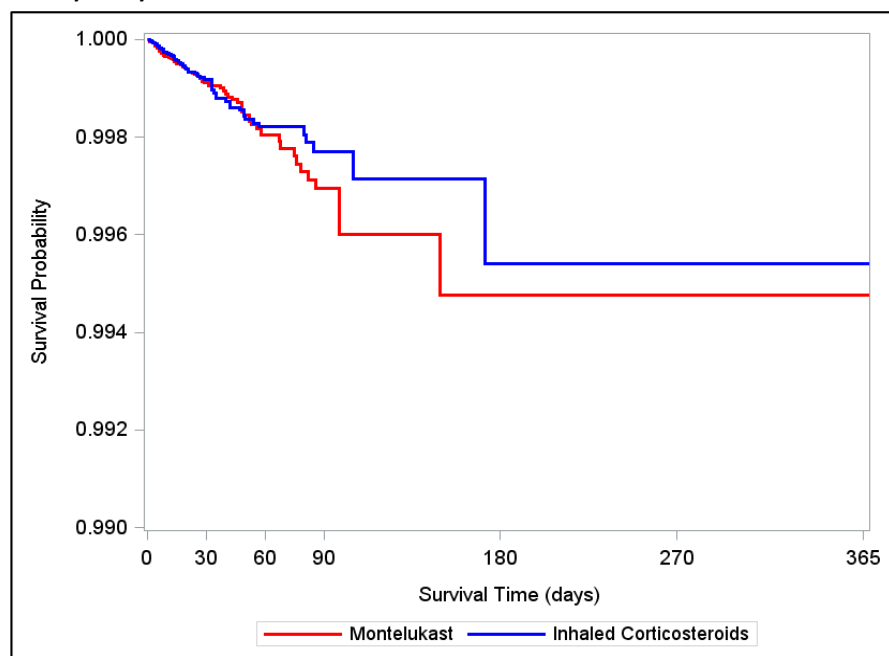
**Figure 4c. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by History of Psychiatric Disorder, No Episode Extension, Conditional Matched Cohort, Follow-Up Truncated to 365 Days**

**No History of Psychiatric Disorder**



|                         | 0       | 30     | 60     | 90    | 180 | 270 | 365 |
|-------------------------|---------|--------|--------|-------|-----|-----|-----|
| Montelukast             | 287,308 | 22,903 | 11,021 | 2,373 | 296 | 86  | 28  |
| Inhaled Corticosteroids | 287,308 | 22,903 | 11,021 | 2,373 | 296 | 86  | 28  |

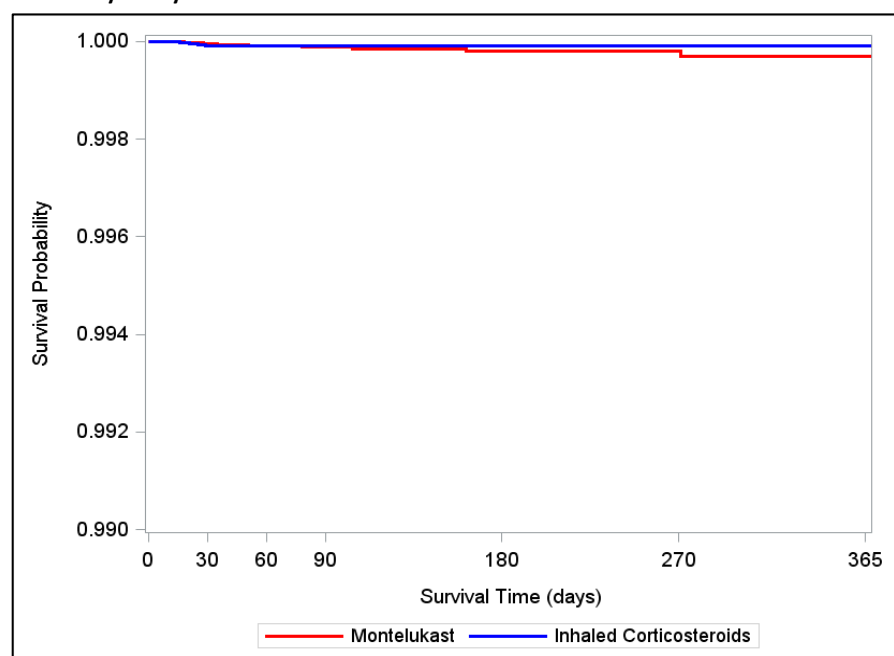
**History of Psychiatric Disorder**



|                         | 0       | 30     | 60    | 90    | 180 | 270 | 365 |
|-------------------------|---------|--------|-------|-------|-----|-----|-----|
| Montelukast             | 166,642 | 19,157 | 9,338 | 2,546 | 434 | 118 | 45  |
| Inhaled Corticosteroids | 166,642 | 19,157 | 9,338 | 2,546 | 434 | 118 | 45  |

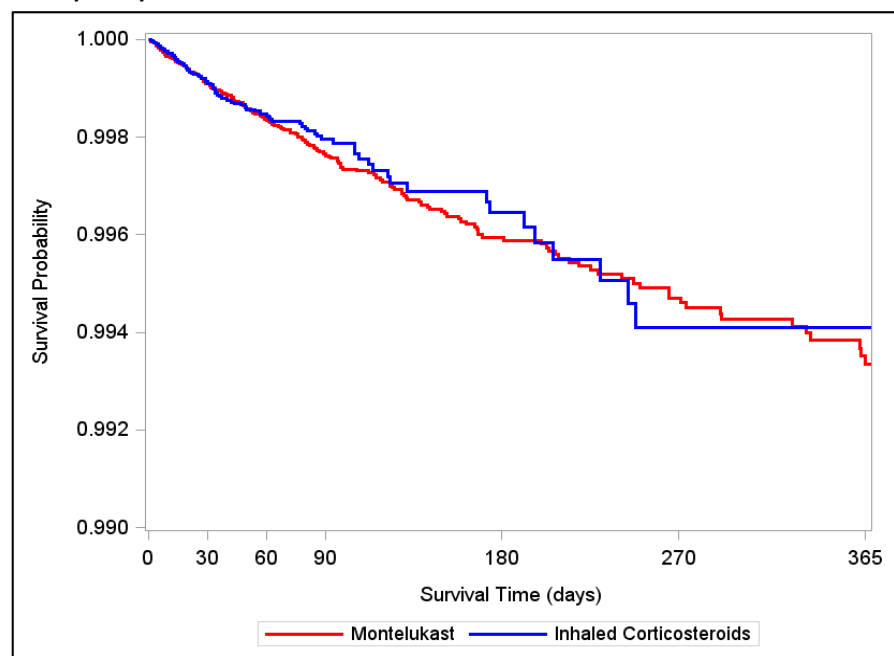
**Figure 4d. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by History of Psychiatric Disorder, No Episode Extension, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days**

**No History of Psychiatric Disorder**



|                         | 0       | 30     | 60     | 90     | 180    | 270    | 365   |
|-------------------------|---------|--------|--------|--------|--------|--------|-------|
| Montelukast             | 287,308 | 98,013 | 77,837 | 41,994 | 17,940 | 10,125 | 6,385 |
| Inhaled Corticosteroids | 287,308 | 60,833 | 36,597 | 14,769 | 4,324  | 1,981  | 1,031 |

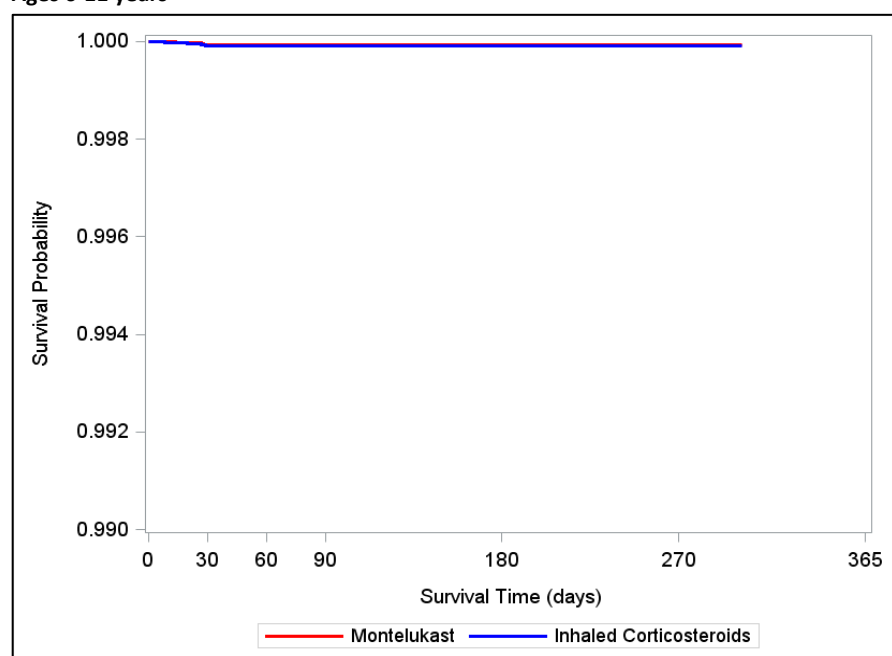
**History of Psychiatric Disorder**



|                         | 0       | 30     | 60     | 90     | 180    | 270   | 365   |
|-------------------------|---------|--------|--------|--------|--------|-------|-------|
| Montelukast             | 166,642 | 70,179 | 55,944 | 33,763 | 16,197 | 9,492 | 6,075 |
| Inhaled Corticosteroids | 166,642 | 43,340 | 26,499 | 11,595 | 3,766  | 1,701 | 911   |

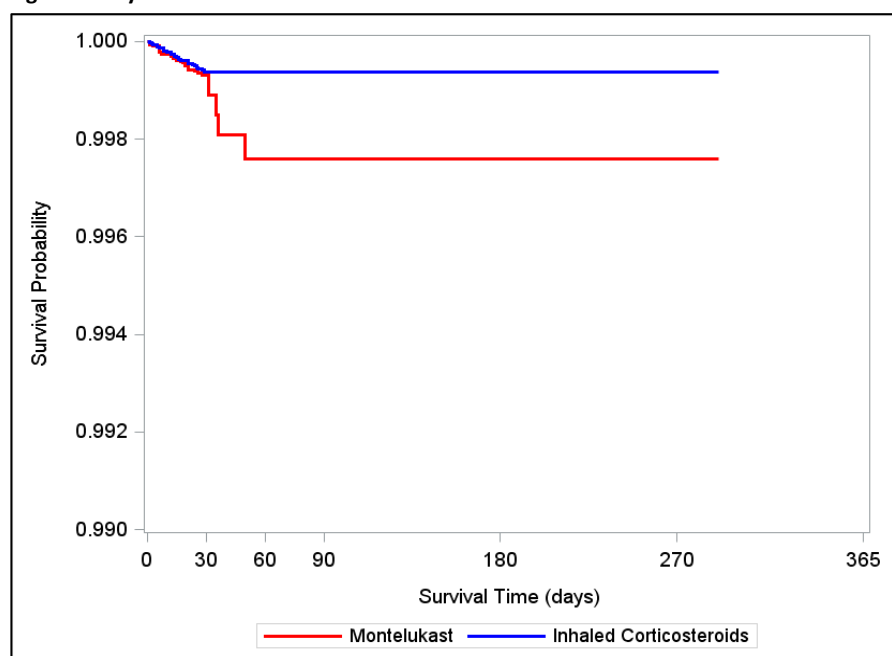
**Figure 4e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, No Episode Extension, Conditional Matched Cohort, Follow-Up Truncated to 365 Days**

**Ages 6-11 years**



|                         | 0      | 30    | 60    | 90  | 180 | 270 | 365 |
|-------------------------|--------|-------|-------|-----|-----|-----|-----|
| Montelukast             | 82,677 | 5,302 | 2,286 | 514 | 37  | 4   | 0   |
| Inhaled Corticosteroids | 82,677 | 5,302 | 2,286 | 514 | 37  | 4   | 0   |

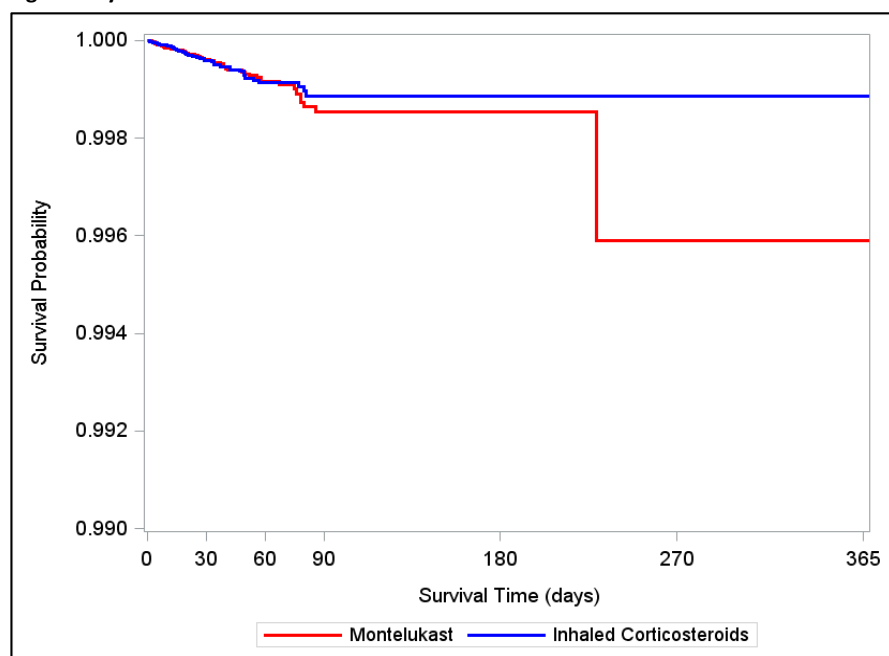
**Ages 12-17 years**



|                         | 0      | 30    | 60    | 90  | 180 | 270 | 365 |
|-------------------------|--------|-------|-------|-----|-----|-----|-----|
| Montelukast             | 50,266 | 2,680 | 1,124 | 228 | 11  | 1   | 0   |
| Inhaled Corticosteroids | 50,266 | 2,680 | 1,124 | 228 | 11  | 1   | 0   |

**Figure 4e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, No Episode Extension, Conditional Matched Cohort, Follow-Up Truncated to 365 Days**

**Ages 18+ years**

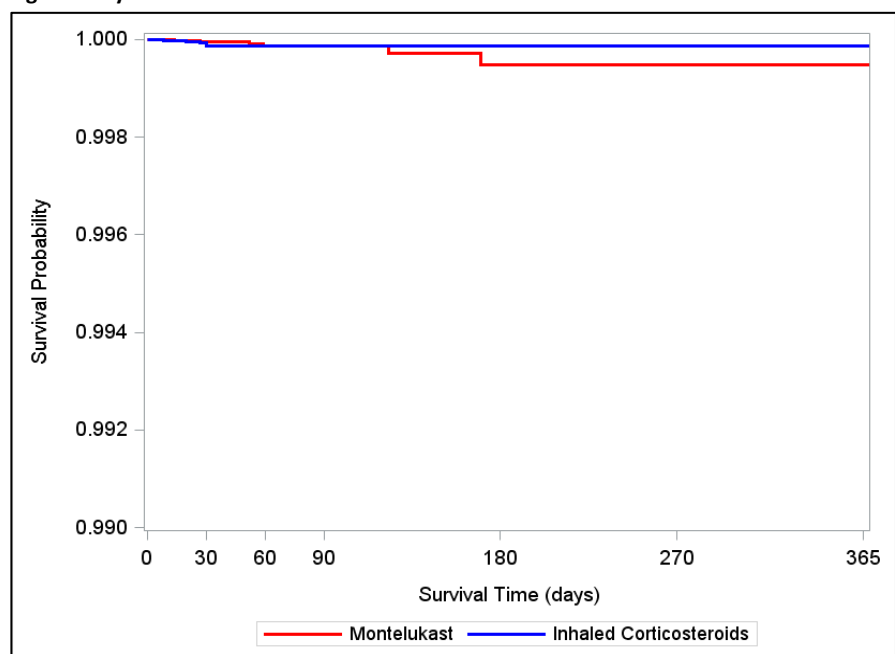


|                         | 0       | 30     | 60     | 90    | 180 | 270 | 365 |
|-------------------------|---------|--------|--------|-------|-----|-----|-----|
| Montelukast             | 308,205 | 33,761 | 16,945 | 4,288 | 750 | 225 | 80  |
| Inhaled Corticosteroids | 308,205 | 33,761 | 16,945 | 4,288 | 750 | 225 | 80  |



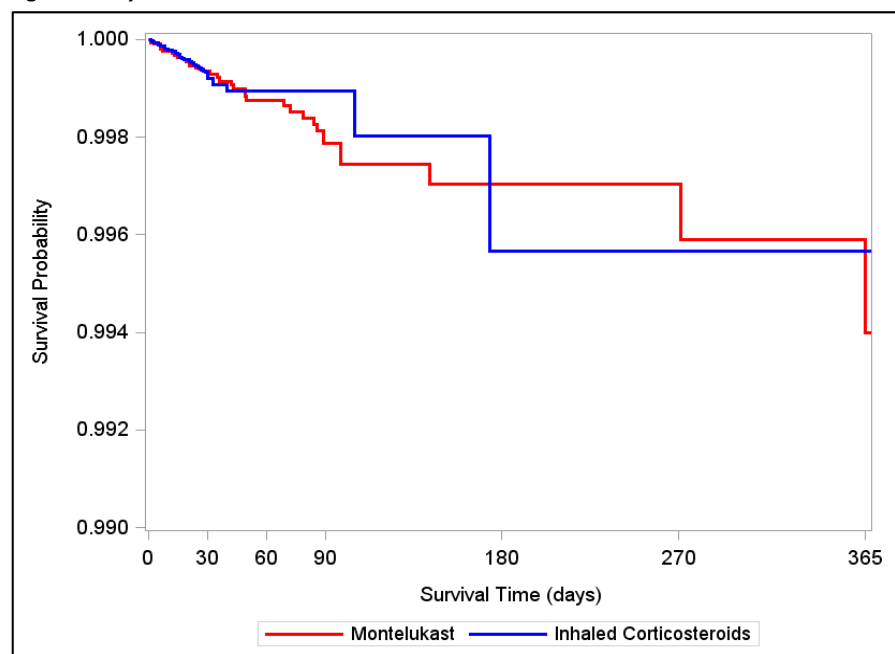
**Figure 4f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, No Episode Extension, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days**

**Ages 6-11 years**



|                         | 0      | 30     | 60     | 90     | 180   | 270   | 365   |
|-------------------------|--------|--------|--------|--------|-------|-------|-------|
| Montelukast             | 82,677 | 25,893 | 20,334 | 10,684 | 3,814 | 1,962 | 1,126 |
| Inhaled Corticosteroids | 82,677 | 14,641 | 8,092  | 3,273  | 686   | 266   | 138   |

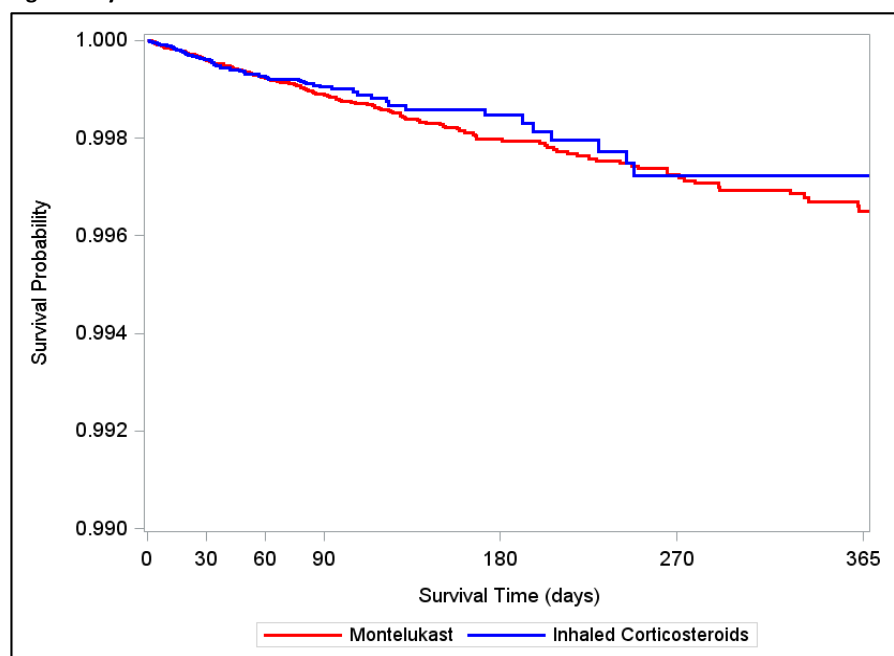
**Ages 12-17 years**



|                         | 0      | 30     | 60     | 90    | 180   | 270 | 365 |
|-------------------------|--------|--------|--------|-------|-------|-----|-----|
| Montelukast             | 50,266 | 13,961 | 10,845 | 5,202 | 1,744 | 879 | 521 |
| Inhaled Corticosteroids | 50,266 | 8,285  | 4,410  | 1,676 | 352   | 123 | 57  |

**Figure 4f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, No Episode Extension, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days**

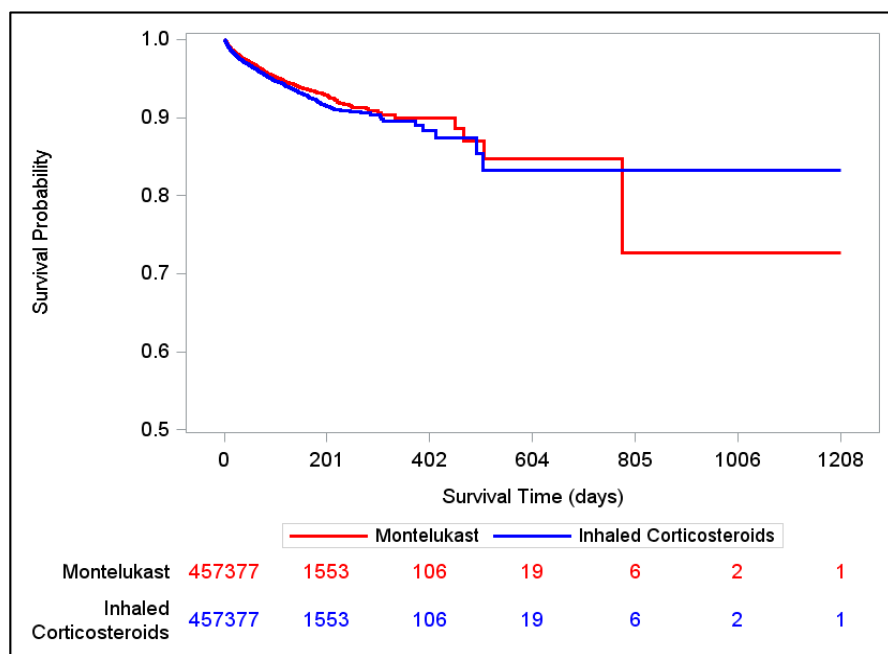
**Ages 18+ years**



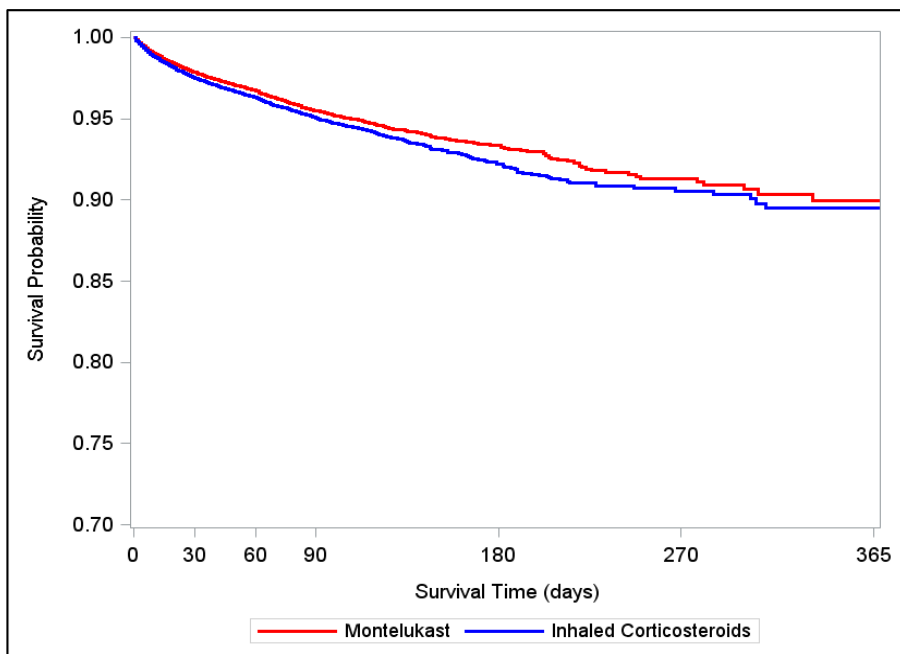
|                         | 0       | 30      | 60     | 90     | 180    | 270    | 365    |
|-------------------------|---------|---------|--------|--------|--------|--------|--------|
| Montelukast             | 308,205 | 124,683 | 99,782 | 58,403 | 28,022 | 16,498 | 10,646 |
| Inhaled Corticosteroids | 308,205 | 79,523  | 49,582 | 21,002 | 6,963  | 3,243  | 1,719  |

**Figure 5a. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Outpatient Depressive Disorder, Conditional Matched Cohort**

**All Available Follow-Up**



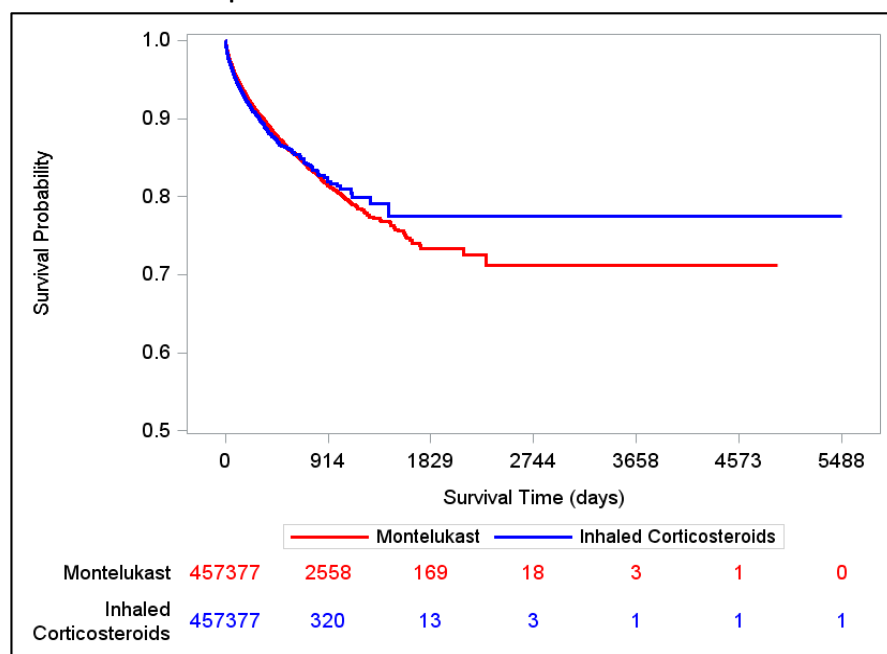
**Follow-Up Truncated at 365 Days**



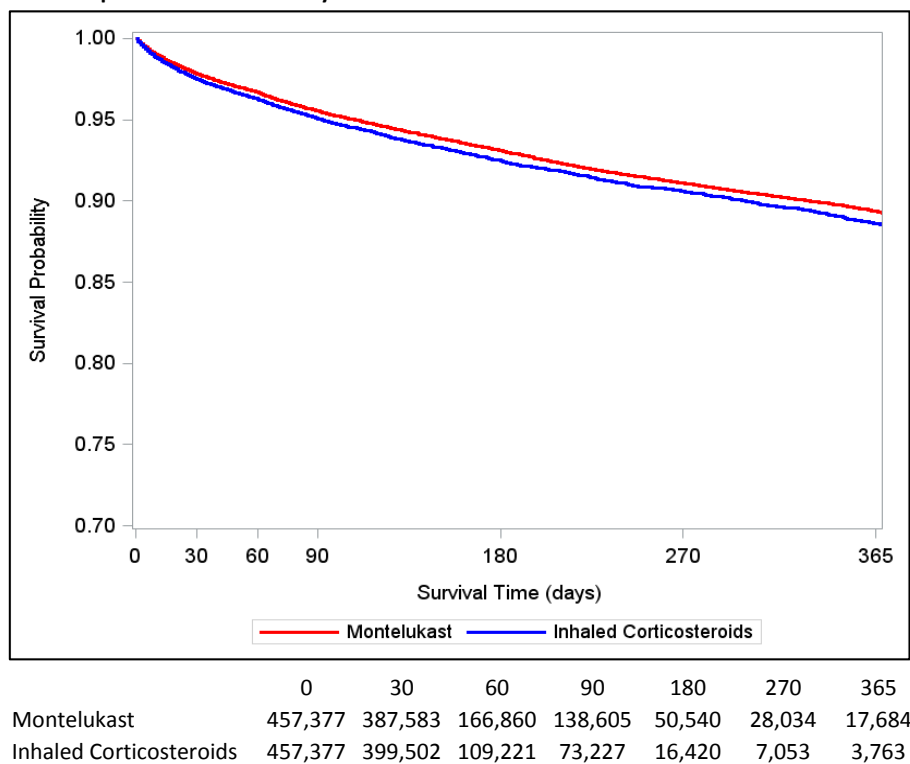
|                         | 0       | 30      | 60     | 90     | 180   | 270 | 365 |
|-------------------------|---------|---------|--------|--------|-------|-----|-----|
| Montelukast             | 457,377 | 338,821 | 42,103 | 23,320 | 2,046 | 508 | 177 |
| Inhaled Corticosteroids | 457,377 | 338,821 | 42,103 | 23,320 | 2,046 | 508 | 177 |

**Figure 5b. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Outpatient Depressive Disorder, Unconditional Matched Cohort**

**All Available Follow-Up**

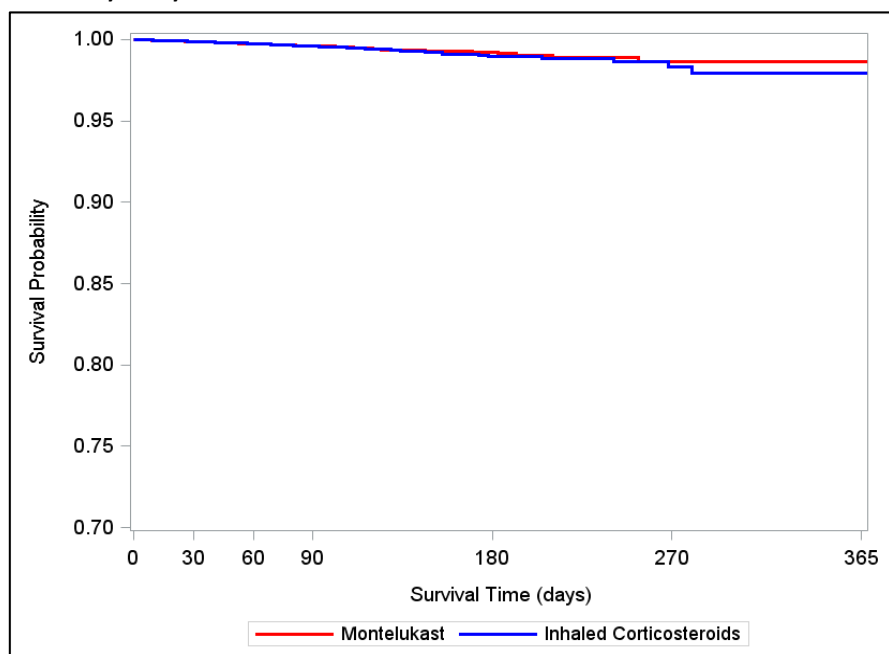


**Follow-Up Truncated at 365 Days**



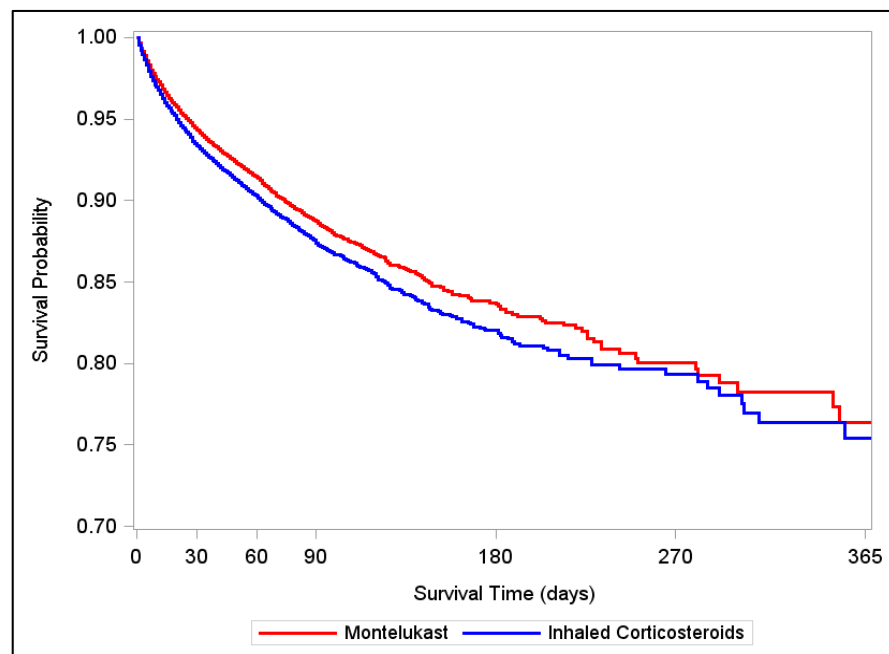
**Figure 5c. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Outpatient Depressive Disorder, by History of Psychiatric Disorder, Conditional Matched Cohort, Follow-Up Truncated to 365 Days**

**No History of Psychiatric Disorder**



|                         | 0       | 30      | 60     | 90     | 180   | 270 | 365 |
|-------------------------|---------|---------|--------|--------|-------|-----|-----|
| Montelukast             | 287,233 | 226,022 | 25,255 | 14,284 | 1,169 | 309 | 109 |
| Inhaled Corticosteroids | 287,233 | 226,022 | 25,255 | 14,284 | 1,169 | 309 | 109 |

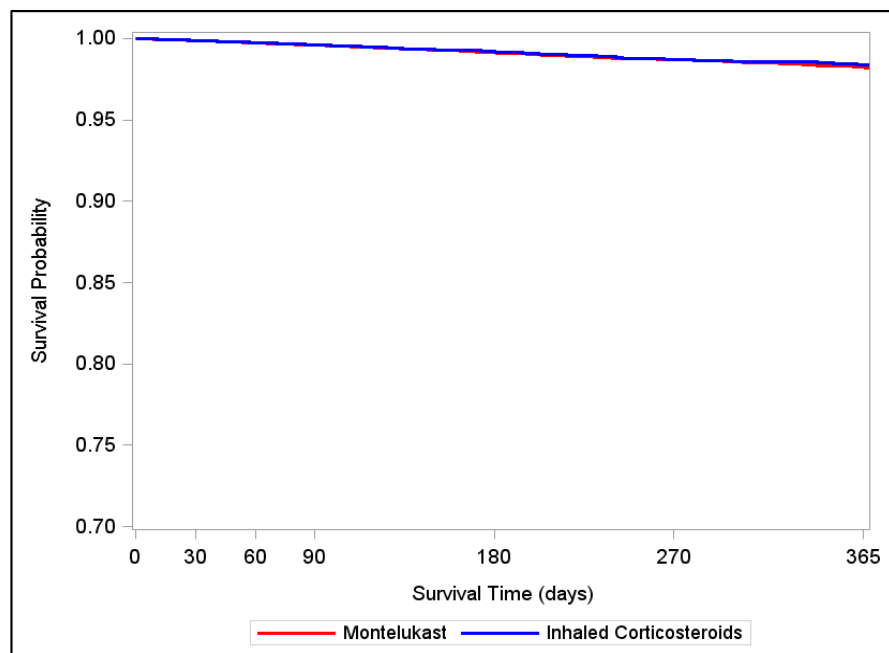
**History of Psychiatric Disorder**



|                         | 0       | 30      | 60     | 90    | 180 | 270 | 365 |
|-------------------------|---------|---------|--------|-------|-----|-----|-----|
| Montelukast             | 166,750 | 110,866 | 16,374 | 8,774 | 863 | 226 | 67  |
| Inhaled Corticosteroids | 166,750 | 110,866 | 16,374 | 8,774 | 863 | 226 | 67  |

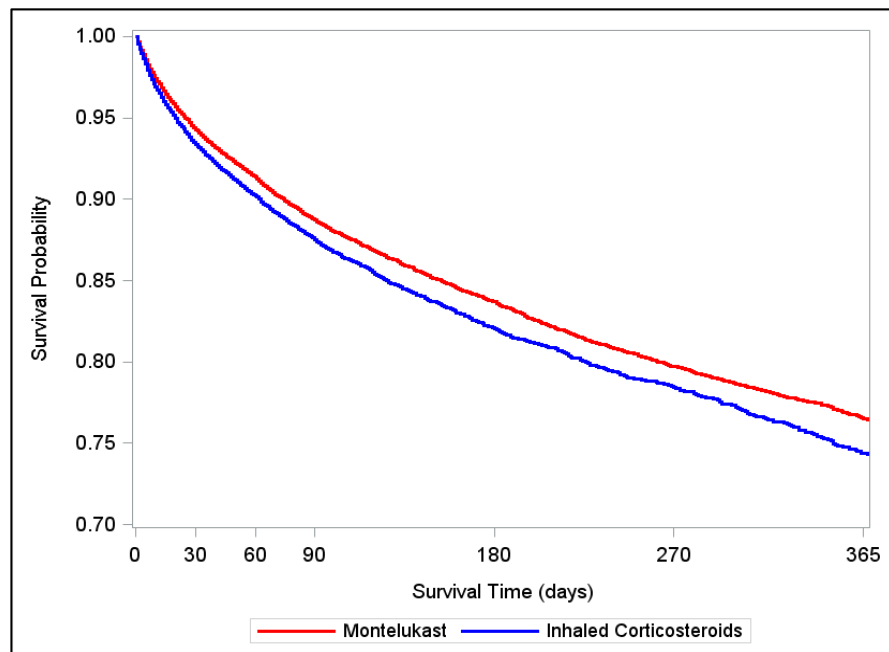
**Figure 5d. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Outpatient Depressive Disorder, by History of Psychiatric Disorder, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days**

**No History of Psychiatric Disorder**



|                         | 0       | 30      | 60      | 90     | 180    | 270    | 365    |
|-------------------------|---------|---------|---------|--------|--------|--------|--------|
| Montelukast             | 287,233 | 250,450 | 102,099 | 85,907 | 30,089 | 16,605 | 10,562 |
| Inhaled Corticosteroids | 287,233 | 259,013 | 66,571  | 45,105 | 9,827  | 4,281  | 2,315  |

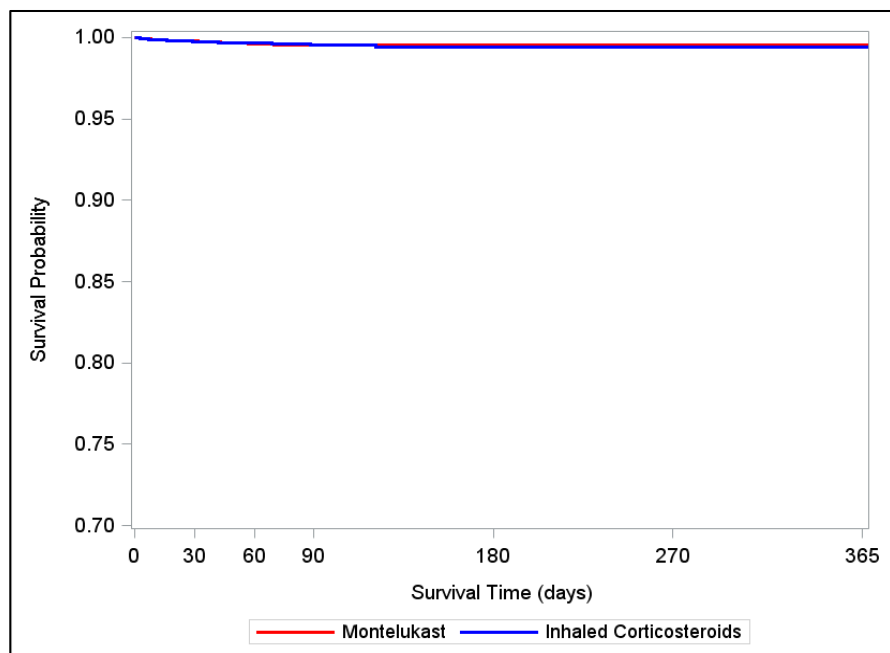
**History of Psychiatric Disorder**



|                         | 0       | 30      | 60     | 90     | 180    | 270    | 365   |
|-------------------------|---------|---------|--------|--------|--------|--------|-------|
| Montelukast             | 166,750 | 134,279 | 63,449 | 51,645 | 20,031 | 11,173 | 6,950 |
| Inhaled Corticosteroids | 166,750 | 137,512 | 41,723 | 27,530 | 6,465  | 2,717  | 1,420 |

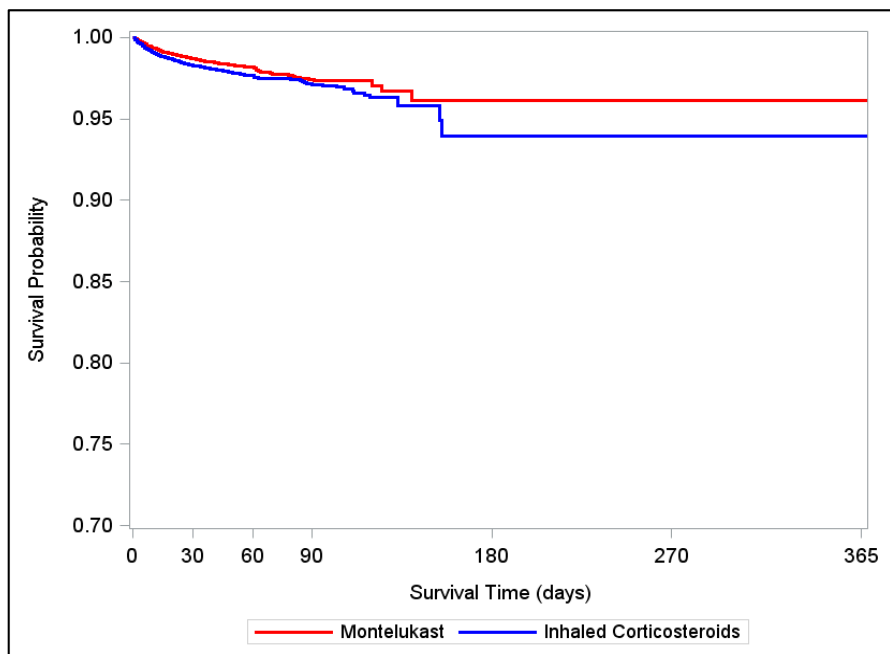
**Figure 5e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Outpatient Depressive Disorder, by Age Group, Conditional Matched Cohort, Follow-Up Truncated to 365 Days**

**Ages 6-11 years**



|                         | 0      | 30     | 60    | 90    | 180 | 270 | 365 |
|-------------------------|--------|--------|-------|-------|-----|-----|-----|
| Montelukast             | 82,660 | 66,734 | 6,210 | 3,223 | 193 | 38  | 8   |
| Inhaled Corticosteroids | 82,660 | 66,734 | 6,210 | 3,223 | 193 | 38  | 8   |

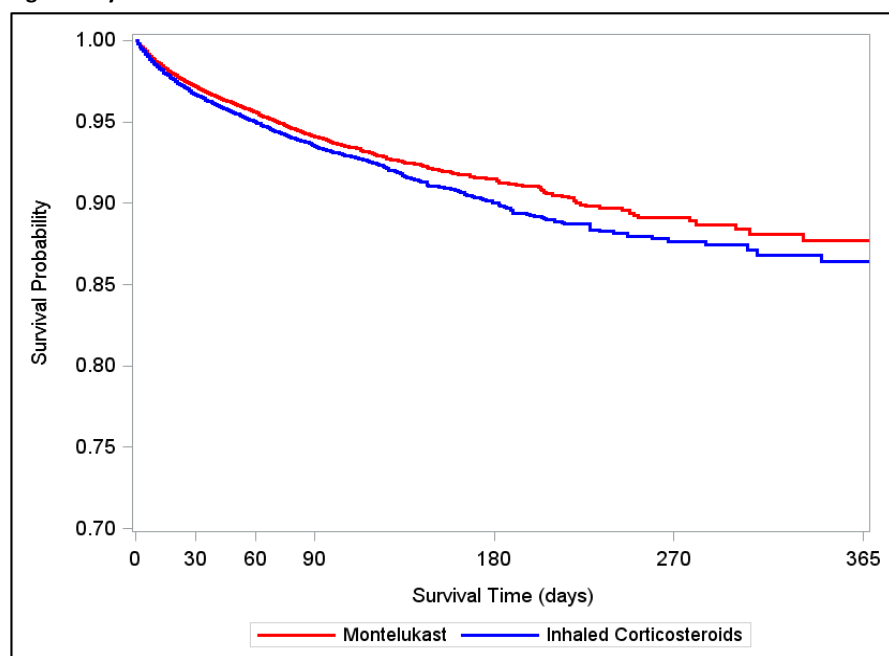
**Ages 12-17 years**



|                         | 0      | 30     | 60    | 90    | 180 | 270 | 365 |
|-------------------------|--------|--------|-------|-------|-----|-----|-----|
| Montelukast             | 50,191 | 39,373 | 2,926 | 1,455 | 49  | 11  | 3   |
| Inhaled Corticosteroids | 50,191 | 39,373 | 2,926 | 1,455 | 49  | 11  | 3   |

**Figure 5e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Outpatient Depressive Disorder, by Age Group, Conditional Matched Cohort, Follow-Up Truncated to 365 Days**

**Ages 18+ years**

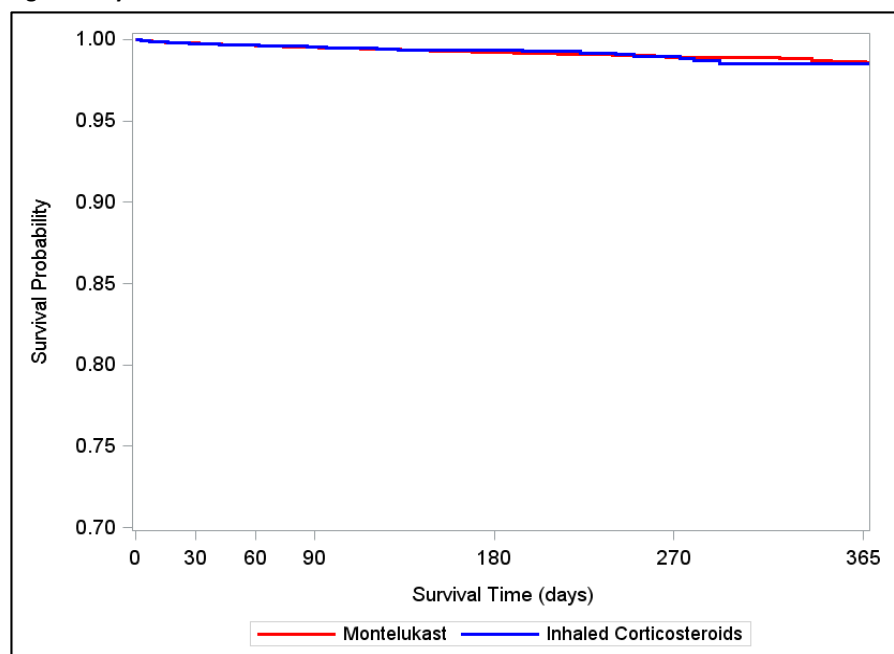


|                         | 0       | 30      | 60     | 90     | 180   | 270 | 365 |
|-------------------------|---------|---------|--------|--------|-------|-----|-----|
| Montelukast             | 308,196 | 220,297 | 32,073 | 18,098 | 1,807 | 469 | 167 |
| Inhaled Corticosteroids | 308,196 | 220,297 | 32,073 | 18,098 | 1,807 | 469 | 167 |



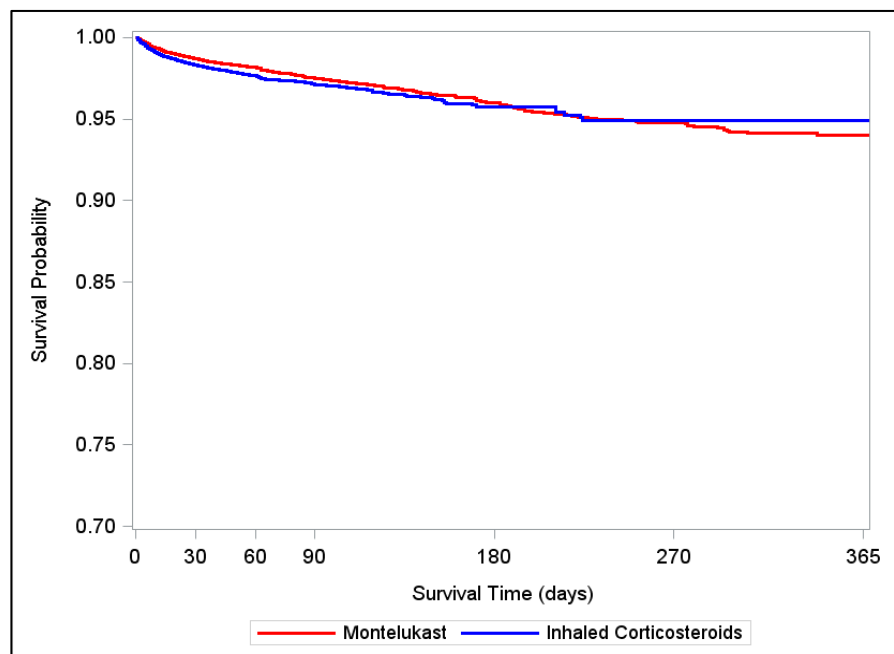
**Figure 5f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Outpatient Depressive Disorder, by Age Group, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days**

**Ages 6-11 years**



|                         | 0      | 30     | 60     | 90     | 180   | 270   | 365   |
|-------------------------|--------|--------|--------|--------|-------|-------|-------|
| Montelukast             | 82,660 | 73,244 | 28,428 | 23,960 | 7,523 | 3,896 | 2,256 |
| Inhaled Corticosteroids | 82,660 | 75,251 | 16,562 | 10,663 | 1,963 | 761   | 381   |

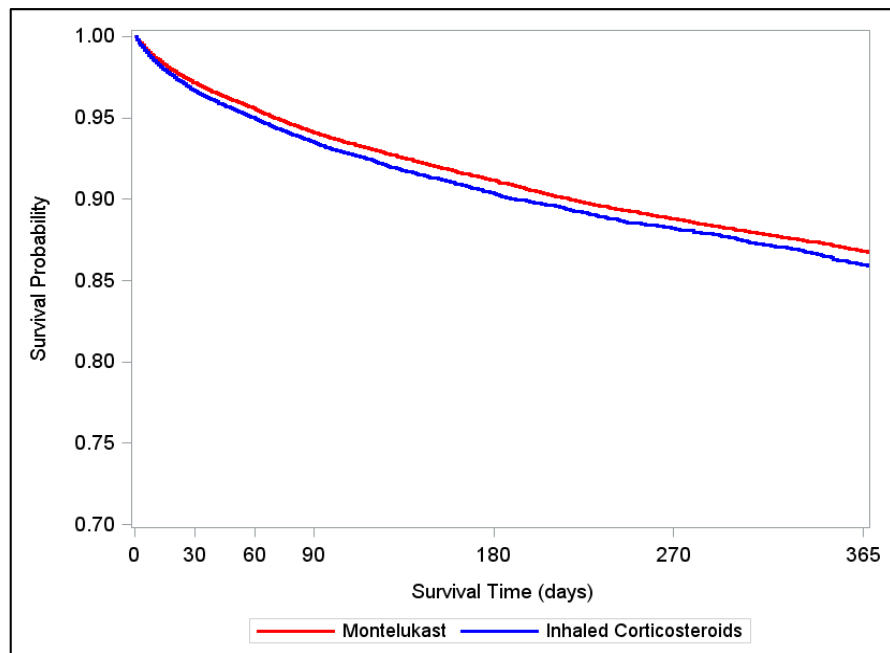
**Ages 12-17 years**



|                         | 0      | 30     | 60     | 90     | 180   | 270   | 365 |
|-------------------------|--------|--------|--------|--------|-------|-------|-----|
| Montelukast             | 50,191 | 44,166 | 14,896 | 12,363 | 3,382 | 1,658 | 948 |
| Inhaled Corticosteroids | 50,191 | 44,781 | 8,805  | 5,493  | 865   | 309   | 147 |

**Figure 5f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Outpatient Depressive Disorder, by Age Group, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days**

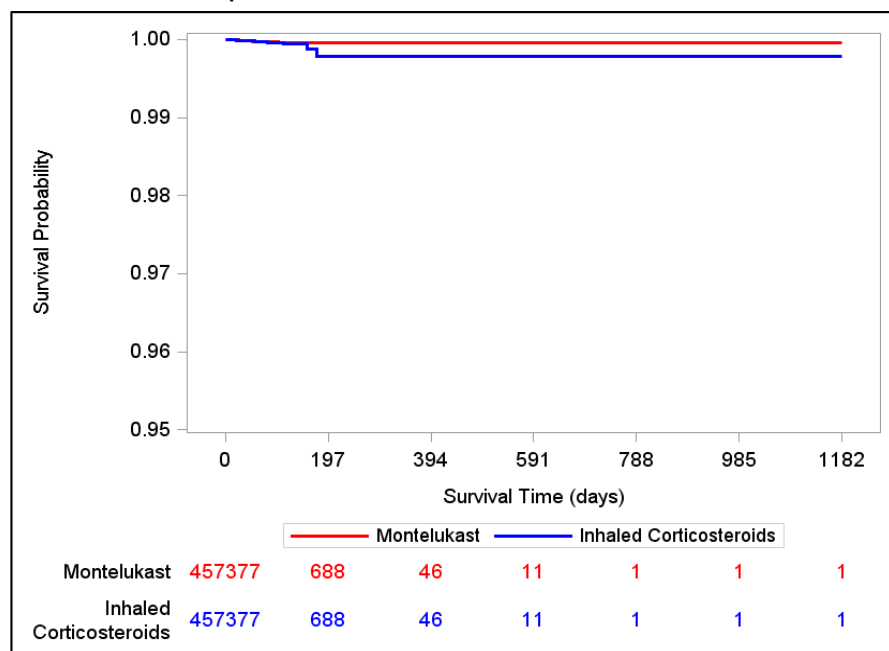
**Ages 18+ years**



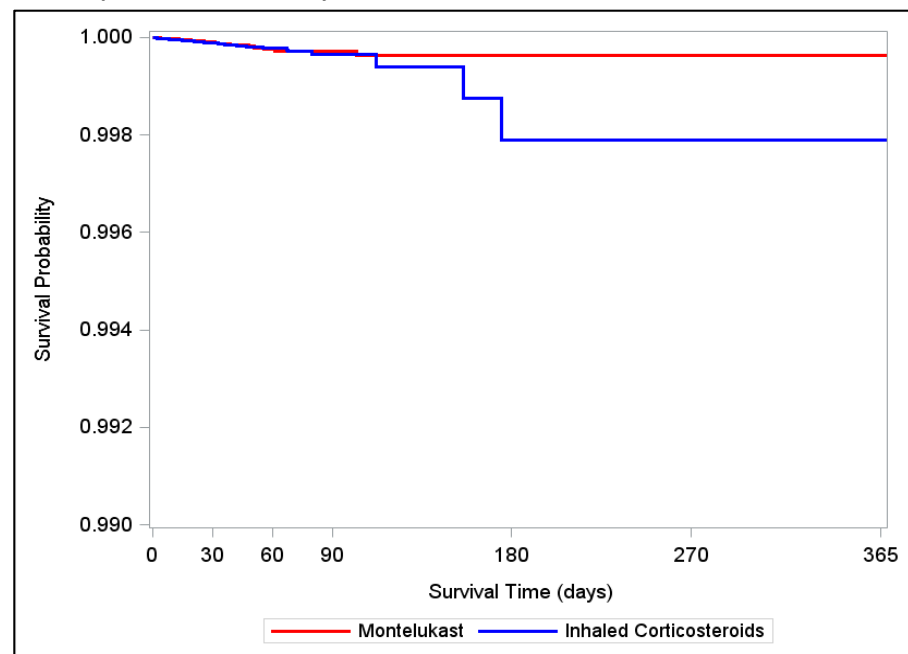
|                         | 0       | 30      | 60      | 90     | 180    | 270    | 365    |
|-------------------------|---------|---------|---------|--------|--------|--------|--------|
| Montelukast             | 308,196 | 256,203 | 118,266 | 97,932 | 38,206 | 21,742 | 14,026 |
| Inhaled Corticosteroids | 308,196 | 264,768 | 80,791  | 55,030 | 13,210 | 5,842  | 3,169  |

**Figure 6a. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm, Conditional Matched Cohort**

**All Available Follow-Up**



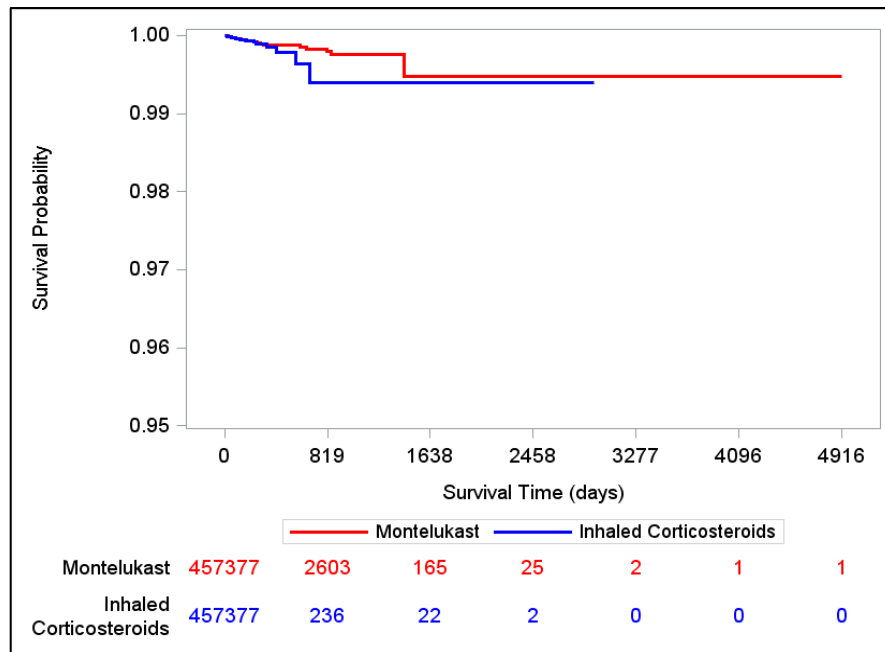
**Follow-Up Truncated at 365 Days**



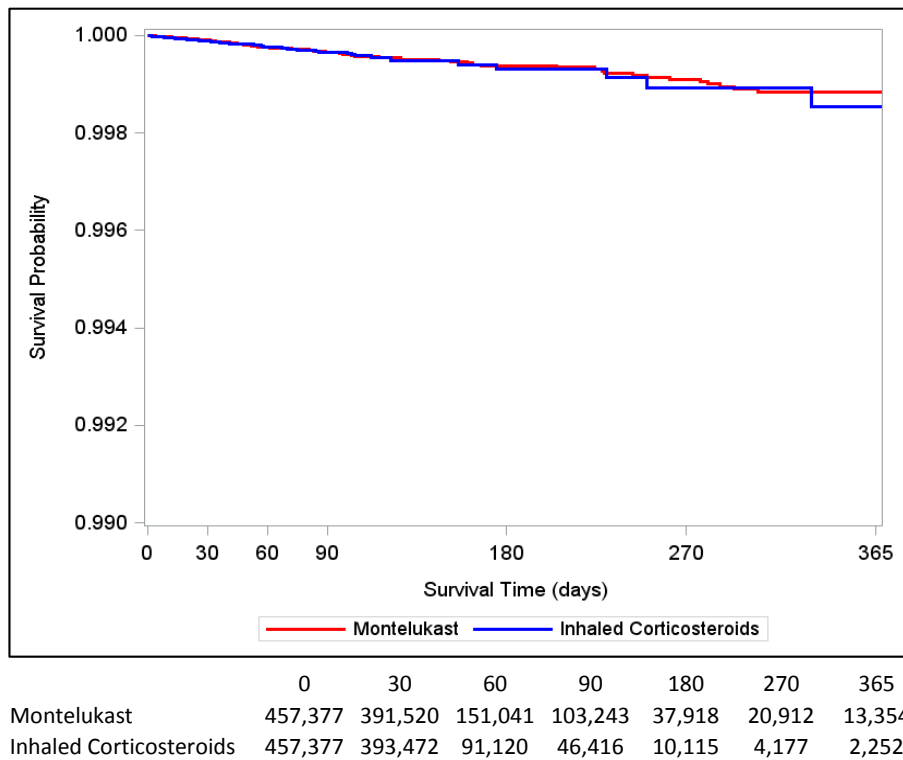
|                         | 0       | 30      | 60     | 90     | 180   | 270 | 365 |
|-------------------------|---------|---------|--------|--------|-------|-----|-----|
| Montelukast             | 457,377 | 336,909 | 33,141 | 12,267 | 1,076 | 253 | 88  |
| Inhaled Corticosteroids | 457,377 | 336,909 | 33,141 | 12,267 | 1,076 | 253 | 88  |

**Figure 6b. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm, Unconditional Matched Cohort**

**All Available Follow-Up**

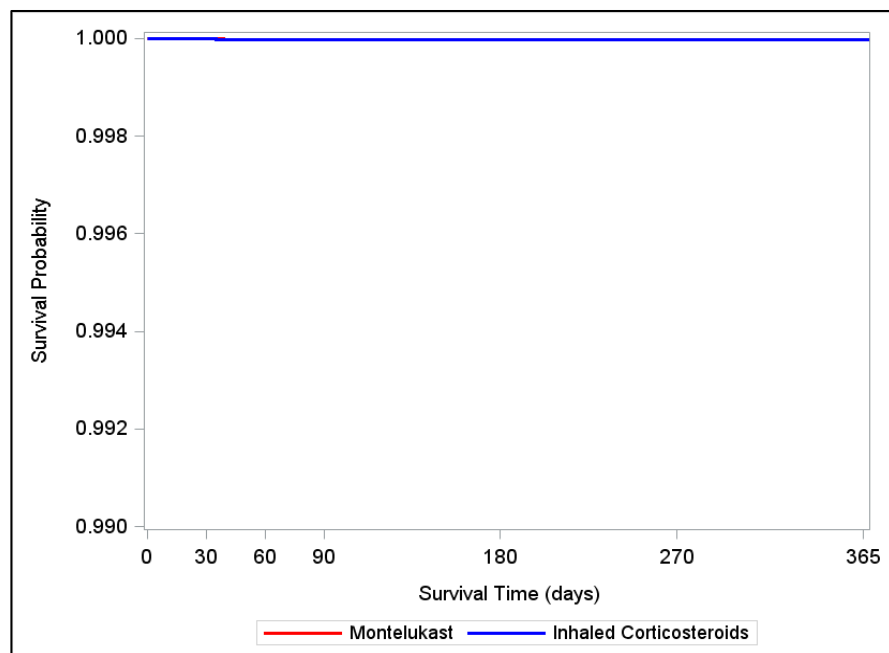


**Follow-Up Truncated at 365 Days**



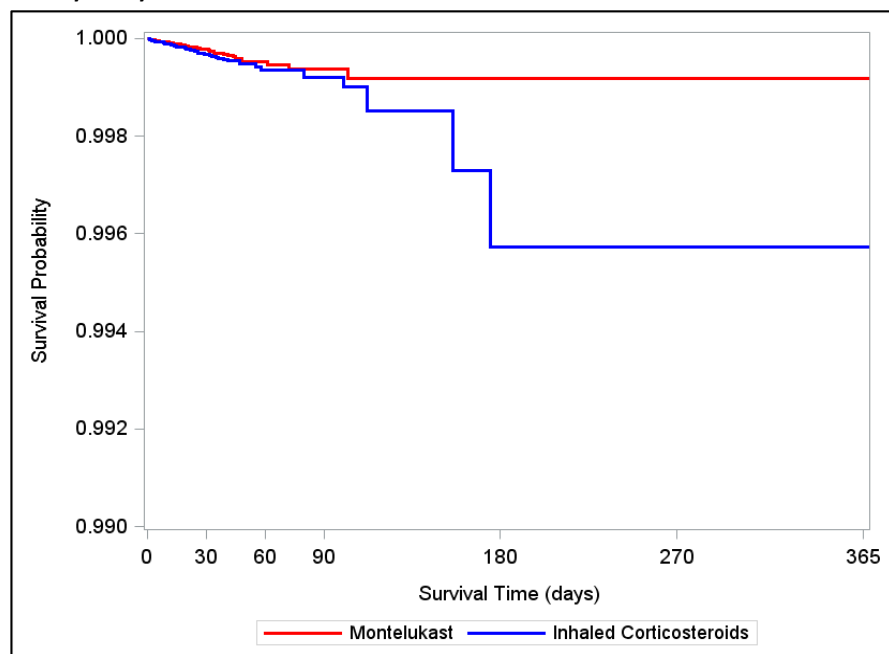
**Figure 6c. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm, by History of Psychiatric Disorder, Conditional Matched Cohort, Follow-Up Truncated to 365 Days**

**No History of Psychiatric Disorder**



|                         | 0       | 30      | 60     | 90    | 180 | 270 | 365 |
|-------------------------|---------|---------|--------|-------|-----|-----|-----|
| Montelukast             | 287,233 | 215,071 | 18,082 | 6,468 | 486 | 123 | 44  |
| Inhaled Corticosteroids | 287,233 | 215,071 | 18,082 | 6,468 | 486 | 123 | 44  |

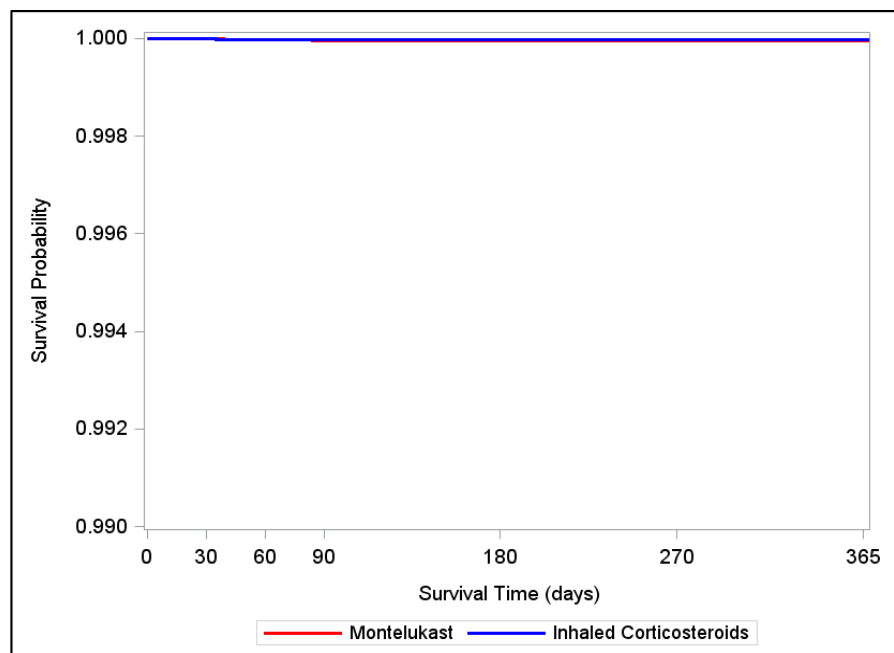
**History of Psychiatric Disorder**



|                         | 0       | 30      | 60     | 90    | 180 | 270 | 365 |
|-------------------------|---------|---------|--------|-------|-----|-----|-----|
| Montelukast             | 166,750 | 119,441 | 14,913 | 5,650 | 586 | 156 | 54  |
| Inhaled Corticosteroids | 166,750 | 119,441 | 14,913 | 5,650 | 586 | 156 | 54  |

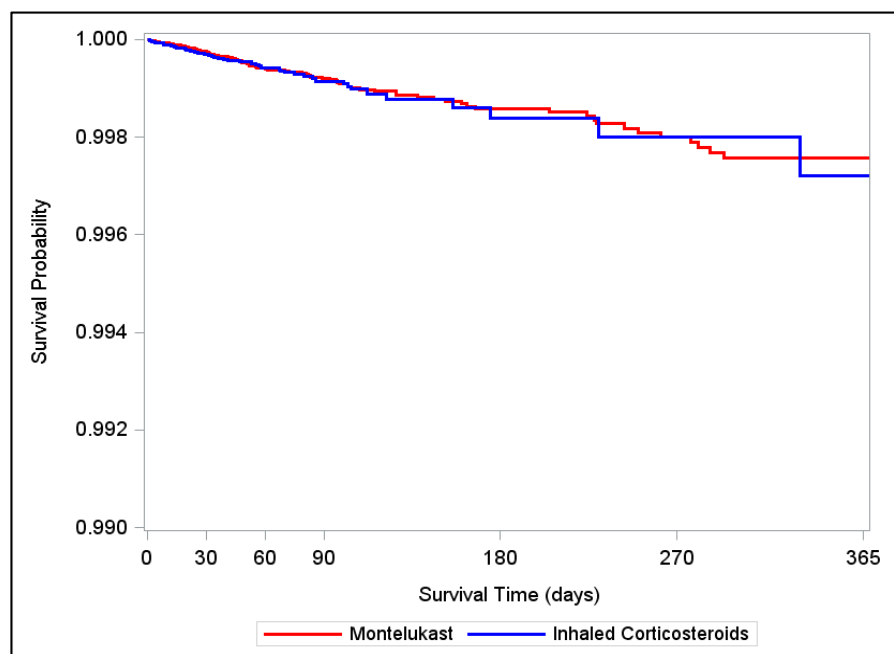
**Figure 6d. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm, by History of Psychiatric Disorder, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days**

**No History of Psychiatric Disorder**



|                         | 0       | 30      | 60     | 90     | 180    | 270    | 365   |
|-------------------------|---------|---------|--------|--------|--------|--------|-------|
| Montelukast             | 287,233 | 248,280 | 87,677 | 58,221 | 19,918 | 10,698 | 6,779 |
| Inhaled Corticosteroids | 287,233 | 248,641 | 52,576 | 26,402 | 5,365  | 2,216  | 1,180 |

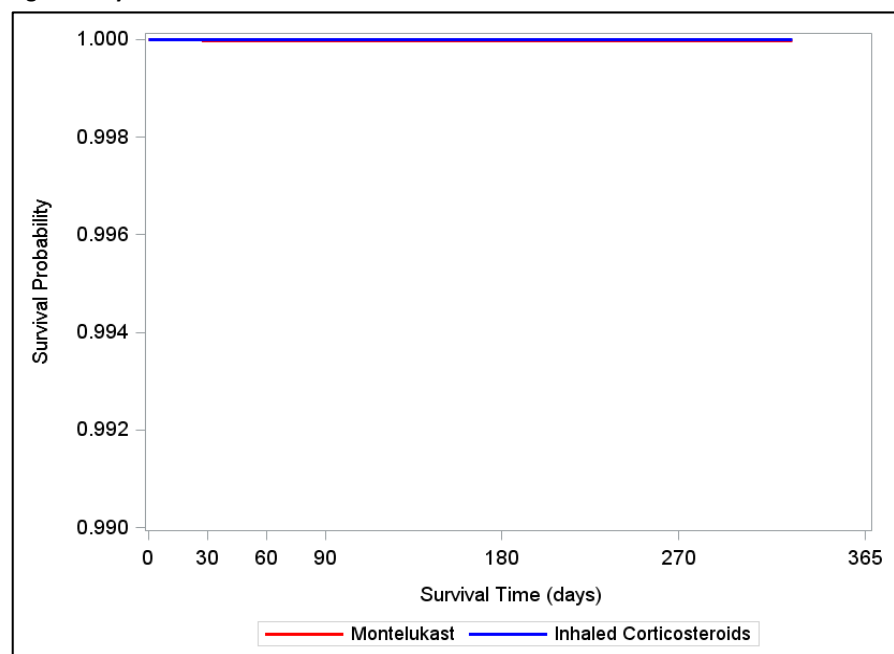
**History of Psychiatric Disorder**



|                         | 0       | 30      | 60     | 90     | 180    | 270    | 365   |
|-------------------------|---------|---------|--------|--------|--------|--------|-------|
| Montelukast             | 166,750 | 140,341 | 62,144 | 44,177 | 17,681 | 10,015 | 6,449 |
| Inhaled Corticosteroids | 166,750 | 141,876 | 37,729 | 19,630 | 4,674  | 1,929  | 1,058 |

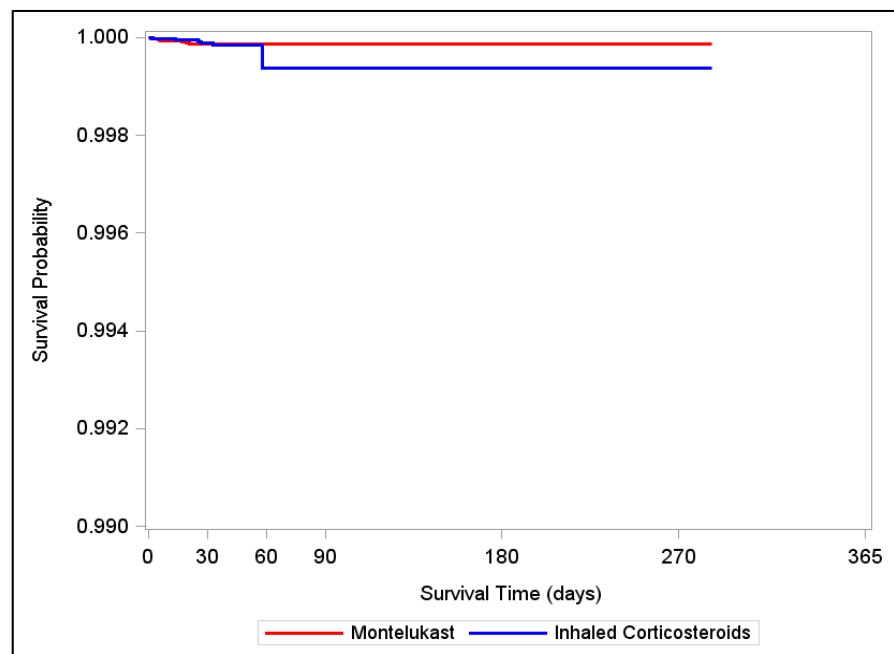
**Figure 6e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm, by Age Group, Conditional Matched Cohort, Follow-Up Truncated to 365 Days**

**Ages 6-11 years**



|                         | 0      | 30     | 60    | 90    | 180 | 270 | 365 |
|-------------------------|--------|--------|-------|-------|-----|-----|-----|
| Montelukast             | 82,660 | 62,451 | 4,138 | 1,156 | 49  | 4   | 0   |
| Inhaled Corticosteroids | 82,660 | 62,451 | 4,138 | 1,156 | 49  | 4   | 0   |

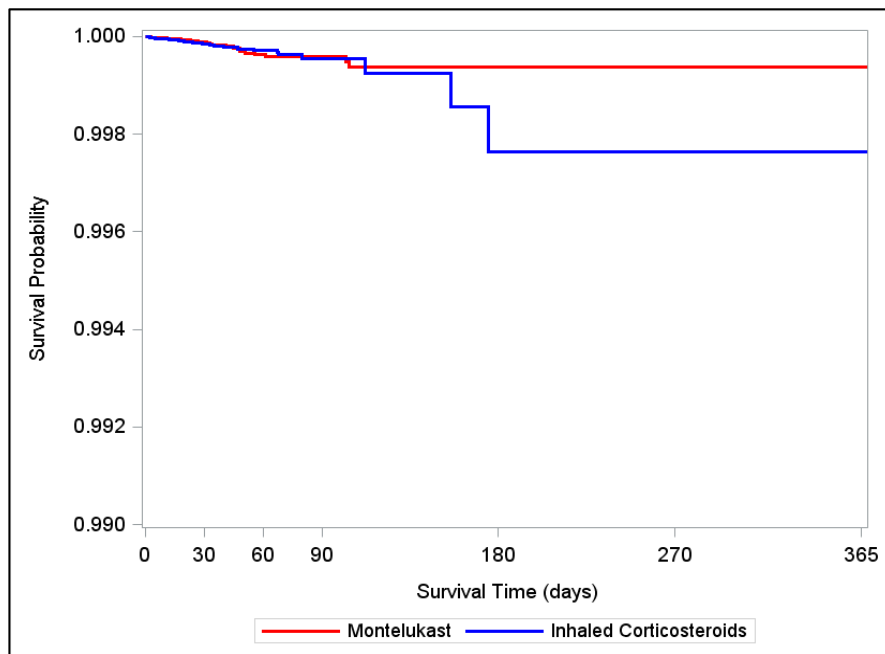
**Ages 12-17 years**



|                         | 0      | 30     | 60    | 90  | 180 | 270 | 365 |
|-------------------------|--------|--------|-------|-----|-----|-----|-----|
| Montelukast             | 50,191 | 38,524 | 2,079 | 604 | 19  | 2   | 0   |
| Inhaled Corticosteroids | 50,191 | 38,524 | 2,079 | 604 | 19  | 2   | 0   |

**Figure 6e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm, by Age Group, Conditional Matched Cohort, Follow-Up Truncated to 365 Days**

**Ages 18+ years**

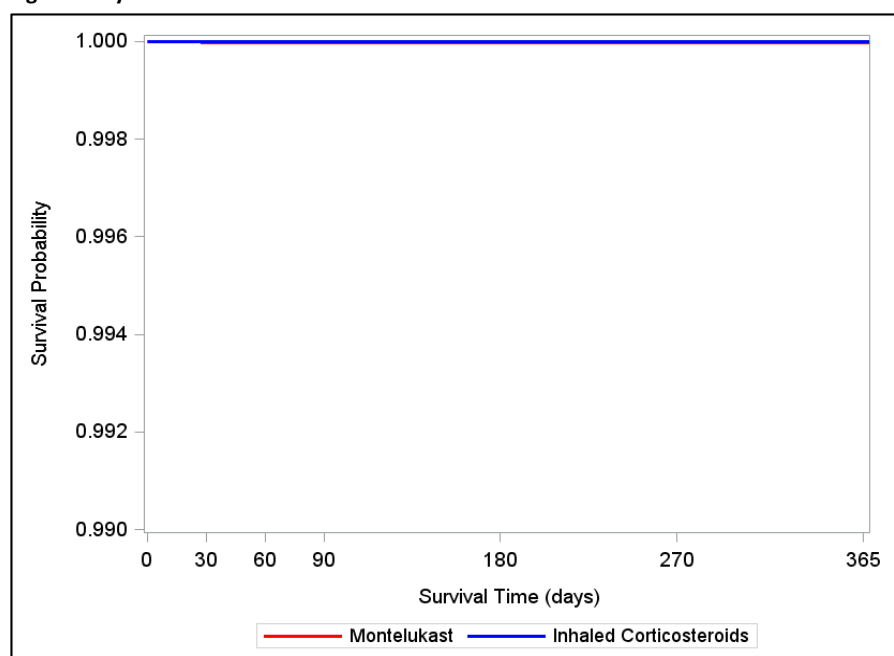


|                         | 0       | 30      | 60     | 90     | 180   | 270 | 365 |
|-------------------------|---------|---------|--------|--------|-------|-----|-----|
| Montelukast             | 308,196 | 224,123 | 26,416 | 10,410 | 1,018 | 259 | 90  |
| Inhaled Corticosteroids | 308,196 | 224,123 | 26,416 | 10,410 | 1,018 | 259 | 90  |



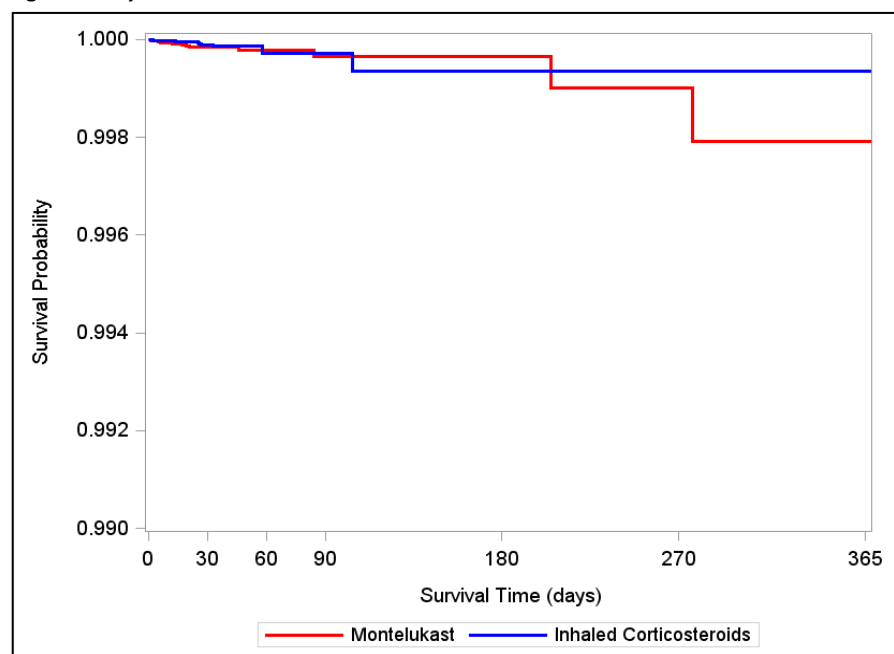
**Figure 6f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm, by Age Group, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days**

**Ages 6-11 years**



|                         | 0      | 30     | 60     | 90     | 180   | 270   | 365   |
|-------------------------|--------|--------|--------|--------|-------|-------|-------|
| Montelukast             | 82,660 | 72,925 | 23,349 | 13,908 | 4,308 | 2,102 | 1,213 |
| Inhaled Corticosteroids | 82,660 | 70,769 | 12,371 | 5,187  | 859   | 308   | 154   |

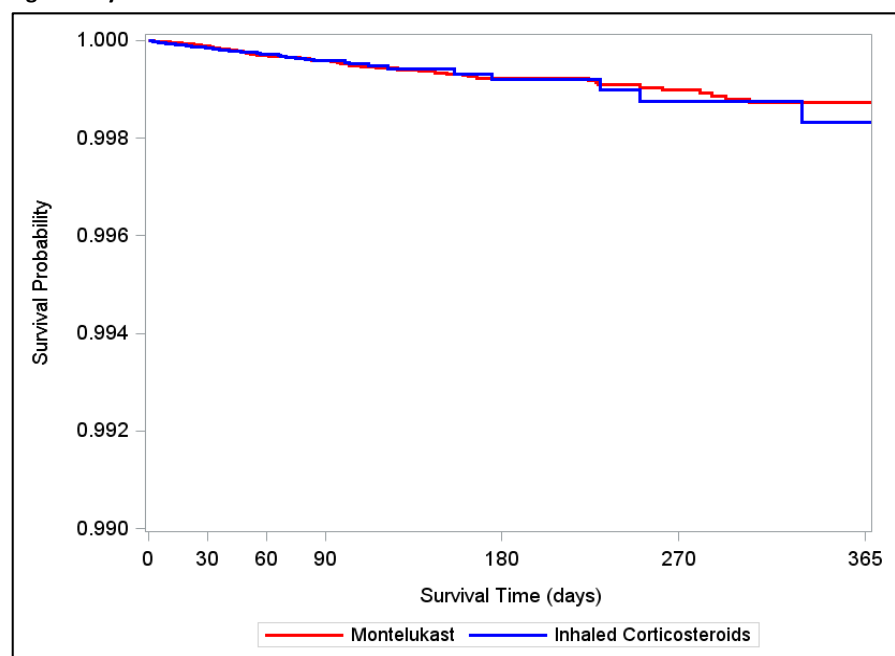
**Ages 12-17 years**



|                         | 0      | 30     | 60     | 90    | 180   | 270 | 365 |
|-------------------------|--------|--------|--------|-------|-------|-----|-----|
| Montelukast             | 50,191 | 44,387 | 12,472 | 7,518 | 1,989 | 944 | 541 |
| Inhaled Corticosteroids | 50,191 | 43,596 | 6,794  | 2,874 | 427   | 148 | 65  |

**Figure 6f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm, by Age Group, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days**

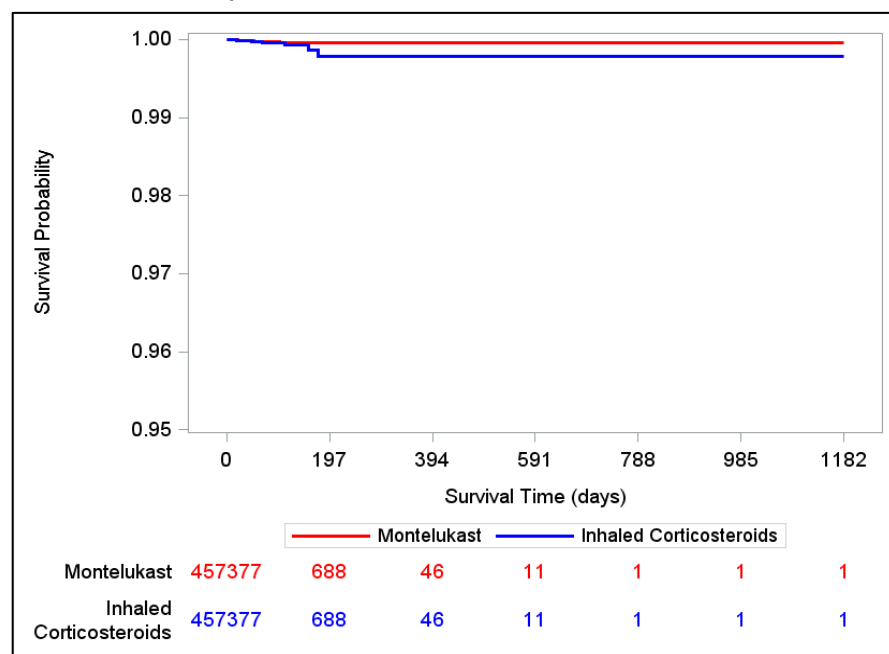
**Ages 18+ years**



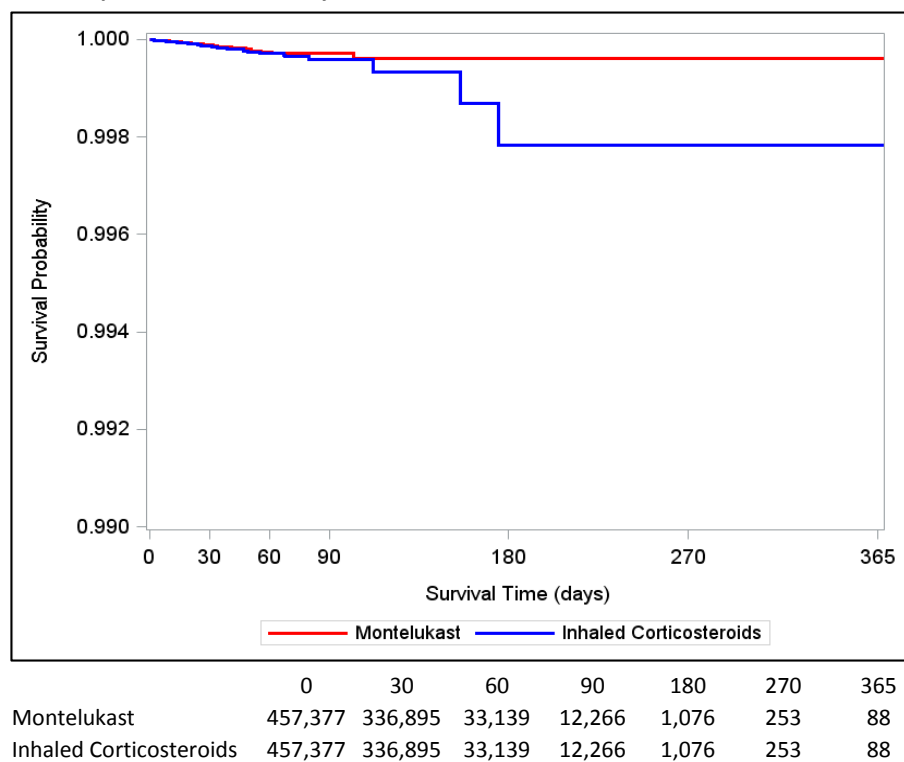
|                         | 0       | 30      | 60      | 90     | 180    | 270    | 365    |
|-------------------------|---------|---------|---------|--------|--------|--------|--------|
| Montelukast             | 308,196 | 260,157 | 110,635 | 78,803 | 30,670 | 17,376 | 11,305 |
| Inhaled Corticosteroids | 308,196 | 265,263 | 69,663  | 37,370 | 8,649  | 3,654  | 2,000  |

**Figure 7a. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm with E-Code, Conditional Matched Cohort**

**All Available Follow-Up**

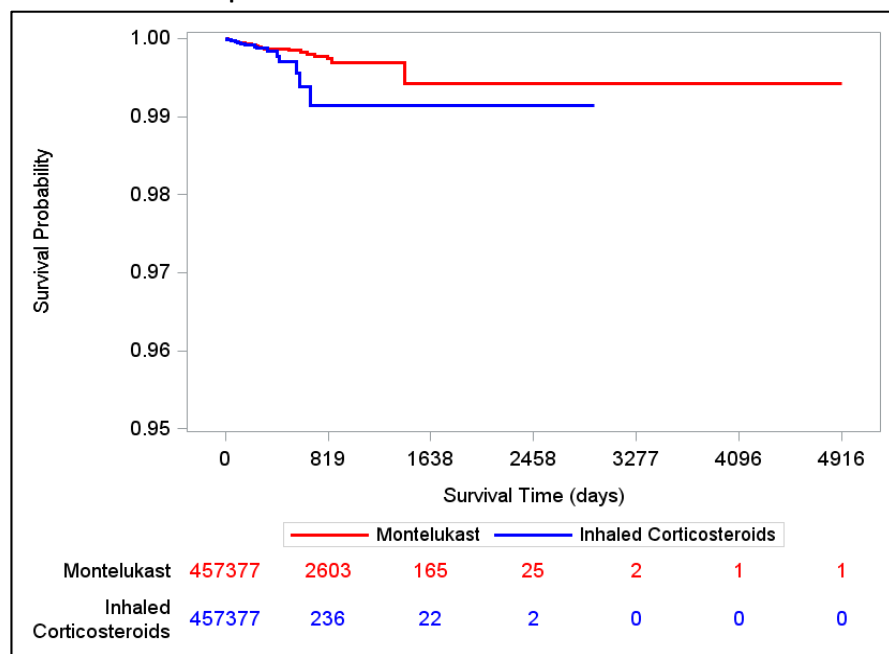


**Follow-Up Truncated at 365 Days**

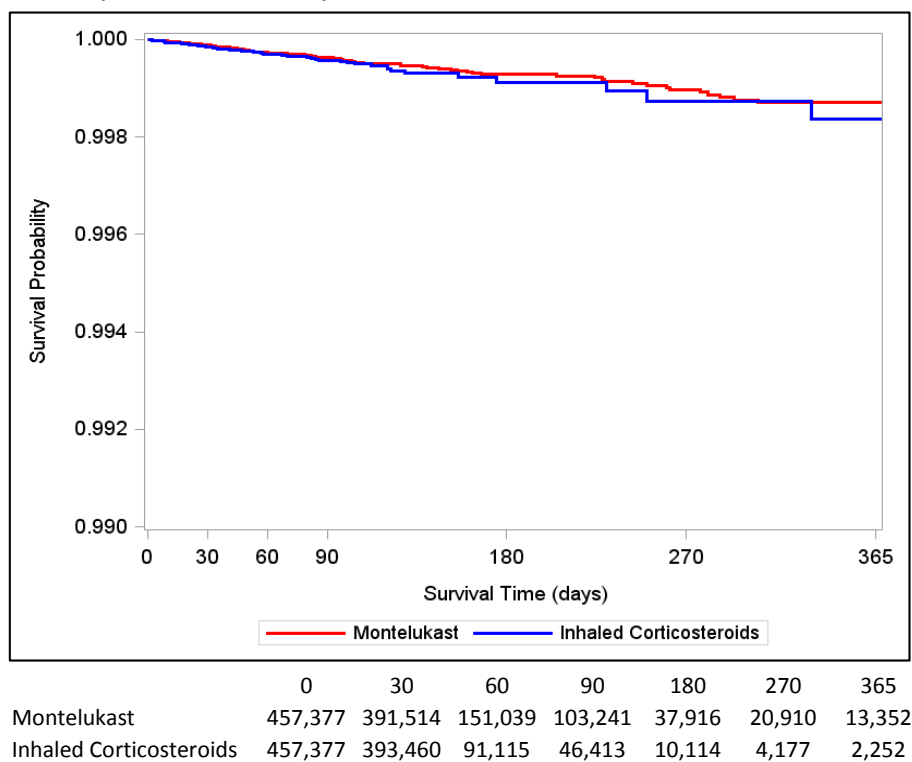


**Figure 7b. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm with E-Code, Unconditional Matched Cohort**

**All Available Follow-Up**

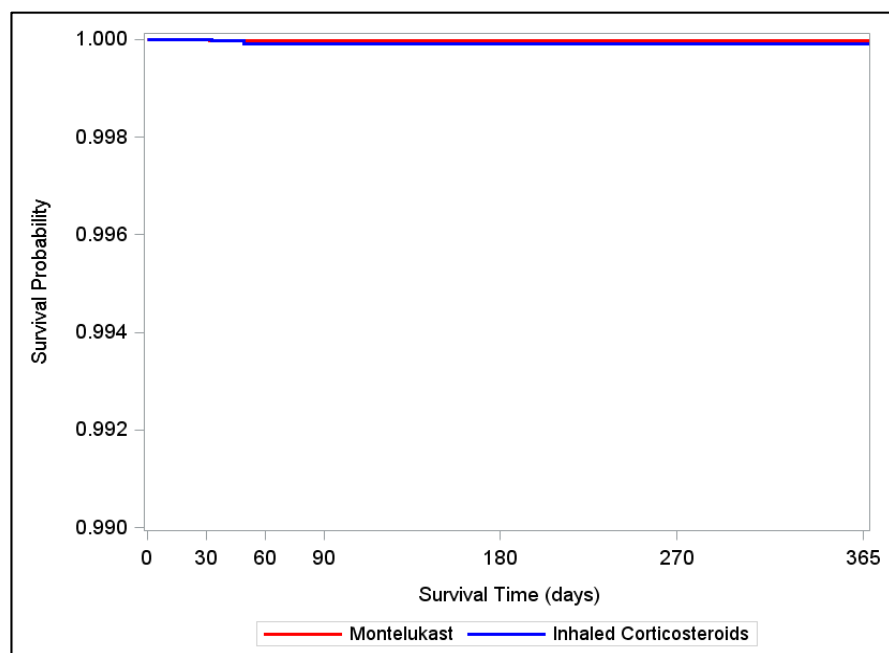


**Follow-Up Truncated at 365 Days**



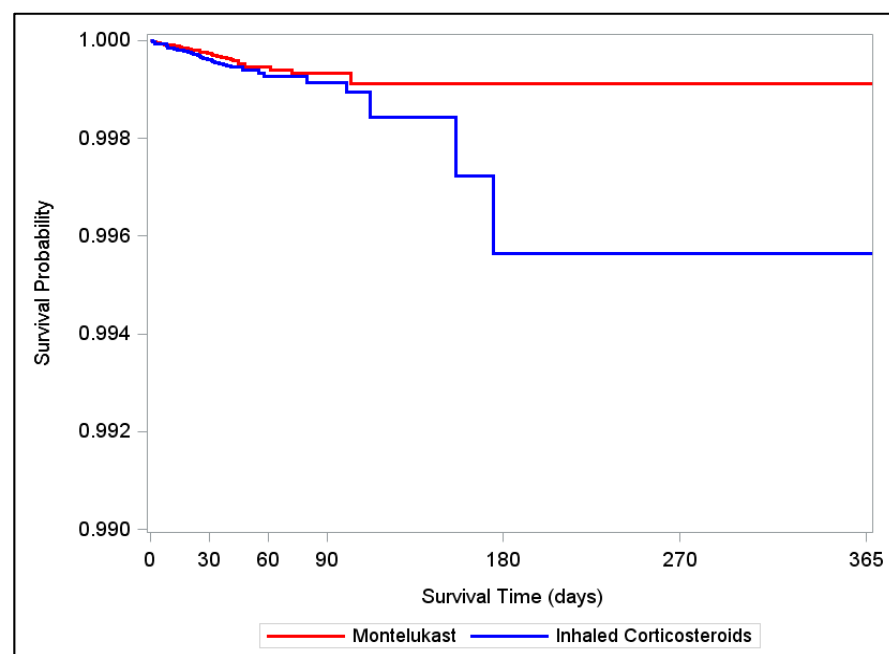
**Figure 7c. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm or E-code, by History of Psychiatric Disorder, Conditional Matched Cohort, Follow-Up Truncated to 365 Days**

**No History of Psychiatric Disorder**



|                         | 0       | 30      | 60     | 90    | 180 | 270 | 365 |
|-------------------------|---------|---------|--------|-------|-----|-----|-----|
| Montelukast             | 287,233 | 215,069 | 18,081 | 6,467 | 486 | 123 | 44  |
| Inhaled Corticosteroids | 287,233 | 215,069 | 18,081 | 6,467 | 486 | 123 | 44  |

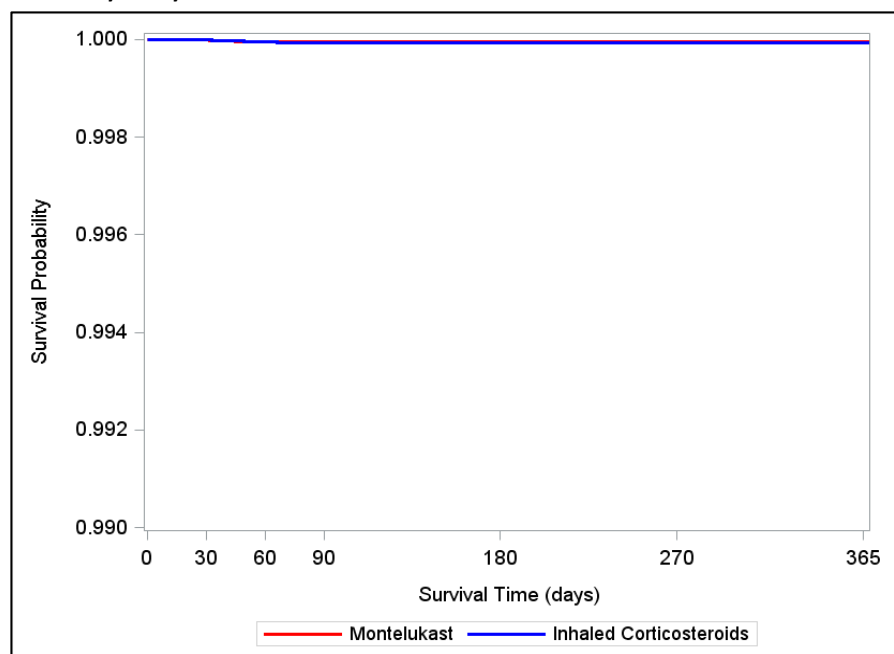
**History of Psychiatric Disorder**



|                         | 0       | 30      | 60     | 90    | 180 | 270 | 365 |
|-------------------------|---------|---------|--------|-------|-----|-----|-----|
| Montelukast             | 166,750 | 119,429 | 14,913 | 5,650 | 586 | 156 | 54  |
| Inhaled Corticosteroids | 166,750 | 119,429 | 14,913 | 5,650 | 586 | 156 | 54  |

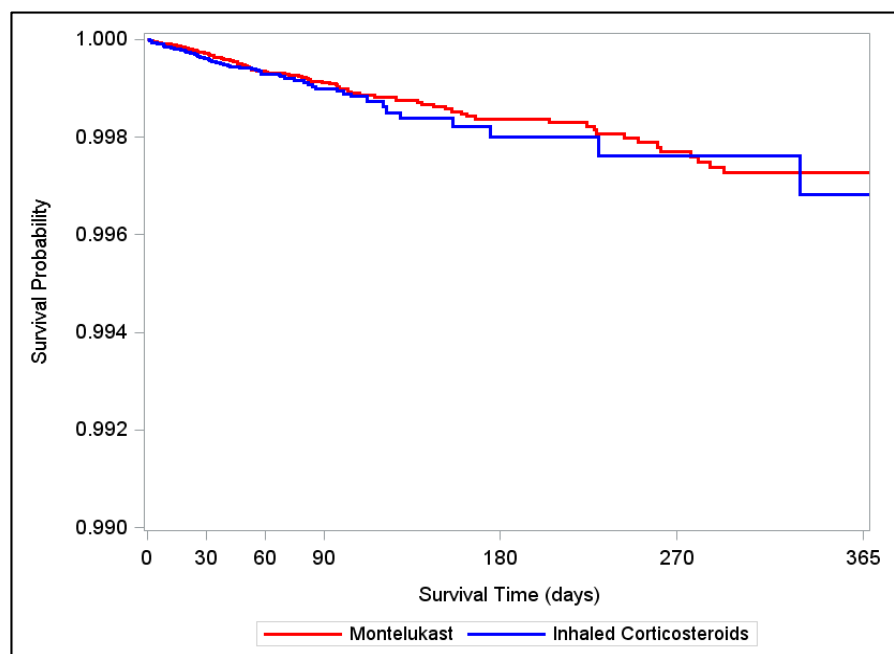
**Figure 7d. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm or E-code, by History of Psychiatric Disorder, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days**

**No History of Psychiatric Disorder**



|                         | 0       | 30      | 60     | 90     | 180    | 270    | 365   |
|-------------------------|---------|---------|--------|--------|--------|--------|-------|
| Montelukast             | 287,233 | 248,279 | 87,677 | 58,221 | 19,918 | 10,698 | 6,779 |
| Inhaled Corticosteroids | 287,233 | 248,640 | 52,574 | 26,401 | 5,365  | 2,216  | 1,180 |

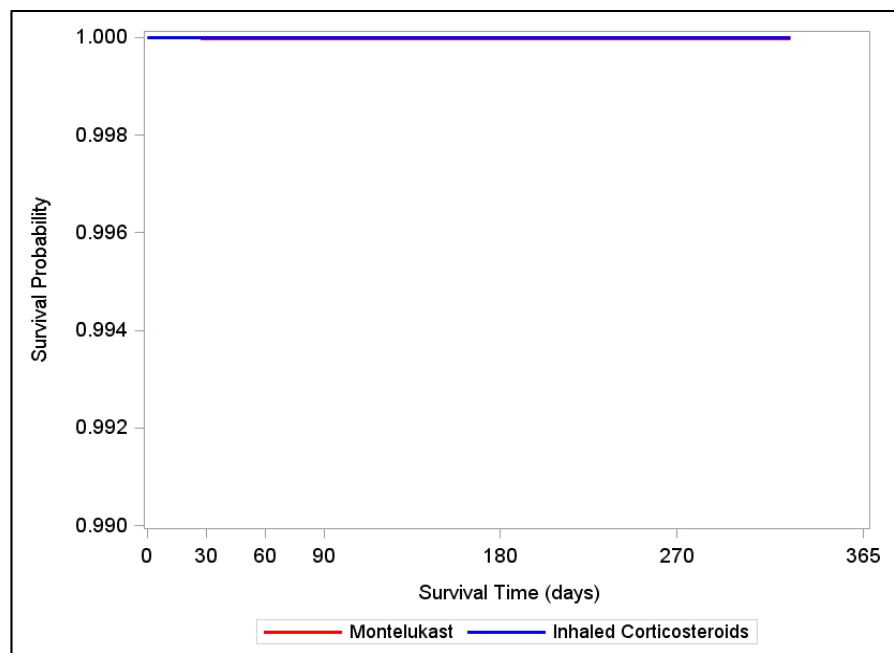
**History of Psychiatric Disorder**



|                         | 0       | 30      | 60     | 90     | 180    | 270    | 365   |
|-------------------------|---------|---------|--------|--------|--------|--------|-------|
| Montelukast             | 166,750 | 140,336 | 62,142 | 44,175 | 17,679 | 10,013 | 6,447 |
| Inhaled Corticosteroids | 166,750 | 141,865 | 37,726 | 19,628 | 4,673  | 1,929  | 1,058 |

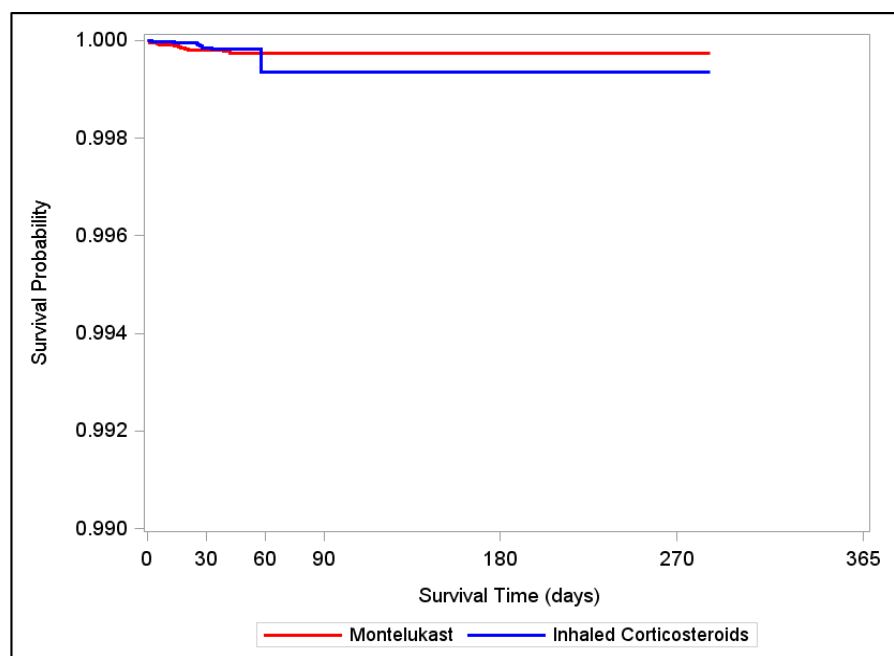
**Figure 7e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm or E-code, by Age Group, Conditional Matched Cohort, Follow-Up Truncated to 365 Days**

**Ages 6-11 years**



|                         | 0      | 30     | 60    | 90    | 180 | 270 | 365 |
|-------------------------|--------|--------|-------|-------|-----|-----|-----|
| Montelukast             | 82,660 | 62,451 | 4,138 | 1,156 | 49  | 4   | 0   |
| Inhaled Corticosteroids | 82,660 | 62,451 | 4,138 | 1,156 | 49  | 4   | 0   |

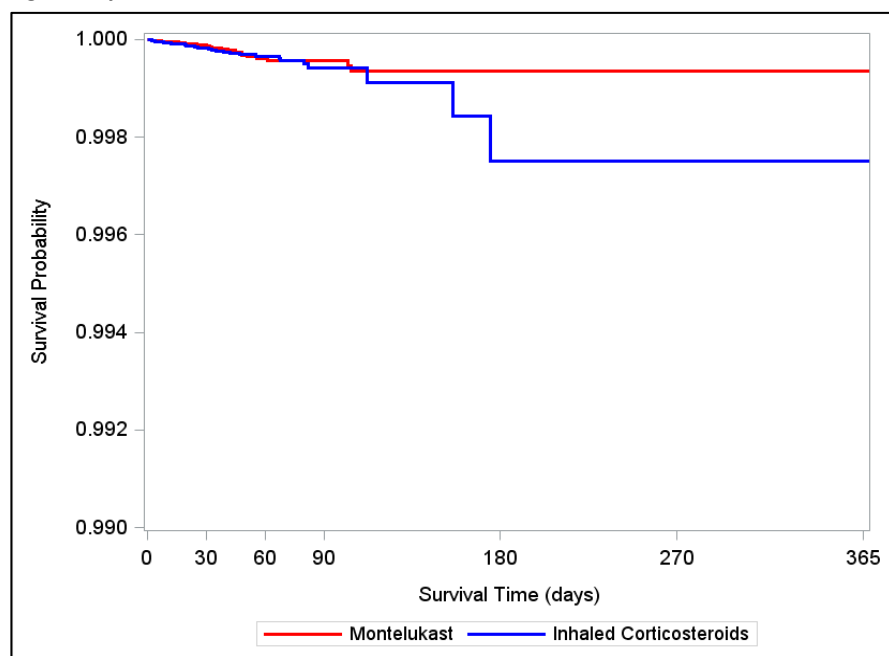
**Ages 12-17 years**



|                         | 0      | 30     | 60    | 90  | 180 | 270 | 365 |
|-------------------------|--------|--------|-------|-----|-----|-----|-----|
| Montelukast             | 50,191 | 38,522 | 2,079 | 604 | 19  | 2   | 0   |
| Inhaled Corticosteroids | 50,191 | 38,522 | 2,079 | 604 | 19  | 2   | 0   |

**Figure 7e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm or E-code, by Age Group, Conditional Matched Cohort, Follow-Up Truncated to 365 Days**

**Ages 18+ years**

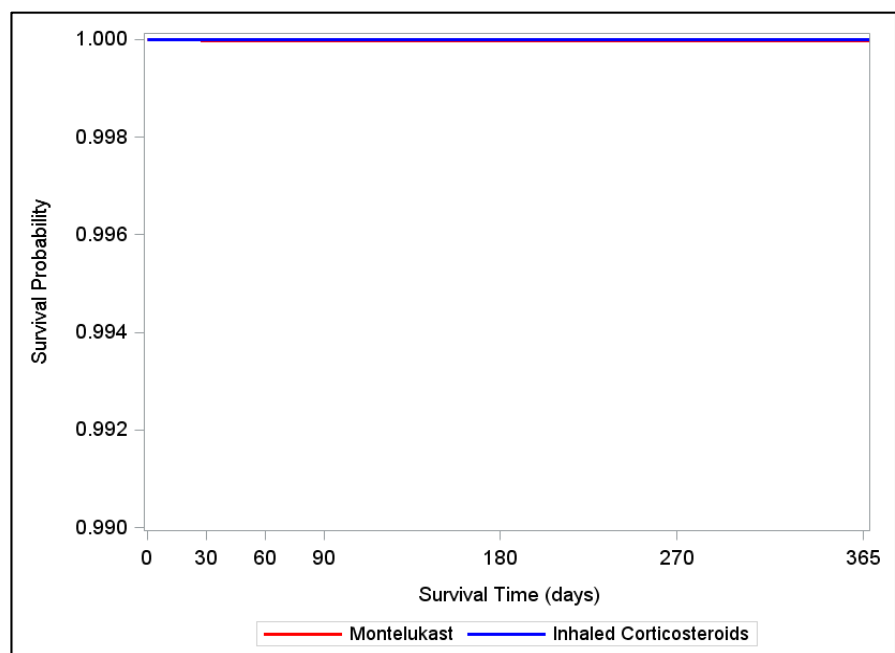


|                         | 0       | 30      | 60     | 90     | 180   | 270 | 365 |
|-------------------------|---------|---------|--------|--------|-------|-----|-----|
| Montelukast             | 308,196 | 224,112 | 26,415 | 10,410 | 1,018 | 259 | 90  |
| Inhaled Corticosteroids | 308,196 | 224,112 | 26,415 | 10,410 | 1,018 | 259 | 90  |



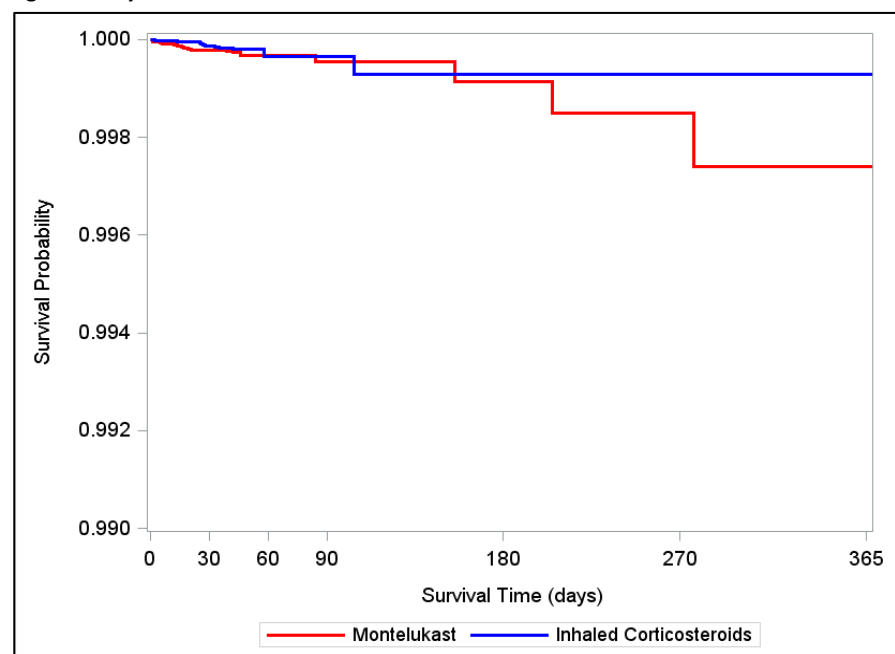
**Figure 7f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm or E-code, by Age Group, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days**

**Ages 6-11 years**



|                         | 0      | 30     | 60     | 90     | 180   | 270   | 365   |
|-------------------------|--------|--------|--------|--------|-------|-------|-------|
| Montelukast             | 82,660 | 72,925 | 23,349 | 13,908 | 4,308 | 2,102 | 1,213 |
| Inhaled Corticosteroids | 82,660 | 70,769 | 12,371 | 5,187  | 859   | 308   | 154   |

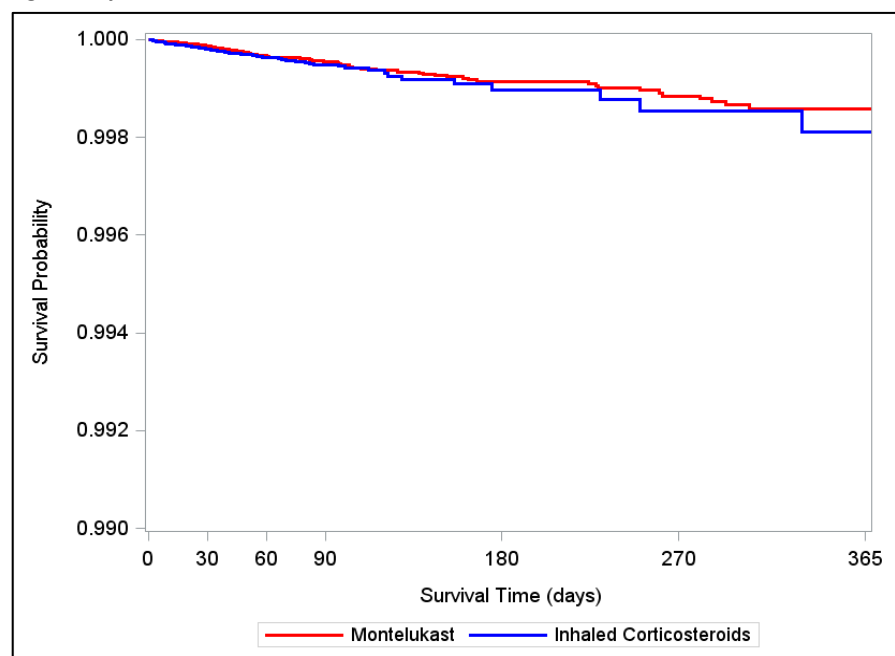
**Ages 12-17 years**



|                         | 0      | 30     | 60     | 90    | 180   | 270 | 365 |
|-------------------------|--------|--------|--------|-------|-------|-----|-----|
| Montelukast             | 50,191 | 44,385 | 12,472 | 7,518 | 1,988 | 943 | 540 |
| Inhaled Corticosteroids | 50,191 | 43,595 | 6,794  | 2,874 | 427   | 148 | 65  |

**Figure 7f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm or E-code, by Age Group, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days**

**Ages 18+ years**



|                         | 0       | 30      | 60      | 90     | 180    | 270    | 365    |
|-------------------------|---------|---------|---------|--------|--------|--------|--------|
| Montelukast             | 308,196 | 260,153 | 110,633 | 78,801 | 30,669 | 17,375 | 11,304 |
| Inhaled Corticosteroids | 308,196 | 265,252 | 69,658  | 37,367 | 8,648  | 3,654  | 2,000  |

**Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (July 17, 2019)**


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| DP ID | Start Date <sup>1</sup> | End Date <sup>1</sup> |
|-------|-------------------------|-----------------------|
| DP01  | 1/1/2000                | 9/30/2015             |
| DP02  | 1/1/2000                | 9/30/2015             |
| DP03  | 1/1/2004                | 9/30/2015             |
| DP04  | 1/1/2008                | 9/30/2015             |
| DP05  | 1/1/2006                | 9/30/2015             |
| DP06  | 1/1/2000                | 9/30/2015             |
| DP07  | 1/1/2010                | 9/30/2015             |
| DP08  | 1/1/2000                | 9/30/2015             |
| DP09  | 6/1/2007                | 9/30/2015             |
| DP10  | 1/1/2000                | 9/30/2015             |
| DP11  | 1/1/2005                | 9/30/2015             |
| DP12  | 1/1/2000                | 9/30/2015             |
| DP13  | 1/1/2000                | 9/30/2015             |
| DP14  | 1/1/2008                | 9/30/2015             |
| DP15  | 1/1/2000                | 9/30/2015             |
| DP16  | 1/1/2012                | 9/30/2015             |

<sup>1</sup>The start and end dates are based on the minimum and maximum dates within each DP. The month with the maximum date must have at least 80% of the number of records in the previous month.

## Appendix B. List of Generic and Brand Drug Names Used to Define Exposures and Comparators in this Request

| Generic Name                                     | Brand Name               |
|--|--------------------------|
| <b>Montelukast</b>                               |                          |
| montelukast sodium                               | Singulair                |
| montelukast sodium                               | montelukast              |
| <b>Inhaled Corticosteroids (ICS) Monotherapy</b> |                          |
| beclomethasone dipropionate                      | Vanceril                 |
| beclomethasone dipropionate                      | Vanceril Double Strength |
| beclomethasone dipropionate                      | Qvar                     |
| beclomethasone dipropionate                      | Beclovent                |
| beclomethasone dipropionate                      | Beclovent Refill         |
| budesonide                                       | budesonide               |
| budesonide                                       | Pulmicort Turbuhaler     |
| budesonide                                       | Pulmicort Flexhaler      |
| budesonide                                       | Pulmicort                |
| ciclesonide                                      | Alvesco                  |
| flunisolide                                      | Aerospan                 |
| flunisolide                                      | Aerobid                  |
| fluticasone furoate                              | Arnuity Ellipta          |
| fluticasone propionate                           | Flovent                  |
| fluticasone propionate                           | Flovent Rotadisk         |
| fluticasone propionate                           | Flovent Diskus           |
| fluticasone propionate                           | Flovent HFA              |
| mometasone furoate                               | Asmanex Twisthaler       |
| mometasone furoate                               | Asmanex HFA              |
| triamcinolone acetonide                          | Azmacort                 |

## Appendix C. List of Generic and Brand Drug Names Used to Define Washout Criteria in this Request

| Generic Name  | Brand Name         |
|---|--------------------|
| <b>Inhaled Corticosteroids (ICS) Combination Products</b> |                    |
| budesonide/formoterol fumarate                            | Symbicort          |
| flunisolide/menthol                                       | Aerobid-M          |
| fluticasone furoate/vilanterol trifenate                  | Breo Ellipta       |
| fluticasone propionate/salmeterol xinafoate               | Advair Diskus      |
| fluticasone propionate/salmeterol xinafoate               | Advair HFA         |
| mometasone furoate/formoterol fumarate                    | Dulera             |
| <b>Long-Acting Beta Agonists (LABAs)</b>                  |                    |
| arformoterol tartrate                                     | Brovana            |
| formoterol fumarate                                       | Foradil Aerolizer  |
| formoterol fumarate                                       | Perforomist        |
| indacaterol maleate                                       | Arcapta Neohaler   |
| indacaterol maleate/glycopyrrolate                        | Utibron Neohaler   |
| olodaterol HCl  | Striverdi Respimat |
| salmeterol xinafoate                                      | Serevent           |
| salmeterol xinafoate                                      | Serevent Refill    |
| salmeterol xinafoate                                      | Serevent Diskus    |
| tiotropium bromide/olodaterol HCl                         | Stiolto Respimat   |
| <b>Leukotriene Receptor Antagonists (LTRA)</b>            |                    |
| zafirlukast   | Accolate           |
| zafirlukast   | zafirlukast        |
| zileuton  | Zyflo              |
| zileuton  | Zyflo CR           |
| zileuton  | zileuton           |

**Appendix D. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Outcomes in this Request**

| Code                       | Description   | Code Type | Code Category |
|----------------------------|---|-----------|---------------|
| <b>Depressive Disorder</b> |   |           |               |
| 311                        | Depressive disorder, not elsewhere classified   | ICD-9-CM  | Diagnosis     |
| 293.83                     | Mood disorder in conditions classified elsewhere  | ICD-9-CM  | Diagnosis     |
| 296.2                      | Major depressive disorder, single episode   | ICD-9-CM  | Diagnosis     |
| 296.20                     | Major depressive disorder, single episode, unspecified  | ICD-9-CM  | Diagnosis     |
| 296.21                     | Major depressive disorder, single episode, mild   | ICD-9-CM  | Diagnosis     |
| 296.22                     | Major depressive disorder, single episode, moderate   | ICD-9-CM  | Diagnosis     |
| 296.23                     | Major depressive disorder, single episode, severe, without mention of psychotic behavior                      | ICD-9-CM  | Diagnosis     |
| 296.24                     | Major depressive disorder, single episode, severe, specified as with psychotic behavior                       | ICD-9-CM  | Diagnosis     |
| 296.25                     | Major depressive disorder, single episode, in partial or unspecified remission                                | ICD-9-CM  | Diagnosis     |
| 296.26                     | Major depressive disorder, single episode in full remission   | ICD-9-CM  | Diagnosis     |
| 296.3                      | Major depressive disorder, recurrent episode  | ICD-9-CM  | Diagnosis     |
| 296.30                     | Major depressive disorder, recurrent episode, unspecified   | ICD-9-CM  | Diagnosis     |
| 296.31                     | Major depressive disorder, recurrent episode, mild  | ICD-9-CM  | Diagnosis     |
| 296.32                     | Major depressive disorder, recurrent episode, moderate  | ICD-9-CM  | Diagnosis     |
| 296.33                     | Major depressive disorder, recurrent episode, severe, without mention of psychotic behavior                   | ICD-9-CM  | Diagnosis     |
| 296.34                     | Major depressive disorder, recurrent episode, severe, specified as with psychotic behavior                    | ICD-9-CM  | Diagnosis     |
| 296.35                     | Major depressive disorder, recurrent episode, in partial or unspecified remission                             | ICD-9-CM  | Diagnosis     |
| 296.36                     | Major depressive disorder, recurrent episode, in full remission   | ICD-9-CM  | Diagnosis     |
| 296.5                      | Bipolar I disorder, most recent episode (or current), depressed   | ICD-9-CM  | Diagnosis     |
| 296.50                     | Bipolar I disorder, most recent episode (or current) depressed, unspecified                                   | ICD-9-CM  | Diagnosis     |
| 296.51                     | Bipolar I disorder, most recent episode (or current) depressed, mild  | ICD-9-CM  | Diagnosis     |
| 296.52                     | Bipolar I disorder, most recent episode (or current) depressed, moderate                                      | ICD-9-CM  | Diagnosis     |
| 296.53                     | Bipolar I disorder, most recent episode (or current) depressed, severe, without mention of psychotic behavior | ICD-9-CM  | Diagnosis     |
| 296.54                     | Bipolar I disorder, most recent episode (or current) depressed, severe, specified as with psychotic behavior  | ICD-9-CM  | Diagnosis     |
| 296.55                     | Bipolar I disorder, most recent episode (or current) depressed, in partial or unspecified remission           | ICD-9-CM  | Diagnosis     |
| 296.56                     | Bipolar I disorder, most recent episode (or current) depressed, in full remission                             | ICD-9-CM  | Diagnosis     |
| 296.90                     | Unspecified episodic mood disorder  | ICD-9-CM  | Diagnosis     |
| 298.0                      | Depressive type psychosis   | ICD-9-CM  | Diagnosis     |
| 300.4                      | Dysthymic disorder  | ICD-9-CM  | Diagnosis     |
| 301.12                     | Chronic depressive personality disorder   | ICD-9-CM  | Diagnosis     |
| 309.0                      | Adjustment disorder with depressed mood   | ICD-9-CM  | Diagnosis     |
| 309.1                      | Prolonged depressive reaction as adjustment reaction  | ICD-9-CM  | Diagnosis     |
| 309.28                     | Adjustment disorder with mixed anxiety and depressed mood   | ICD-9-CM  | Diagnosis     |

**Appendix D. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Outcomes in this Request**

| Code                 | Description   | Code Type | Code Category |
|----------------------|---|-----------|---------------|
| <b>Psychotherapy</b> |   |           |               |
| 90810                | Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient   | CPT-4     | Procedure     |
| 90811                | Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient; with medical evaluation and management services                                    | CPT-4     | Procedure     |
| 90812                | Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient   | CPT-4     | Procedure     |
| 90813                | Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient; with medical evaluation and management services                                    | CPT-4     | Procedure     |
| 90814                | Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 75 to 80 minutes face-to-face with the patient   | CPT-4     | Procedure     |
| 90815                | Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 75 to 80 minutes face-to-face with the patient; with medical evaluation and management services                                    | CPT-4     | Procedure     |
| 90823                | Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient  | CPT-4     | Procedure     |
| 90824                | Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient; with medical evaluation and management services | CPT-4     | Procedure     |
| 90826                | Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient  | CPT-4     | Procedure     |
| 90827                | Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient; with medical evaluation and management services | CPT-4     | Procedure     |
| 90828                | Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient  | CPT-4     | Procedure     |

**Appendix D. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Outcomes in this Request**

| Code                                     | Description   | Code Type | Code Category |
|--|---|-----------|---------------|
| 90829                                    | Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient; with medical evaluation and management services | CPT-4     | Procedure     |
| 90832                                    | Psychotherapy, 30 minutes with patient  | CPT-4     | Procedure     |
| 90833                                    | Psychotherapy, 30 minutes with patient when performed with an evaluation and management service (List separately in addition to the code for primary procedure)   | CPT-4     | Procedure     |
| 90834                                    | Psychotherapy, 45 minutes with patient  | CPT-4     | Procedure     |
| 90836                                    | Psychotherapy, 45 minutes with patient when performed with an evaluation and management service (List separately in addition to the code for primary procedure)   | CPT-4     | Procedure     |
| 90837                                    | Psychotherapy, 60 minutes with patient  | CPT-4     | Procedure     |
| 90838                                    | Psychotherapy, 60 minutes with patient when performed with an evaluation and management service (List separately in addition to the code for primary procedure)   | CPT-4     | Procedure     |
| 90839                                    | Psychotherapy for crisis; first 60 minutes  | CPT-4     | Procedure     |
| 90840                                    | Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary service)  | CPT-4     | Procedure     |
| 90845                                    | Psychoanalysis  | CPT-4     | Procedure     |
| 90853                                    | Group psychotherapy (other than of a multiple-family group)   | CPT-4     | Procedure     |
| 90857                                    | Interactive group psychotherapy   | CPT-4     | Procedure     |
| 94.31                                    | Psychoanalysis  | ICD-9-CM  | Procedure     |
| 94.32                                    | Hypnotherapy  | ICD-9-CM  | Procedure     |
| 94.33                                    | Behavior therapy  | ICD-9-CM  | Procedure     |
| 94.35                                    | Crisis intervention   | ICD-9-CM  | Procedure     |
| 94.36                                    | Play psychotherapy  | ICD-9-CM  | Procedure     |
| 94.37                                    | Exploratory verbal psychotherapy  | ICD-9-CM  | Procedure     |
| 94.38                                    | Supportive verbal psychotherapy   | ICD-9-CM  | Procedure     |
| 94.39                                    | Other individual psychotherapy  | ICD-9-CM  | Procedure     |
| 94.43                                    | Psychodrama   | ICD-9-CM  | Procedure     |
| 94.44                                    | Other group therapy   | ICD-9-CM  | Procedure     |
| <b>Self Harm - Psychiatric Component</b> |   |           |               |
| <i>Depression</i>                        |   |           |               |
| 311                                      | Depressive disorder, not elsewhere classified   | ICD-9-CM  | Diagnosis     |
| 296.3                                    | Major depressive disorder, recurrent episode  | ICD-9-CM  | Diagnosis     |
| 296.30                                   | Major depressive disorder, recurrent episode, unspecified   | ICD-9-CM  | Diagnosis     |
| 296.31                                   | Major depressive disorder, recurrent episode, mild  | ICD-9-CM  | Diagnosis     |
| 296.32                                   | Major depressive disorder, recurrent episode, moderate  | ICD-9-CM  | Diagnosis     |
| 296.33                                   | Major depressive disorder, recurrent episode, severe, without mention of psychotic behavior   | ICD-9-CM  | Diagnosis     |
| 296.34                                   | Major depressive disorder, recurrent episode, severe, specified as with psychotic behavior  | ICD-9-CM  | Diagnosis     |
| 296.35                                   | Major depressive disorder, recurrent episode, in partial or unspecified remission   | ICD-9-CM  | Diagnosis     |
| 296.36                                   | Major depressive disorder, recurrent episode, in full remission   | ICD-9-CM  | Diagnosis     |
| 296.90                                   | Unspecified episodic mood disorder  | ICD-9-CM  | Diagnosis     |
| 298.0                                    | Depressive type psychosis   | ICD-9-CM  | Diagnosis     |
| 300.4                                    | Dysthymic disorder  | ICD-9-CM  | Diagnosis     |



**Appendix D. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Outcomes in this Request**

| Code         | Description   | Code Type | Code Category |
|--------------|---|-----------|---------------|
| 309.0        | Adjustment disorder with depressed mood   | ICD-9-CM  | Diagnosis     |
| 309.1        | Prolonged depressive reaction as adjustment reaction  | ICD-9-CM  | Diagnosis     |
| 309.28       | Adjustment disorder with mixed anxiety and depressed mood   | ICD-9-CM  | Diagnosis     |
| <b>Mania</b> |   |           |               |
| 296.0        | Bipolar I disorder, single manic episode  | ICD-9-CM  | Diagnosis     |
| 296.00       | Bipolar I disorder, single manic episode, unspecified   | ICD-9-CM  | Diagnosis     |
| 296.01       | Bipolar I disorder, single manic episode, mild  | ICD-9-CM  | Diagnosis     |
| 296.02       | Bipolar I disorder, single manic episode, moderate  | ICD-9-CM  | Diagnosis     |
| 296.03       | Bipolar I disorder, single manic episode, severe, without mention of psychotic behavior                       | ICD-9-CM  | Diagnosis     |
| 296.04       | Bipolar I disorder, single manic episode, severe, specified as with psychotic behavior                        | ICD-9-CM  | Diagnosis     |
| 296.05       | Bipolar I disorder, single manic episode, in partial or unspecified remission                                 | ICD-9-CM  | Diagnosis     |
| 296.06       | Bipolar I disorder, single manic episode, in full remission   | ICD-9-CM  | Diagnosis     |
| 296.1        | Manic disorder, recurrent episode   | ICD-9-CM  | Diagnosis     |
| 296.10       | Manic disorder, recurrent episode, unspecified  | ICD-9-CM  | Diagnosis     |
| 296.11       | Manic disorder, recurrent episode, mild   | ICD-9-CM  | Diagnosis     |
| 296.12       | Manic disorder, recurrent episode, moderate   | ICD-9-CM  | Diagnosis     |
| 296.13       | Manic disorder, recurrent episode, severe, without mention of psychotic behavior                              | ICD-9-CM  | Diagnosis     |
| 296.14       | Manic disorder, recurrent episode, severe, specified as with psychotic behavior                               | ICD-9-CM  | Diagnosis     |
| 296.15       | Manic disorder, recurrent episode, in partial or unspecified remission  | ICD-9-CM  | Diagnosis     |
| 296.16       | Manic disorder, recurrent episode, in full remission  | ICD-9-CM  | Diagnosis     |
| 296.4        | Bipolar I disorder, most recent episode (or current) manic  | ICD-9-CM  | Diagnosis     |
| 296.40       | Bipolar I disorder, most recent episode (or current) manic, unspecified                                       | ICD-9-CM  | Diagnosis     |
| 296.41       | Bipolar I disorder, most recent episode (or current) manic, mild  | ICD-9-CM  | Diagnosis     |
| 296.42       | Bipolar I disorder, most recent episode (or current) manic, moderate  | ICD-9-CM  | Diagnosis     |
| 296.43       | Bipolar I disorder, most recent episode (or current) manic, severe, without mention of psychotic behavior     | ICD-9-CM  | Diagnosis     |
| 296.44       | Bipolar I disorder, most recent episode (or current) manic, severe, specified as with psychotic behavior      | ICD-9-CM  | Diagnosis     |
| 296.45       | Bipolar I disorder, most recent episode (or current) manic, in partial or unspecified remission               | ICD-9-CM  | Diagnosis     |
| 296.46       | Bipolar I disorder, most recent episode (or current) manic, in full remission                                 | ICD-9-CM  | Diagnosis     |
| 296.5        | Bipolar I disorder, most recent episode (or current), depressed   | ICD-9-CM  | Diagnosis     |
| 296.50       | Bipolar I disorder, most recent episode (or current) depressed, unspecified                                   | ICD-9-CM  | Diagnosis     |
| 296.51       | Bipolar I disorder, most recent episode (or current) depressed, mild  | ICD-9-CM  | Diagnosis     |
| 296.52       | Bipolar I disorder, most recent episode (or current) depressed, moderate                                      | ICD-9-CM  | Diagnosis     |
| 296.53       | Bipolar I disorder, most recent episode (or current) depressed, severe, without mention of psychotic behavior | ICD-9-CM  | Diagnosis     |
| 296.54       | Bipolar I disorder, most recent episode (or current) depressed, severe, specified as with psychotic behavior  | ICD-9-CM  | Diagnosis     |
| 296.55       | Bipolar I disorder, most recent episode (or current) depressed, in partial or unspecified remission           | ICD-9-CM  | Diagnosis     |
| 296.56       | Bipolar I disorder, most recent episode (or current) depressed, in full remission                             | ICD-9-CM  | Diagnosis     |
| 296.6        | Bipolar I disorder, most recent episode (or current), mixed   | ICD-9-CM  | Diagnosis     |
| 296.60       | Bipolar I disorder, most recent episode (or current) mixed, unspecified                                       | ICD-9-CM  | Diagnosis     |
| 296.61       | Bipolar I disorder, most recent episode (or current) mixed, mild  | ICD-9-CM  | Diagnosis     |

**Appendix D. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Outcomes in this Request**

| Code                        | Description   | Code Type | Code Category |
|-----------------------------|---|-----------|---------------|
| 296.62                      | Bipolar I disorder, most recent episode (or current) mixed, moderate                                      | ICD-9-CM  | Diagnosis     |
| 296.63                      | Bipolar I disorder, most recent episode (or current) mixed, severe, without mention of psychotic behavior | ICD-9-CM  | Diagnosis     |
| 296.64                      | Bipolar I disorder, most recent episode (or current) mixed, severe, specified as with psychotic behavior  | ICD-9-CM  | Diagnosis     |
| 296.65                      | Bipolar I disorder, most recent episode (or current) mixed, in partial or unspecified remission           | ICD-9-CM  | Diagnosis     |
| 296.66                      | Bipolar I disorder, most recent episode (or current) mixed, in full remission                             | ICD-9-CM  | Diagnosis     |
| 296.7                       | Bipolar I disorder, most recent episode (or current) unspecified  | ICD-9-CM  | Diagnosis     |
| 296.8                       | Other and unspecified bipolar disorders   | ICD-9-CM  | Diagnosis     |
| 296.80                      | Bipolar disorder, unspecified   | ICD-9-CM  | Diagnosis     |
| 296.81                      | Atypical manic disorder   | ICD-9-CM  | Diagnosis     |
| 296.82                      | Atypical depressive disorder  | ICD-9-CM  | Diagnosis     |
| 296.89                      | Other and unspecified bipolar disorders   | ICD-9-CM  | Diagnosis     |
| 296.99                      | Other specified episodic mood disorder  | ICD-9-CM  | Diagnosis     |
| <i>Personality disorder</i> |   |           |               |
| 301.0                       | Paranoid personality disorder   | ICD-9-CM  | Diagnosis     |
| 301.1                       | Affective personality disorder  | ICD-9-CM  | Diagnosis     |
| 301.10                      | Affective personality disorder, unspecified   | ICD-9-CM  | Diagnosis     |
| 301.11                      | Chronic hypomanic personality disorder  | ICD-9-CM  | Diagnosis     |
| 301.12                      | Chronic depressive personality disorder   | ICD-9-CM  | Diagnosis     |
| 301.13                      | Cyclothymic disorder  | ICD-9-CM  | Diagnosis     |
| 301.2                       | Schizoid personality disorder   | ICD-9-CM  | Diagnosis     |
| 301.20                      | Schizoid personality disorder, unspecified  | ICD-9-CM  | Diagnosis     |
| 301.21                      | Introverted personality   | ICD-9-CM  | Diagnosis     |
| 301.22                      | Schizotypal personality disorder  | ICD-9-CM  | Diagnosis     |
| 301.3                       | Explosive personality disorder  | ICD-9-CM  | Diagnosis     |
| 301.4                       | Obsessive-compulsive personality disorder   | ICD-9-CM  | Diagnosis     |
| 301.5                       | Histrionic personality disorder   | ICD-9-CM  | Diagnosis     |
| 301.50                      | Histrionic personality disorder, unspecified  | ICD-9-CM  | Diagnosis     |
| 301.51                      | Chronic factitious illness with physical symptoms   | ICD-9-CM  | Diagnosis     |
| 301.59                      | Other histrionic personality disorder   | ICD-9-CM  | Diagnosis     |
| 301.6                       | Dependent personality disorder  | ICD-9-CM  | Diagnosis     |
| 301.7                       | Antisocial personality disorder   | ICD-9-CM  | Diagnosis     |
| 301.8                       | Other personality disorders   | ICD-9-CM  | Diagnosis     |
| 301.81                      | Narcissistic personality disorder   | ICD-9-CM  | Diagnosis     |
| 301.82                      | Avoidant personality disorder   | ICD-9-CM  | Diagnosis     |
| 301.83                      | Borderline personality disorder   | ICD-9-CM  | Diagnosis     |
| 301.84                      | Passive-aggressive personality  | ICD-9-CM  | Diagnosis     |
| 301.89                      | Other personality disorder  | ICD-9-CM  | Diagnosis     |
| 301.9                       | Unspecified personality disorder  | ICD-9-CM  | Diagnosis     |
| <i>Adjustment reaction</i>  |   |           |               |
| 309.2                       | Predominant disturbance of other emotions as adjustment reaction  | ICD-9-CM  | Diagnosis     |
| 309.21                      | Separation anxiety disorder   | ICD-9-CM  | Diagnosis     |
| 309.22                      | Emancipation disorder of adolescence and early adult life   | ICD-9-CM  | Diagnosis     |

**Appendix D. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Outcomes in this Request**

| Code   | Description  | Code Type | Code Category |
|--|--|-----------|---------------|
| 309.23   | Specific academic or work inhibition as adjustment reaction              | ICD-9-CM  | Diagnosis     |
| 309.24   | Adjustment disorder with anxiety   | ICD-9-CM  | Diagnosis     |
| 309.29   | Other adjustment reaction with predominant disturbance of other emotions | ICD-9-CM  | Diagnosis     |
| 309.3  | Adjustment disorder with disturbance of conduct                          | ICD-9-CM  | Diagnosis     |
| 309.4  | Adjustment disorder with mixed disturbance of emotions and conduct       | ICD-9-CM  | Diagnosis     |
| 309.8  | Other specified adjustment reactions                                     | ICD-9-CM  | Diagnosis     |
| 309.81   | Posttraumatic stress disorder  | ICD-9-CM  | Diagnosis     |
| 309.82   | Adjustment reaction with physical symptoms                               | ICD-9-CM  | Diagnosis     |
| 309.83   | Adjustment reaction with withdrawal                                      | ICD-9-CM  | Diagnosis     |
| 309.89   | Other specified adjustment reaction                                      | ICD-9-CM  | Diagnosis     |
| 309.9  | Unspecified adjustment reaction  | ICD-9-CM  | Diagnosis     |
| <i>Unspecified non-psychotic mental disorder</i> |  |           |               |
| 300.9  | Unspecified nonpsychotic mental disorder                                 | ICD-9-CM  | Diagnosis     |
| <b>Self Harm - Physical Component</b>            |  |           |               |
| <i>Open wound to elbow, forearm, or wrist</i>    |  |           |               |
| 881  | Open wound of elbow, forearm, and wrist                                  | ICD-9-CM  | Diagnosis     |
| <i>Poisoning</i>                                 |  |           |               |
| 960  | Poisoning by antibiotics   | ICD-9-CM  | Diagnosis     |
| 960.0  | Poisoning by penicillins   | ICD-9-CM  | Diagnosis     |
| 960.1  | Poisoning by antifungal antibiotics                                      | ICD-9-CM  | Diagnosis     |
| 960.2  | Poisoning by chloramphenicol group                                       | ICD-9-CM  | Diagnosis     |
| 960.3  | Poisoning by erythromycin and other macrolides                           | ICD-9-CM  | Diagnosis     |
| 960.4  | Poisoning by tetracycline group  | ICD-9-CM  | Diagnosis     |
| 960.5  | Poisoning of cephalosporin group   | ICD-9-CM  | Diagnosis     |
| 960.6  | Poisoning of antimycobacterial antibiotics                               | ICD-9-CM  | Diagnosis     |
| 960.7  | Poisoning by antineoplastic antibiotics                                  | ICD-9-CM  | Diagnosis     |
| 960.8  | Poisoning by other specified antibiotics                                 | ICD-9-CM  | Diagnosis     |
| 960.9  | Poisoning by unspecified antibiotic                                      | ICD-9-CM  | Diagnosis     |
| 961  | Poisoning by other anti-infectives                                       | ICD-9-CM  | Diagnosis     |
| 961.0  | Poisoning by sulfonamides  | ICD-9-CM  | Diagnosis     |
| 961.1  | Poisoning by arsenical anti-infectives                                   | ICD-9-CM  | Diagnosis     |
| 961.2  | Poisoning by heavy metal anti-infectives                                 | ICD-9-CM  | Diagnosis     |
| 961.3  | Poisoning by quinoline and hydroxyquinoline derivatives                  | ICD-9-CM  | Diagnosis     |
| 961.4  | Poisoning by antimalarials and drugs acting on other blood protozoa      | ICD-9-CM  | Diagnosis     |
| 961.5  | Poisoning by other antiprotozoal drugs                                   | ICD-9-CM  | Diagnosis     |
| 961.6  | Poisoning by anthelmintics   | ICD-9-CM  | Diagnosis     |
| 961.7  | Poisoning by antiviral drugs   | ICD-9-CM  | Diagnosis     |
| 961.8  | Poisoning by other antimycobacterial drugs                               | ICD-9-CM  | Diagnosis     |
| 961.9  | Poisoning by other and unspecified anti-infectives                       | ICD-9-CM  | Diagnosis     |
| 962  | Poisoning by hormones and synthetic substitutes                          | ICD-9-CM  | Diagnosis     |
| 962.0  | Poisoning by adrenal cortical steroids                                   | ICD-9-CM  | Diagnosis     |
| 962.1  | Poisoning by androgens and anabolic congeners                            | ICD-9-CM  | Diagnosis     |
| 962.2  | Poisoning by ovarian hormones and synthetic substitutes                  | ICD-9-CM  | Diagnosis     |
| 962.3  | Poisoning by insulins and antidiabetic agents                            | ICD-9-CM  | Diagnosis     |
| 962.4  | Poisoning by anterior pituitary hormones                                 | ICD-9-CM  | Diagnosis     |

**Appendix D. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Outcomes in this Request**

| Code   | Description   | Code Type | Code Category |
|--------|---|-----------|---------------|
| 962.5  | Poisoning by posterior pituitary hormones                             | ICD-9-CM  | Diagnosis     |
| 962.6  | Poisoning by parathyroid and parathyroid derivatives                  | ICD-9-CM  | Diagnosis     |
| 962.7  | Poisoning by thyroid and thyroid derivatives                          | ICD-9-CM  | Diagnosis     |
| 962.8  | Poisoning by antithyroid agents                                       | ICD-9-CM  | Diagnosis     |
| 962.9  | Poisoning by other and unspecified hormones and synthetic substitutes | ICD-9-CM  | Diagnosis     |
| 963    | Poisoning by primarily systemic agents                                | ICD-9-CM  | Diagnosis     |
| 963.0  | Poisoning by antiallergic and antiemetic drugs                        | ICD-9-CM  | Diagnosis     |
| 963.1  | Poisoning by antineoplastic and immunosuppressive drugs               | ICD-9-CM  | Diagnosis     |
| 963.2  | Poisoning by acidifying agents  | ICD-9-CM  | Diagnosis     |
| 963.3  | Poisoning by alkalizing agents  | ICD-9-CM  | Diagnosis     |
| 963.4  | Poisoning by enzymes, not elsewhere classified                        | ICD-9-CM  | Diagnosis     |
| 963.5  | Poisoning by vitamins, not elsewhere classified                       | ICD-9-CM  | Diagnosis     |
| 963.8  | Poisoning by other specified systemic agents                          | ICD-9-CM  | Diagnosis     |
| 963.9  | Poisoning by unspecified systemic agent                               | ICD-9-CM  | Diagnosis     |
| 964    | Poisoning by agents primarily affecting blood constituents            | ICD-9-CM  | Diagnosis     |
| 964.0  | Poisoning by iron and its compounds                                   | ICD-9-CM  | Diagnosis     |
| 964.1  | Poisoning by liver preparations and other antianemic agents           | ICD-9-CM  | Diagnosis     |
| 964.2  | Poisoning by anticoagulants   | ICD-9-CM  | Diagnosis     |
| 964.3  | Poisoning by vitamin K (phytonadione)                                 | ICD-9-CM  | Diagnosis     |
| 964.4  | Poisoning by fibrinolysis-affecting drugs                             | ICD-9-CM  | Diagnosis     |
| 964.5  | Poisoning by anticoagulant antagonists and other coagulants           | ICD-9-CM  | Diagnosis     |
| 964.6  | Poisoning by gamma globulin   | ICD-9-CM  | Diagnosis     |
| 964.7  | Poisoning by natural blood and blood products                         | ICD-9-CM  | Diagnosis     |
| 964.8  | Poisoning by other specified agents affecting blood constituents      | ICD-9-CM  | Diagnosis     |
| 964.9  | Poisoning by unspecified agent affecting blood constituents           | ICD-9-CM  | Diagnosis     |
| 965    | Poisoning by analgesics, antipyretics, and antirheumatics             | ICD-9-CM  | Diagnosis     |
| 965.0  | Poisoning by opiates and related narcotics                            | ICD-9-CM  | Diagnosis     |
| 965.00 | Poisoning by opium (alkaloids), unspecified                           | ICD-9-CM  | Diagnosis     |
| 965.01 | Poisoning by heroin   | ICD-9-CM  | Diagnosis     |
| 965.02 | Poisoning by methadone  | ICD-9-CM  | Diagnosis     |
| 965.09 | Poisoning by opiates and related narcotics, other                     | ICD-9-CM  | Diagnosis     |
| 965.1  | Poisoning by salicylates  | ICD-9-CM  | Diagnosis     |
| 965.4  | Poisoning by aromatic analgesics, not elsewhere classified            | ICD-9-CM  | Diagnosis     |
| 965.5  | Poisoning by pyrazole derivatives                                     | ICD-9-CM  | Diagnosis     |
| 965.6  | Poisoning by antirheumatics (antiphlogistics)                         | ICD-9-CM  | Diagnosis     |
| 965.61 | Poisoning by propionic acid derivatives                               | ICD-9-CM  | Diagnosis     |
| 965.69 | Poisoning by other antirheumatics                                     | ICD-9-CM  | Diagnosis     |
| 965.7  | Poisoning by other non-narcotic analgesics                            | ICD-9-CM  | Diagnosis     |
| 965.8  | Poisoning by other specified analgesics and antipyretics              | ICD-9-CM  | Diagnosis     |
| 965.9  | Poisoning by unspecified analgesic and antipyretic                    | ICD-9-CM  | Diagnosis     |
| 966    | Poisoning by anticonvulsants and anti-Parkinsonism drugs              | ICD-9-CM  | Diagnosis     |
| 966.0  | Poisoning by oxazolidine derivatives                                  | ICD-9-CM  | Diagnosis     |
| 966.1  | Poisoning by hydantoin derivatives                                    | ICD-9-CM  | Diagnosis     |
| 966.2  | Poisoning by succinimides   | ICD-9-CM  | Diagnosis     |
| 966.3  | Poisoning by other and unspecified anticonvulsants                    | ICD-9-CM  | Diagnosis     |

**Appendix D. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Outcomes in this Request**

| Code   | Description   | Code Type | Code Category |
|--------|---|-----------|---------------|
| 966.4  | Poisoning by anti-Parkinsonism drugs  | ICD-9-CM  | Diagnosis     |
| 967    | Poisoning by sedatives and hypnotics  | ICD-9-CM  | Diagnosis     |
| 967.0  | Poisoning by barbiturates   | ICD-9-CM  | Diagnosis     |
| 967.1  | Poisoning by chloral hydrate group  | ICD-9-CM  | Diagnosis     |
| 967.2  | Poisoning by paraldehyde  | ICD-9-CM  | Diagnosis     |
| 967.3  | Poisoning by bromine compounds  | ICD-9-CM  | Diagnosis     |
| 967.4  | Poisoning by methaqualone compounds   | ICD-9-CM  | Diagnosis     |
| 967.5  | Poisoning by glutethimide group   | ICD-9-CM  | Diagnosis     |
| 967.6  | Poisoning by mixed sedatives, not elsewhere classified  | ICD-9-CM  | Diagnosis     |
| 967.8  | Poisoning by other sedatives and hypnotics  | ICD-9-CM  | Diagnosis     |
| 967.9  | Poisoning by unspecified sedative or hypnotic   | ICD-9-CM  | Diagnosis     |
| 968    | Poisoning by other central nervous system depressants and anesthetics   | ICD-9-CM  | Diagnosis     |
| 968.0  | Poisoning by central nervous system muscle-tone depressants   | ICD-9-CM  | Diagnosis     |
| 968.1  | Poisoning by halothane  | ICD-9-CM  | Diagnosis     |
| 968.2  | Poisoning by other gaseous anesthetics  | ICD-9-CM  | Diagnosis     |
| 968.3  | Poisoning by intravenous anesthetics  | ICD-9-CM  | Diagnosis     |
| 968.4  | Poisoning by other and unspecified general anesthetics  | ICD-9-CM  | Diagnosis     |
| 968.5  | Poisoning by other central nervous system depressants and anesthetics, Surface (topical) and infiltration anesthetics | ICD-9-CM  | Diagnosis     |
| 968.6  | Poisoning by peripheral nerve- and plexus-blocking anesthetics  | ICD-9-CM  | Diagnosis     |
| 968.7  | Poisoning by spinal anesthetics   | ICD-9-CM  | Diagnosis     |
| 968.9  | Poisoning by other and unspecified local anesthetics  | ICD-9-CM  | Diagnosis     |
| 969    | Poisoning by psychotropic agents  | ICD-9-CM  | Diagnosis     |
| 969.0  | Poisoning by antidepressants  | ICD-9-CM  | Diagnosis     |
| 969.00 | Poisoning by antidepressant, unspecified  | ICD-9-CM  | Diagnosis     |
| 969.01 | Poisoning by monoamine oxidase inhibitors   | ICD-9-CM  | Diagnosis     |
| 969.02 | Poisoning by selective serotonin and norepinephrine reuptake inhibitors   | ICD-9-CM  | Diagnosis     |
| 969.03 | Poisoning by selective serotonin reuptake inhibitors  | ICD-9-CM  | Diagnosis     |
| 969.04 | Poisoning by tetracyclic antidepressants  | ICD-9-CM  | Diagnosis     |
| 969.05 | Poisoning by tricyclic antidepressants  | ICD-9-CM  | Diagnosis     |
| 969.09 | Poisoning by other antidepressants  | ICD-9-CM  | Diagnosis     |
| 969.1  | Poisoning by phenothiazine-based tranquilizers  | ICD-9-CM  | Diagnosis     |
| 969.2  | Poisoning by butyrophenone-based tranquilizers  | ICD-9-CM  | Diagnosis     |
| 969.3  | Poisoning by other antipsychotics, neuroleptics, and major tranquilizers  | ICD-9-CM  | Diagnosis     |
| 969.4  | Poisoning by benzodiazepine-based tranquilizers   | ICD-9-CM  | Diagnosis     |
| 969.5  | Poisoning by other tranquilizers  | ICD-9-CM  | Diagnosis     |
| 969.6  | Poisoning by psychodysleptics (hallucinogens)   | ICD-9-CM  | Diagnosis     |
| 969.7  | Poisoning by psychostimulants   | ICD-9-CM  | Diagnosis     |
| 969.70 | Poisoning by psychostimulant, unspecified   | ICD-9-CM  | Diagnosis     |
| 969.71 | Poisoning by caffeine   | ICD-9-CM  | Diagnosis     |
| 969.72 | Poisoning by amphetamines   | ICD-9-CM  | Diagnosis     |
| 969.73 | Poisoning by methylphenidate  | ICD-9-CM  | Diagnosis     |
| 969.79 | Poisoning by other psychostimulants   | ICD-9-CM  | Diagnosis     |
| 969.8  | Poisoning by other specified psychotropic agents  | ICD-9-CM  | Diagnosis     |
| 969.9  | Poisoning by unspecified psychotropic agent   | ICD-9-CM  | Diagnosis     |

**Appendix D. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Outcomes in this Request**

| Code  | Description  | Code Type | Code Category |
|-------|--|-----------|---------------|
| 970   | Poisoning by central nervous system stimulants   | ICD-9-CM  | Diagnosis     |
| 970.0 | Poisoning by analeptics  | ICD-9-CM  | Diagnosis     |
| 970.1 | Poisoning by opiate antagonists  | ICD-9-CM  | Diagnosis     |
| 970.8 | Poisoning by other specified central nervous system stimulants                                 | ICD-9-CM  | Diagnosis     |
| 970.9 | Poisoning by unspecified central nervous system stimulant                                      | ICD-9-CM  | Diagnosis     |
| 971   | Poisoning by drugs primarily affecting the autonomic nervous system                            | ICD-9-CM  | Diagnosis     |
| 971.0 | Poisoning by parasympathomimetics (cholinergics)   | ICD-9-CM  | Diagnosis     |
| 971.1 | Poisoning by parasympatholytics (anticholinergics and antimuscarinics) and spasmolytics        | ICD-9-CM  | Diagnosis     |
| 971.2 | Poisoning by sympathomimetics (adrenergics)  | ICD-9-CM  | Diagnosis     |
| 971.3 | Poisoning by sympatholytics (antiadrenergics)  | ICD-9-CM  | Diagnosis     |
| 971.9 | Poisoning by unspecified drug primarily affecting autonomic nervous system                     | ICD-9-CM  | Diagnosis     |
| 972   | Poisoning by agents primarily affecting the cardiovascular system                              | ICD-9-CM  | Diagnosis     |
| 972.0 | Poisoning by cardiac rhythm regulators   | ICD-9-CM  | Diagnosis     |
| 972.1 | Poisoning by cardiotonic glycosides and drugs of similar action                                | ICD-9-CM  | Diagnosis     |
| 972.2 | Poisoning by antilipemic and antiarteriosclerotic drugs  | ICD-9-CM  | Diagnosis     |
| 972.3 | Poisoning by ganglion-blocking agents  | ICD-9-CM  | Diagnosis     |
| 972.4 | Poisoning by coronary vasodilators   | ICD-9-CM  | Diagnosis     |
| 972.5 | Poisoning by other vasodilators  | ICD-9-CM  | Diagnosis     |
| 972.6 | Poisoning by other antihypertensive agents   | ICD-9-CM  | Diagnosis     |
| 972.7 | Poisoning by antivaricose drugs, including sclerosing agents                                   | ICD-9-CM  | Diagnosis     |
| 972.8 | Poisoning by capillary-active drugs  | ICD-9-CM  | Diagnosis     |
| 972.9 | Poisoning by other and unspecified agents primarily affecting the cardiovascular system        | ICD-9-CM  | Diagnosis     |
| 973   | Poisoning by agents primarily affecting the gastrointestinal system                            | ICD-9-CM  | Diagnosis     |
| 973.0 | Poisoning by antacids and antigastric secretion drugs  | ICD-9-CM  | Diagnosis     |
| 973.1 | Poisoning by irritant cathartics   | ICD-9-CM  | Diagnosis     |
| 973.2 | Poisoning by emollient cathartics  | ICD-9-CM  | Diagnosis     |
| 973.3 | Poisoning by other cathartics, including intestinal atonia drugs                               | ICD-9-CM  | Diagnosis     |
| 973.4 | Poisoning by digestants  | ICD-9-CM  | Diagnosis     |
| 973.5 | Poisoning by antidiarrheal drugs   | ICD-9-CM  | Diagnosis     |
| 973.6 | Poisoning by emetics   | ICD-9-CM  | Diagnosis     |
| 973.8 | Poisoning by other specified agents primarily affecting the gastrointestinal system            | ICD-9-CM  | Diagnosis     |
| 973.9 | Poisoning by unspecified agent primarily affecting the gastrointestinal system                 | ICD-9-CM  | Diagnosis     |
| 974   | Poisoning by water, mineral, and uric acid metabolism drugs                                    | ICD-9-CM  | Diagnosis     |
| 974.0 | Poisoning by mercurial diuretics   | ICD-9-CM  | Diagnosis     |
| 974.1 | Poisoning by purine derivative diuretics   | ICD-9-CM  | Diagnosis     |
| 974.2 | Poisoning by carbonic acid anhydrase inhibitors  | ICD-9-CM  | Diagnosis     |
| 974.3 | Poisoning by saluretics  | ICD-9-CM  | Diagnosis     |
| 974.4 | Poisoning by other diuretics   | ICD-9-CM  | Diagnosis     |
| 974.5 | Poisoning by electrolytic, caloric, and water-balance agents                                   | ICD-9-CM  | Diagnosis     |
| 974.6 | Poisoning by other mineral salts, not elsewhere classified                                     | ICD-9-CM  | Diagnosis     |
| 974.7 | Poisoning by uric acid metabolism drugs  | ICD-9-CM  | Diagnosis     |
| 975   | Poisoning by agents primarily acting on the smooth and skeletal muscles and respiratory system | ICD-9-CM  | Diagnosis     |
| 975.0 | Poisoning by oxytocic agents   | ICD-9-CM  | Diagnosis     |
| 975.1 | Poisoning by smooth muscle relaxants   | ICD-9-CM  | Diagnosis     |



**Appendix D. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Outcomes in this Request**

| Code  | Description  | Code Type | Code Category |
|-------|--|-----------|---------------|
| 975.2 | Poisoning by skeletal muscle relaxants   | ICD-9-CM  | Diagnosis     |
| 975.3 | Poisoning by other and unspecified drugs acting on muscles   | ICD-9-CM  | Diagnosis     |
| 975.4 | Poisoning by antitussives  | ICD-9-CM  | Diagnosis     |
| 975.5 | Poisoning by expectorants  | ICD-9-CM  | Diagnosis     |
| 975.6 | Poisoning by anti-common cold drugs  | ICD-9-CM  | Diagnosis     |
| 975.7 | Poisoning by antiasthmatics  | ICD-9-CM  | Diagnosis     |
| 975.8 | Poisoning by other and unspecified respiratory drugs   | ICD-9-CM  | Diagnosis     |
| 976   | Poisoning by agents primarily affecting skin and mucous membrane, ophthalmological, otorhinolaryngological, and dental drugs | ICD-9-CM  | Diagnosis     |
| 976.0 | Poisoning by local anti-infectives and anti-inflammatory drugs   | ICD-9-CM  | Diagnosis     |
| 976.1 | Poisoning by antipruritics   | ICD-9-CM  | Diagnosis     |
| 976.2 | Poisoning by local astringents and local detergents  | ICD-9-CM  | Diagnosis     |
| 976.3 | Poisoning by emollients, demulcents, and protectants   | ICD-9-CM  | Diagnosis     |
| 976.4 | Poisoning by keratolytics, keratoplastics, other hair treatment drugs and preparations                                       | ICD-9-CM  | Diagnosis     |
| 976.5 | Poisoning by eye anti-infectives and other eye drugs   | ICD-9-CM  | Diagnosis     |
| 976.6 | Poisoning by anti-infectives and other drugs and preparations for ear, nose, and throat                                      | ICD-9-CM  | Diagnosis     |
| 976.7 | Poisoning by dental drugs topically applied  | ICD-9-CM  | Diagnosis     |
| 976.8 | Poisoning by other agents primarily affecting skin and mucous membrane   | ICD-9-CM  | Diagnosis     |
| 976.9 | Poisoning by unspecified agent primarily affecting skin and mucous membrane  | ICD-9-CM  | Diagnosis     |
| 977   | Poisoning by other and unspecified drugs and medicinal substances  | ICD-9-CM  | Diagnosis     |
| 977.0 | Poisoning by dietetics   | ICD-9-CM  | Diagnosis     |
| 977.1 | Poisoning by lipotropic drugs  | ICD-9-CM  | Diagnosis     |
| 977.2 | Poisoning by antidotes and chelating agents, not elsewhere classified  | ICD-9-CM  | Diagnosis     |
| 977.3 | Poisoning by alcohol deterrents  | ICD-9-CM  | Diagnosis     |
| 977.4 | Poisoning by pharmaceutical excipients   | ICD-9-CM  | Diagnosis     |
| 977.8 | Poisoning by other specified drugs and medicinal substances  | ICD-9-CM  | Diagnosis     |
| 977.9 | Poisoning by unspecified drug or medicinal substance   | ICD-9-CM  | Diagnosis     |
| 978   | Poisoning by bacterial vaccines  | ICD-9-CM  | Diagnosis     |
| 978.0 | Poisoning by BCG vaccine   | ICD-9-CM  | Diagnosis     |
| 978.1 | Poisoning by typhoid and paratyphoid vaccine   | ICD-9-CM  | Diagnosis     |
| 978.2 | Poisoning by cholera vaccine   | ICD-9-CM  | Diagnosis     |
| 978.3 | Poisoning by plague vaccine  | ICD-9-CM  | Diagnosis     |
| 978.4 | Poisoning by tetanus vaccine   | ICD-9-CM  | Diagnosis     |
| 978.5 | Poisoning by diphtheria vaccine  | ICD-9-CM  | Diagnosis     |
| 978.6 | Poisoning by pertussis vaccine, including combinations with pertussis component  | ICD-9-CM  | Diagnosis     |
| 978.8 | Poisoning by other and unspecified bacterial vaccines  | ICD-9-CM  | Diagnosis     |
| 978.9 | Poisoning by mixed bacterial vaccines, except combinations with pertussis component  | ICD-9-CM  | Diagnosis     |
| 979   | Poisoning by other vaccines and biological substances  | ICD-9-CM  | Diagnosis     |
| 979.0 | Poisoning by smallpox vaccine  | ICD-9-CM  | Diagnosis     |
| 979.1 | Poisoning by rabies vaccine  | ICD-9-CM  | Diagnosis     |
| 979.2 | Poisoning by typhus vaccine  | ICD-9-CM  | Diagnosis     |
| 979.3 | Poisoning by yellow fever vaccine  | ICD-9-CM  | Diagnosis     |
| 979.4 | Poisoning by measles vaccine   | ICD-9-CM  | Diagnosis     |
| 979.5 | Poisoning by poliomyelitis vaccine   | ICD-9-CM  | Diagnosis     |
| 979.6 | Poisoning by other and unspecified viral and rickettsial vaccines  | ICD-9-CM  | Diagnosis     |

**Appendix D. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Outcomes in this Request**

| Code            | Description   | Code Type | Code Category |
|-----------------|---|-----------|---------------|
| 979.7           | Poisoning by mixed viral-rickettsial and bacterial vaccines, except combinations with pertussis component | ICD-9-CM  | Diagnosis     |
| 979.9           | Poisoning by other and unspecified vaccines and biological substances                                     | ICD-9-CM  | Diagnosis     |
| <i>Toxicity</i> |   |           |               |
| 980             | Toxic effect of alcohol   | ICD-9-CM  | Diagnosis     |
| 980.0           | Toxic effect of ethyl alcohol   | ICD-9-CM  | Diagnosis     |
| 980.1           | Toxic effect of methyl alcohol  | ICD-9-CM  | Diagnosis     |
| 980.2           | Toxic effect of isopropyl alcohol   | ICD-9-CM  | Diagnosis     |
| 980.3           | Toxic effect of fusel oil   | ICD-9-CM  | Diagnosis     |
| 980.8           | Toxic effect of other specified alcohols  | ICD-9-CM  | Diagnosis     |
| 980.9           | Toxic effect of unspecified alcohol   | ICD-9-CM  | Diagnosis     |
| 981             | Toxic effect of petroleum products  | ICD-9-CM  | Diagnosis     |
| 982             | Toxic effect of solvents other than petroleum-based   | ICD-9-CM  | Diagnosis     |
| 982.0           | Toxic effect of benzene and homologues  | ICD-9-CM  | Diagnosis     |
| 982.1           | Toxic effect of carbon tetrachloride  | ICD-9-CM  | Diagnosis     |
| 982.2           | Toxic effect of carbon disulfide  | ICD-9-CM  | Diagnosis     |
| 982.3           | Toxic effect of other chlorinated hydrocarbon solvents  | ICD-9-CM  | Diagnosis     |
| 982.4           | Toxic effect of nitroglycol   | ICD-9-CM  | Diagnosis     |
| 982.8           | Toxic effect of other nonpetroleum-based solvents   | ICD-9-CM  | Diagnosis     |
| 983             | Toxic effect of corrosive aromatics, acids, and caustic alkalis   | ICD-9-CM  | Diagnosis     |
| 983.0           | Toxic effect of corrosive aromatics   | ICD-9-CM  | Diagnosis     |
| 983.1           | Toxic effect of acids   | ICD-9-CM  | Diagnosis     |
| 983.2           | Toxic effect of caustic alkalis   | ICD-9-CM  | Diagnosis     |
| 983.9           | Toxic effect of caustic, unspecified  | ICD-9-CM  | Diagnosis     |
| 984             | Toxic effect of lead and its compounds (including fumes)  | ICD-9-CM  | Diagnosis     |
| 984.0           | Toxic effect of inorganic lead compounds  | ICD-9-CM  | Diagnosis     |
| 984.1           | Toxic effect of organic lead compounds  | ICD-9-CM  | Diagnosis     |
| 984.8           | Toxic effect of other lead compounds  | ICD-9-CM  | Diagnosis     |
| 984.9           | Toxic effect of unspecified lead compound   | ICD-9-CM  | Diagnosis     |
| 985             | Toxic effect of other metals  | ICD-9-CM  | Diagnosis     |
| 985.0           | Toxic effect of mercury and its compounds   | ICD-9-CM  | Diagnosis     |
| 985.1           | Toxic effect of arsenic and its compounds   | ICD-9-CM  | Diagnosis     |
| 985.2           | Toxic effect of manganese and its compounds   | ICD-9-CM  | Diagnosis     |
| 985.3           | Toxic effect of beryllium and its compounds   | ICD-9-CM  | Diagnosis     |
| 985.4           | Toxic effect of antimony and its compounds  | ICD-9-CM  | Diagnosis     |
| 985.5           | Toxic effect of cadmium and its compounds   | ICD-9-CM  | Diagnosis     |
| 985.6           | Toxic effect of chromium  | ICD-9-CM  | Diagnosis     |
| 985.8           | Toxic effect of other specified metals  | ICD-9-CM  | Diagnosis     |
| 985.9           | Toxic effect of unspecified metal   | ICD-9-CM  | Diagnosis     |
| 986             | Toxic effect of carbon monoxide   | ICD-9-CM  | Diagnosis     |
| 987             | Toxic effect of other gases, fumes, or vapors   | ICD-9-CM  | Diagnosis     |
| 987.0           | Toxic effect of liquefied petroleum gases   | ICD-9-CM  | Diagnosis     |
| 987.1           | Toxic effect of other hydrocarbon gas   | ICD-9-CM  | Diagnosis     |
| 987.2           | Toxic effect of nitrogen oxides   | ICD-9-CM  | Diagnosis     |
| 987.3           | Toxic effect of sulfur dioxide  | ICD-9-CM  | Diagnosis     |



**Appendix D. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Outcomes in this Request**

| Code                       | Description  | Code Type | Code Category |
|----------------------------|--|-----------|---------------|
| 987.4                      | Toxic effect of freon  | ICD-9-CM  | Diagnosis     |
| 987.5                      | Toxic effect of lacrimogenic gas   | ICD-9-CM  | Diagnosis     |
| 987.6                      | Toxic effect of chlorine gas   | ICD-9-CM  | Diagnosis     |
| 987.7                      | Toxic effect of hydrocyanic acid gas                                       | ICD-9-CM  | Diagnosis     |
| 987.8                      | Toxic effect of other specified gases, fumes, or vapors                    | ICD-9-CM  | Diagnosis     |
| 987.9                      | Toxic effect of unspecified gas, fume, or vapor                            | ICD-9-CM  | Diagnosis     |
| 988                        | Toxic effect of noxious substances eaten as food                           | ICD-9-CM  | Diagnosis     |
| 988.0                      | Toxic effect of fish and shellfish   | ICD-9-CM  | Diagnosis     |
| 988.1                      | Toxic effect of mushrooms  | ICD-9-CM  | Diagnosis     |
| 988.2                      | Toxic effect of berries and other plants                                   | ICD-9-CM  | Diagnosis     |
| 988.8                      | Toxic effect of other specified noxious substances                         | ICD-9-CM  | Diagnosis     |
| 988.9                      | Toxic effect of unspecified noxious substance                              | ICD-9-CM  | Diagnosis     |
| 989                        | Toxic effect of other substances, chiefly nonmedicinal as to source        | ICD-9-CM  | Diagnosis     |
| 989.0                      | Toxic effect of hydrocyanic acid and cyanides                              | ICD-9-CM  | Diagnosis     |
| 989.1                      | Toxic effect of strychnine and salts                                       | ICD-9-CM  | Diagnosis     |
| 989.2                      | Toxic effect of chlorinated hydrocarbons                                   | ICD-9-CM  | Diagnosis     |
| 989.3                      | Toxic effect of organophosphate and carbamate                              | ICD-9-CM  | Diagnosis     |
| 989.4                      | Toxic effect of other pesticides, not elsewhere classified                 | ICD-9-CM  | Diagnosis     |
| 989.5                      | Toxic effect of venom  | ICD-9-CM  | Diagnosis     |
| 989.6                      | Toxic effect of soaps and detergents                                       | ICD-9-CM  | Diagnosis     |
| 989.7                      | Toxic effect of aflatoxin and other mycotoxin (food contaminants)          | ICD-9-CM  | Diagnosis     |
| 989.8                      | Toxic effect of other substances, chiefly nonmedicinal as to source        | ICD-9-CM  | Diagnosis     |
| 989.81                     | Toxic effect of asbestos   | ICD-9-CM  | Diagnosis     |
| 989.82                     | Toxic effect of latex  | ICD-9-CM  | Diagnosis     |
| 989.83                     | Toxic effect of silicone   | ICD-9-CM  | Diagnosis     |
| 989.84                     | Toxic effect of tobacco  | ICD-9-CM  | Diagnosis     |
| 989.89                     | Toxic effect of other substances   | ICD-9-CM  | Diagnosis     |
| 989.9                      | Toxic effect of unspecified substance, chiefly nonmedicinal as to source   | ICD-9-CM  | Diagnosis     |
| <i>Asphyxiation</i>        |  |           |               |
| 994.7                      | Asphyxiation and strangulation   | ICD-9-CM  | Diagnosis     |
| <b>Self Harm - E Codes</b> |  |           |               |
| E950                       | Suicide and self-inflicted poisoning by solid or liquid substances         | ICD-9-CM  | Diagnosis     |
| E951                       | Suicide and self-inflicted poisoning by gases in domestic use              | ICD-9-CM  | Diagnosis     |
| E952                       | Suicide and self-inflicted poisoning by other gases and vapors             | ICD-9-CM  | Diagnosis     |
| E953                       | Suicide and self-inflicted injury by hanging strangulation and suffocation | ICD-9-CM  | Diagnosis     |
| E954                       | Suicide and self-inflicted injury by submersion [drowning]                 | ICD-9-CM  | Diagnosis     |
| E955                       | Suicide and self-inflicted injury by firearms air guns and explosives      | ICD-9-CM  | Diagnosis     |
| E956                       | Suicide and self-inflicted injury by cutting and piercing instrument       | ICD-9-CM  | Diagnosis     |
| E957                       | Suicide and self-inflicted injuries by jumping from high place             | ICD-9-CM  | Diagnosis     |
| E958                       | Suicide and self-inflicted injury by other and unspecified means           | ICD-9-CM  | Diagnosis     |

## Appendix E. List of Generic and Brand Drug Names Used to Define Outcomes in this Request

| Generic Name                                       | Brand Name                     |
|--|--------------------------------|
| <b>Antidepressants</b>                             |                                |
| amitriptyline HCl                                  | Elavil                         |
| amitriptyline HCl                                  | Amitriptyline                  |
| amitriptyline HCl                                  | Vanatrip                       |
| amitriptyline HCl                                  | EnovaRx-Amitriptyline          |
| amitriptyline HCl/chlordiazepoxide                 | Limbitrol                      |
| amitriptyline HCl/chlordiazepoxide                 | Limbitrol DS                   |
| amitriptyline HCl/chlordiazepoxide                 | Amitriptyline-chlordiazepoxide |
| amoxapine  | Amoxapine                      |
| bupropion HBr                                      | Aplenzin                       |
| bupropion HCl                                      | Bupropion HCl                  |
| bupropion HCl                                      | Budeprion XL                   |
| bupropion HCl                                      | Budeprion SR                   |
| bupropion HCl                                      | Buproban                       |
| bupropion HCl                                      | Wellbutrin SR                  |
| bupropion HCl                                      | Wellbutrin                     |
| bupropion HCl                                      | Zyban                          |
| bupropion HCl                                      | Wellbutrin XL                  |
| bupropion HCl                                      | Bupropion HCl (smoking deter)  |
| bupropion HCl                                      | Forfivo XL                     |
| bupropion HCl/dietary supplement combination no.15 | Appbutamone-D                  |
| bupropion HCl/dietary supplement combination no.16 | Appbutamone                    |
| citalopram hydrobromide                            | Citalopram                     |
| citalopram hydrobromide                            | Celexa                         |
| clomipramine HCl                                   | Anafranil                      |
| clomipramine HCl                                   | Clomipramine                   |
| desipramine HCl                                    | Desipramine                    |
| desipramine HCl                                    | Norpramin                      |
| desvenlafaxine                                     | Desvenlafaxine                 |
| desvenlafaxine                                     | Khedeza                        |
| desvenlafaxine fumarate                            | Desvenlafaxine fumarate        |
| desvenlafaxine succinate                           | Pristiq                        |
| desvenlafaxine succinate                           | Desvenlafaxine succinate       |
| doxepin HCl  | Doxepin                        |
| doxepin HCl  | Sinequan                       |
| doxepin HCl  | Silenor                        |
| doxepin HCl  | Prudoxin                       |
| doxepin HCl  | Zonalon                        |
| duloxetine HCl                                     | Cymbalta                       |
| duloxetine HCl                                     | Duloxetine                     |
| duloxetine HCl                                     | Irenka                         |
| escitalopram oxalate                               | Escitalopram oxalate           |
| escitalopram oxalate                               | Lexapro                        |
| fluoxetine HCl                                     | Prozac Weekly                  |
| fluoxetine HCl                                     | Sarafem                        |
| fluoxetine HCl                                     | Prozac                         |

## Appendix E. List of Generic and Brand Drug Names Used to Define Outcomes in this Request

| Generic Name                            | Brand Name                      |
|---|---------------------------------|
| fluoxetine HCl                          | Fluoxetine                      |
| fluoxetine HCl                          | Selfemra                        |
| fluoxetine HCl                          | Rapiflux                        |
| fluoxetine HCl/dietary supplement no.17 | Gaboxetine                      |
| fluoxetine HCl/dietary supplement no.8  | Sentroxtatine                   |
| fluvoxamine maleate                     | Luvox                           |
| fluvoxamine maleate                     | fluvoxamine                     |
| fluvoxamine maleate                     | Luvox CR                        |
| imipramine HCl                          | Tofranil                        |
| imipramine HCl                          | Imipramine HCl                  |
| imipramine pamoate                      | Tofranil-PM                     |
| imipramine pamoate                      | Imipramine pamoate              |
| isocarboxazid                           | Marplan                         |
| levomilnacipran HCl                     | Fetzima                         |
| maprotiline HCl                         | Ludiomil                        |
| maprotiline HCl                         | Maprotiline                     |
| mirtazapine                             | Remeron                         |
| mirtazapine                             | Remeron SolTab                  |
| mirtazapine                             | Mirtazapine                     |
| naltrexone HCl/bupropion HCl            | Contrave                        |
| nefazodone HCl                          | Nefazodone                      |
| nefazodone HCl                          | Serzone                         |
| nortriptyline HCl                       | Aventyl                         |
| nortriptyline HCl                       | Pamelor                         |
| nortriptyline HCl                       | Nortriptyline                   |
| olanzapine/fluoxetine HCl               | Symbyax                         |
| olanzapine/fluoxetine HCl               | Olanzapine-fluoxetine           |
| paroxetine HCl                          | Paxil CR                        |
| paroxetine HCl                          | Paxil                           |
| paroxetine HCl                          | Paroxetine HCl                  |
| paroxetine mesylate                     | Paroxetine mesylate (menop.sym) |
| paroxetine mesylate                     | Pexeva                          |
| paroxetine mesylate                     | Brisdelle                       |
| perphenazine/amitriptyline HCl          | Etrafon 2-10                    |
| perphenazine/amitriptyline HCl          | Etrafon 2-25                    |
| perphenazine/amitriptyline HCl          | Etrafon Forte 4-25              |
| perphenazine/amitriptyline HCl          | Perphenazine-amitriptyline      |
| perphenazine/amitriptyline HCl          | Duo-Vil 2-10                    |
| perphenazine/amitriptyline HCl          | Duo-Vil 2-25                    |
| perphenazine/amitriptyline HCl          | Triavil 2-10                    |
| perphenazine/amitriptyline HCl          | Triavil 2-25                    |
| perphenazine/amitriptyline HCl          | Triavil 4-25                    |
| phenelzine sulfate                      | Nardil                          |
| phenelzine sulfate                      | Phenelzine                      |
| selegiline                              | Emsam                           |
| selegiline HCl                          | Zelapar                         |

#### Appendix E. List of Generic and Brand Drug Names Used to Define Outcomes in this Request

| Generic Name                          | Brand Name      |
|---------------------------------------|-----------------|
| selegiline HCl                        | Selegiline HCl  |
| selegiline HCl                        | Eldepryl        |
| selegiline HCl                        | Carbex          |
| sertraline HCl                        | Zoloft          |
| sertraline HCl                        | Sertraline      |
| tranylcypromine sulfate               | Parnate         |
| tranylcypromine sulfate               | Tranylcypromine |
| trazodone HCl/dietary supplement no.8 | Trazamine       |
| trimipramine maleate                  | Surmontil       |
| trimipramine maleate                  | Trimipramine    |
| venlafaxine HCl                       | Effexor         |
| venlafaxine HCl                       | Effexor XR      |
| venlafaxine HCl                       | Venlafaxine     |
| vilazodone HCl                        | Viibryd         |
| vortioxetine hydrobromide             | Brintellix      |
| vortioxetine hydrobromide             | Trintellix      |

**Appendix F. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes Used to Define Inclusion and Exclusion Criteria in this Request**

| Code  | Description   | Code Type | Code Category |
|---|---|-----------|---------------|
| <b>Asthma</b>                                       |   |           |               |
| 493.0   | Extrinsic asthma  | ICD-9-CM  | Diagnosis     |
| 493.00  | Extrinsic asthma, unspecified                             | ICD-9-CM  | Diagnosis     |
| 493.02  | Extrinsic asthma, with (acute) exacerbation               | ICD-9-CM  | Diagnosis     |
| 493.1   | Intrinsic asthma  | ICD-9-CM  | Diagnosis     |
| 493.10  | Intrinsic asthma, unspecified                             | ICD-9-CM  | Diagnosis     |
| 493.12  | Intrinsic asthma, with (acute) exacerbation               | ICD-9-CM  | Diagnosis     |
| 493.8   | Other forms of asthma                                     | ICD-9-CM  | Diagnosis     |
| 493.81  | Exercise induced bronchospasm                             | ICD-9-CM  | Diagnosis     |
| 493.82  | Cough variant asthma                                      | ICD-9-CM  | Diagnosis     |
| 493.9   | Unspecified asthma  | ICD-9-CM  | Diagnosis     |
| 493.90  | Asthma, unspecified, unspecified status                   | ICD-9-CM  | Diagnosis     |
| 493.92  | Asthma, unspecified, with (acute) exacerbation            | ICD-9-CM  | Diagnosis     |
| <b>Chronic Obstructive Pulmonary Disease (COPD)</b> |   |           |               |
| 490   | Bronchitis, not specified as acute or chronic             | ICD-9-CM  | Diagnosis     |
| 491   | Chronic bronchitis  | ICD-9-CM  | Diagnosis     |
| 491.0   | Simple chronic bronchitis                                 | ICD-9-CM  | Diagnosis     |
| 491.1   | Mucopurulent chronic bronchitis                           | ICD-9-CM  | Diagnosis     |
| 491.20  | Obstructive chronic bronchitis, without exacerbation      | ICD-9-CM  | Diagnosis     |
| 491.2   | Obstructive chronic bronchitis                            | ICD-9-CM  | Diagnosis     |
| 491.21  | Obstructive chronic bronchitis, with (acute) exacerbation | ICD-9-CM  | Diagnosis     |
| 491.22  | Obstructive chronic bronchitis with acute bronchitis      | ICD-9-CM  | Diagnosis     |
| 491.8   | Other chronic bronchitis                                  | ICD-9-CM  | Diagnosis     |
| 491.9   | Unspecified chronic bronchitis                            | ICD-9-CM  | Diagnosis     |
| 492   | Emphysema   | ICD-9-CM  | Diagnosis     |
| 492.0   | Emphysematous bleb  | ICD-9-CM  | Diagnosis     |
| 492.8   | Other emphysema   | ICD-9-CM  | Diagnosis     |
| 493.2   | Chronic obstructive asthma                                | ICD-9-CM  | Diagnosis     |
| 493.20  | Chronic obstructive asthma, unspecified                   | ICD-9-CM  | Diagnosis     |
| 493.21  | Chronic obstructive asthma with status asthmaticus        | ICD-9-CM  | Diagnosis     |
| 493.22  | Chronic obstructive asthma, with (acute) exacerbation     | ICD-9-CM  | Diagnosis     |
| 494   | Bronchiectasis  | ICD-9-CM  | Diagnosis     |
| 494.0   | Bronchiectasis without acute exacerbation                 | ICD-9-CM  | Diagnosis     |
| 494.1   | Bronchiectasis with acute exacerbation                    | ICD-9-CM  | Diagnosis     |

**Appendix G. List of Healthcare Common Procedure Coding System (HCPCS) Codes Used to Define Censoring Criteria in this Request**

| Code                        | Description  | Code Type | Code Category |
|-----------------------------|--|-----------|---------------|
| <b>Oral Corticosteroids</b> |  |           |               |
| J7506                       | Prednisone, oral, per 5 mg                                   | HCPCS     | Procedure     |
| J7509                       | Methylprednisolone, oral, per 4 mg                           | HCPCS     | Procedure     |
| J7510                       | Prednisolone, oral, per 5 mg                                 | HCPCS     | Procedure     |
| J7512                       | Prednisone, immediate release or delayed release, oral, 1 mg | HCPCS     | Procedure     |
| J8540                       | Dexamethasone, oral, 0.25 mg                                 | HCPCS     | Procedure     |
| S0173                       | Dexamethasone, oral, 4 mg                                    | HCPCS     | Procedure     |

## Appendix H. List of Generic and Brand Drug Names Used to Define Censoring Criteria in this Request

| Generic Name  | Brand Name             |
|---|------------------------|
| <b>Oral Corticosteroids</b>                               |                        |
| cortisone acetate   | Cortisone              |
| dexamethasone   | Decadron               |
| dexamethasone   | Decadron Dose Pack     |
| dexamethasone   | Dexone                 |
| dexamethasone   | Dexamethasone Intensol |
| dexamethasone   | Dexamethasone          |
| dexamethasone   | DexPak 10 day          |
| dexamethasone   | DexPak 13 Day          |
| dexamethasone   | DexPak 6 Day           |
| dexamethasone   | TaperDex               |
| dexamethasone   | ZoDex                  |
| dexamethasone   | Zema-Pak               |
| dexamethasone   | Baycadron              |
| dexamethasone   | ZonaCort               |
| dexamethasone   | LoCort                 |
| methylprednisolone  | Medrol                 |
| methylprednisolone  | Medrol (Pak)           |
| methylprednisolone  | Methylprednisolone     |
| methylprednisolone  | Meprolone Unipak       |
| methylprednisolone  | Methylpred             |
| prednisolone  | Prednisolone           |
| prednisolone  | Pre lone               |
| prednisolone  | Millipred              |
| prednisolone  | Millipred DP           |
| prednisone  | Deltasone              |
| prednisone  | Prednisone             |
| prednisone  | Prednisone Intensol    |
| prednisone  | Meticorten             |
| prednisone  | Sterapred DS           |
| prednisone  | Sterapred              |
| prednisone  | Liquid Pred            |
| prednisone  | Deltasone Dose Pack    |
| prednisone  | Rayos                  |
| <b>Inhaled Corticosteroids (ICS) Combination Products</b> |                        |
| budesonide/formoterol fumarate                            | Symbicort              |
| flunisolide/menthol                                       | Aerobid-M              |
| fluticasone furoate/vilanterol trifenate                  | Breo Ellipta           |
| fluticasone propionate/salmeterol xinafoate               | Advair Diskus          |
| fluticasone propionate/salmeterol xinafoate               | Advair HFA             |
| mometasone furoate/formoterol fumarate                    | Dulera                 |
| <b>Long-Acting Beta Agonists (LABAs)</b>                  |                        |
| arformoterol tartrate                                     | Brovana                |
| formoterol fumarate                                       | Foradil Aerolizer      |
| formoterol fumarate                                       | Perforomist            |
| indacaterol maleate                                       | Arcapta Neohaler       |

# Appendix H. List of Generic and Brand Drug Names Used to Define Censoring Criteria in this Request

| Generic Name                                   | Brand Name         |
|--|--------------------|
| indacaterol maleate/glycopyrrolate             | Utibron Neohaler   |
| olodaterol HCl                                 | Striverdi Respimat |
| salmeterol xinafoate                           | Serevent           |
| salmeterol xinafoate                           | Serevent Refill    |
| salmeterol xinafoate                           | Serevent Diskus    |
| tiotropium bromide/olodaterol HCl              | Stiolto Respimat   |
| <b>Leukotriene Receptor Antagonists (LTRA)</b> |                    |
| zafirlukast                                    | Accolate           |
| zafirlukast                                    | Zafirlukast        |
| zileuton                                       | Zyflo              |
| zileuton                                       | Zyflo CR           |
| zileuton                                       | Zileuton           |



**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code                       | Description  | Code Type | Code Category |
|----------------------------|--|-----------|---------------|
| <b>Asthma Exacerbation</b> |  |           |               |
| 493.92                     | Asthma, unspecified, with (acute) exacerbation           | ICD-9-CM  | Diagnosis     |
| 493.11                     | Intrinsic asthma with status asthmaticus                 | ICD-9-CM  | Diagnosis     |
| 493.91                     | Asthma, unspecified with status asthmaticus              | ICD-9-CM  | Diagnosis     |
| 493.01                     | Extrinsic asthma with status asthmaticus                 | ICD-9-CM  | Diagnosis     |
| <b>Substance Abuse</b>     |  |           |               |
| 291.0                      | Alcohol withdrawal delirium                              | ICD-9-CM  | Diagnosis     |
| 291.1                      | Alcohol-induced persisting amnesic disorder              | ICD-9-CM  | Diagnosis     |
| 291.2                      | Alcohol-induced persisting dementia                      | ICD-9-CM  | Diagnosis     |
| 291.3                      | Alcohol-induced psychotic disorder with hallucinations   | ICD-9-CM  | Diagnosis     |
| 291.4                      | Idiosyncratic alcohol intoxication                       | ICD-9-CM  | Diagnosis     |
| 291.5                      | Alcohol-induced psychotic disorder with delusions        | ICD-9-CM  | Diagnosis     |
| 291.8                      | Other specified alcohol-induced mental disorders         | ICD-9-CM  | Diagnosis     |
| 291.81                     | Alcohol withdrawal                                       | ICD-9-CM  | Diagnosis     |
| 291.82                     | Alcohol induced sleep disorders                          | ICD-9-CM  | Diagnosis     |
| 291.89                     | Other specified alcohol-induced mental disorders         | ICD-9-CM  | Diagnosis     |
| 291.9                      | Unspecified alcohol-induced mental disorders             | ICD-9-CM  | Diagnosis     |
| 292.0                      | Drug withdrawal  | ICD-9-CM  | Diagnosis     |
| 292.1                      | Drug-induced psychotic disorder                          | ICD-9-CM  | Diagnosis     |
| 292.11                     | Drug-induced psychotic disorder with delusions           | ICD-9-CM  | Diagnosis     |
| 292.12                     | Drug-induced psychotic disorder with hallucinations      | ICD-9-CM  | Diagnosis     |
| 292.2                      | Pathological drug intoxication                           | ICD-9-CM  | Diagnosis     |
| 292.8                      | Other specified drug-induced mental disorders            | ICD-9-CM  | Diagnosis     |
| 292.89                     | Other specified drug-induced mental disorder             | ICD-9-CM  | Diagnosis     |
| 292.9                      | Unspecified drug-induced mental disorder                 | ICD-9-CM  | Diagnosis     |
| 303.0                      | Acute alcoholic intoxication                             | ICD-9-CM  | Diagnosis     |
| 303.00                     | Acute alcoholic intoxication, unspecified                | ICD-9-CM  | Diagnosis     |
| 303.01                     | Acute alcoholic intoxication, continuous                 | ICD-9-CM  | Diagnosis     |
| 303.02                     | Acute alcoholic intoxication, episodic                   | ICD-9-CM  | Diagnosis     |
| 303.03                     | Acute alcoholic intoxication, in remission               | ICD-9-CM  | Diagnosis     |
| 303.9                      | Other and unspecified alcohol dependence                 | ICD-9-CM  | Diagnosis     |
| 303.90                     | Other and unspecified alcohol dependence, unspecified    | ICD-9-CM  | Diagnosis     |
| 303.91                     | Other and unspecified alcohol dependence, continuous     | ICD-9-CM  | Diagnosis     |
| 303.92                     | Other and unspecified alcohol dependence, episodic       | ICD-9-CM  | Diagnosis     |
| 303.93                     | Other and unspecified alcohol dependence, in remission   | ICD-9-CM  | Diagnosis     |
| 304.0                      | Opioid type dependence                                   | ICD-9-CM  | Diagnosis     |
| 304.00                     | Opioid type dependence, unspecified                      | ICD-9-CM  | Diagnosis     |
| 304.01                     | Opioid type dependence, continuous                       | ICD-9-CM  | Diagnosis     |
| 304.02                     | Opioid type dependence, episodic                         | ICD-9-CM  | Diagnosis     |
| 304.03                     | Opioid type dependence, in remission                     | ICD-9-CM  | Diagnosis     |
| 304.1                      | Sedative, hypnotic or anxiolytic dependence              | ICD-9-CM  | Diagnosis     |
| 304.10                     | Sedative, hypnotic or anxiolytic dependence, unspecified | ICD-9-CM  | Diagnosis     |
| 304.11                     | Sedative, hypnotic or anxiolytic dependence, continuous  | ICD-9-CM  | Diagnosis     |
| 304.12                     | Sedative, hypnotic or anxiolytic dependence, episodic    | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code   | Description   | Code Type | Code Category |
|--------|---|-----------|---------------|
| 304.13 | Sedative, hypnotic or anxiolytic dependence, in remission                     | ICD-9-CM  | Diagnosis     |
| 304.2  | Cocaine dependence  | ICD-9-CM  | Diagnosis     |
| 304.20 | Cocaine dependence, unspecified   | ICD-9-CM  | Diagnosis     |
| 304.21 | Cocaine dependence, continuous  | ICD-9-CM  | Diagnosis     |
| 304.22 | Cocaine dependence, episodic  | ICD-9-CM  | Diagnosis     |
| 304.23 | Cocaine dependence, in remission  | ICD-9-CM  | Diagnosis     |
| 304.3  | Cannabis dependence   | ICD-9-CM  | Diagnosis     |
| 304.30 | Cannabis dependence, unspecified  | ICD-9-CM  | Diagnosis     |
| 304.31 | Cannabis dependence, continuous   | ICD-9-CM  | Diagnosis     |
| 304.32 | Cannabis dependence, episodic   | ICD-9-CM  | Diagnosis     |
| 304.33 | Cannabis dependence, in remission   | ICD-9-CM  | Diagnosis     |
| 304.4  | Amphetamine and other psychostimulant dependence                              | ICD-9-CM  | Diagnosis     |
| 304.40 | Amphetamine and other psychostimulant dependence, unspecified                 | ICD-9-CM  | Diagnosis     |
| 304.41 | Amphetamine and other psychostimulant dependence, continuous                  | ICD-9-CM  | Diagnosis     |
| 304.42 | Amphetamine and other psychostimulant dependence, episodic                    | ICD-9-CM  | Diagnosis     |
| 304.43 | Amphetamine and other psychostimulant dependence, in remission                | ICD-9-CM  | Diagnosis     |
| 304.5  | Hallucinogen dependence   | ICD-9-CM  | Diagnosis     |
| 304.50 | Hallucinogen dependence, unspecified  | ICD-9-CM  | Diagnosis     |
| 304.51 | Hallucinogen dependence, continuous   | ICD-9-CM  | Diagnosis     |
| 304.52 | Hallucinogen dependence, episodic   | ICD-9-CM  | Diagnosis     |
| 304.53 | Hallucinogen dependence, in remission   | ICD-9-CM  | Diagnosis     |
| 304.6  | Other specified drug dependence   | ICD-9-CM  | Diagnosis     |
| 304.60 | Other specified drug dependence, unspecified                                  | ICD-9-CM  | Diagnosis     |
| 304.61 | Other specified drug dependence, continuous                                   | ICD-9-CM  | Diagnosis     |
| 304.62 | Other specified drug dependence, episodic                                     | ICD-9-CM  | Diagnosis     |
| 304.63 | Other specified drug dependence, in remission                                 | ICD-9-CM  | Diagnosis     |
| 304.7  | Combinations of opioid type drug with any other drug dependence               | ICD-9-CM  | Diagnosis     |
| 304.70 | Combinations of opioid type drug with any other drug dependence, unspecified  | ICD-9-CM  | Diagnosis     |
| 304.71 | Combinations of opioid type drug with any other drug dependence, continuous   | ICD-9-CM  | Diagnosis     |
| 304.72 | Combinations of opioid type drug with any other drug dependence, episodic     | ICD-9-CM  | Diagnosis     |
| 304.73 | Combinations of opioid type drug with any other drug dependence, in remission | ICD-9-CM  | Diagnosis     |
| 304.8  | Combinations of drug dependence excluding opioid type drug                    | ICD-9-CM  | Diagnosis     |
| 304.80 | Combinations of drug dependence excluding opioid type drug, unspecified       | ICD-9-CM  | Diagnosis     |
| 304.81 | Combinations of drug dependence excluding opioid type drug, continuous        | ICD-9-CM  | Diagnosis     |
| 304.82 | Combinations of drug dependence excluding opioid type drug, episodic          | ICD-9-CM  | Diagnosis     |
| 304.83 | Combinations of drug dependence excluding opioid type drug, in remission      | ICD-9-CM  | Diagnosis     |
| 304.9  | Unspecified drug dependence   | ICD-9-CM  | Diagnosis     |
| 304.90 | Unspecified drug dependence, unspecified                                      | ICD-9-CM  | Diagnosis     |
| 304.91 | Unspecified drug dependence, continuous                                       | ICD-9-CM  | Diagnosis     |
| 304.92 | Unspecified drug dependence, episodic   | ICD-9-CM  | Diagnosis     |
| 304.93 | Unspecified drug dependence, in remission                                     | ICD-9-CM  | Diagnosis     |
| 305.0  | Nondependent alcohol abuse  | ICD-9-CM  | Diagnosis     |
| 305.00 | Nondependent alcohol abuse, unspecified                                       | ICD-9-CM  | Diagnosis     |
| 305.01 | Nondependent alcohol abuse, continuous  | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code                     | Description  | Code Type | Code Category |
|--------------------------|--|-----------|---------------|
| 305.02                   | Nondependent alcohol abuse, episodic   | ICD-9-CM  | Diagnosis     |
| 305.03                   | Nondependent alcohol abuse, in remission                                       | ICD-9-CM  | Diagnosis     |
| 305.2                    | Nondependent cannabis abuse  | ICD-9-CM  | Diagnosis     |
| 305.20                   | Nondependent cannabis abuse, unspecified                                       | ICD-9-CM  | Diagnosis     |
| 305.21                   | Nondependent cannabis abuse, continuous  | ICD-9-CM  | Diagnosis     |
| 305.22                   | Nondependent cannabis abuse, episodic  | ICD-9-CM  | Diagnosis     |
| 305.23                   | Nondependent cannabis abuse, in remission                                      | ICD-9-CM  | Diagnosis     |
| 305.3                    | Nondependent hallucinogen abuse  | ICD-9-CM  | Diagnosis     |
| 305.30                   | Nondependent hallucinogen abuse, unspecified                                   | ICD-9-CM  | Diagnosis     |
| 305.31                   | Nondependent hallucinogen abuse, continuous                                    | ICD-9-CM  | Diagnosis     |
| 305.32                   | Nondependent hallucinogen abuse, episodic                                      | ICD-9-CM  | Diagnosis     |
| 305.33                   | Nondependent hallucinogen abuse, in remission                                  | ICD-9-CM  | Diagnosis     |
| 305.4                    | Nondependent sedative, hypnotic or anxiolytic abuse                            | ICD-9-CM  | Diagnosis     |
| 305.40                   | Nondependent sedative, hypnotic or anxiolytic abuse, unspecified               | ICD-9-CM  | Diagnosis     |
| 305.41                   | Nondependent sedative hypnotic or anxiolytic abuse, continuous                 | ICD-9-CM  | Diagnosis     |
| 305.42                   | Nondependent sedative, hypnotic or anxiolytic abuse, episodic                  | ICD-9-CM  | Diagnosis     |
| 305.43                   | Nondependent sedative, hypnotic or anxiolytic abuse, in remission              | ICD-9-CM  | Diagnosis     |
| 305.5                    | Nondependent opioid abuse  | ICD-9-CM  | Diagnosis     |
| 305.50                   | Nondependent opioid abuse, unspecified   | ICD-9-CM  | Diagnosis     |
| 305.51                   | Nondependent opioid abuse, continuous  | ICD-9-CM  | Diagnosis     |
| 305.52                   | Nondependent opioid abuse, episodic  | ICD-9-CM  | Diagnosis     |
| 305.53                   | Nondependent opioid abuse, in remission  | ICD-9-CM  | Diagnosis     |
| 305.6                    | Nondependent cocaine abuse   | ICD-9-CM  | Diagnosis     |
| 305.60                   | Nondependent cocaine abuse, unspecified  | ICD-9-CM  | Diagnosis     |
| 305.61                   | Nondependent cocaine abuse, continuous   | ICD-9-CM  | Diagnosis     |
| 305.62                   | Nondependent cocaine abuse, episodic   | ICD-9-CM  | Diagnosis     |
| 305.63                   | Nondependent cocaine abuse, in remission                                       | ICD-9-CM  | Diagnosis     |
| 305.7                    | Nondependent amphetamine or related acting sympathomimetic abuse               | ICD-9-CM  | Diagnosis     |
| 305.70                   | Nondependent amphetamine or related acting sympathomimetic abuse, unspecified  | ICD-9-CM  | Diagnosis     |
| 305.71                   | Nondependent amphetamine or related acting sympathomimetic abuse, continuous   | ICD-9-CM  | Diagnosis     |
| 305.72                   | Nondependent amphetamine or related acting sympathomimetic abuse, episodic     | ICD-9-CM  | Diagnosis     |
| 305.73                   | Nondependent amphetamine or related acting sympathomimetic abuse, in remission | ICD-9-CM  | Diagnosis     |
| 305.8                    | Nondependent antidepressant type abuse   | ICD-9-CM  | Diagnosis     |
| 305.80                   | Nondependent antidepressant type abuse, unspecified                            | ICD-9-CM  | Diagnosis     |
| 305.81                   | Nondependent antidepressant type abuse, continuous                             | ICD-9-CM  | Diagnosis     |
| 305.82                   | Nondependent antidepressant type abuse, episodic                               | ICD-9-CM  | Diagnosis     |
| 305.83                   | Nondependent antidepressant type abuse, in remission                           | ICD-9-CM  | Diagnosis     |
| 305.9                    | Other, mixed, or unspecified nondependent drug abuse                           | ICD-9-CM  | Diagnosis     |
| 305.90                   | Other, mixed, or unspecified nondependent drug abuse, unspecified              | ICD-9-CM  | Diagnosis     |
| 305.91                   | Other, mixed, or unspecified nondependent drug abuse, continuous               | ICD-9-CM  | Diagnosis     |
| 305.92                   | Other, mixed, or unspecified nondependent drug abuse, episodic                 | ICD-9-CM  | Diagnosis     |
| 305.93                   | Other, mixed, or unspecified nondependent drug abuse, in remission             | ICD-9-CM  | Diagnosis     |
| <b>Allergic Rhinitis</b> |  |           |               |
| 472.0                    | Chronic rhinitis   | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code   | Description   | Code Type | Code Category |
|--|---|-----------|---------------|
| 477  | Allergic rhinitis   | ICD-9-CM  | Diagnosis     |
| 477.0  | Allergic rhinitis due to pollen                             | ICD-9-CM  | Diagnosis     |
| 477.1  | Allergic rhinitis, due to food                              | ICD-9-CM  | Diagnosis     |
| 477.2  | Allergic rhinitis due to animal (cat) (dog) hair and dander | ICD-9-CM  | Diagnosis     |
| 477.8  | Allergic rhinitis due to other allergen                     | ICD-9-CM  | Diagnosis     |
| 477.9  | Allergic rhinitis, cause unspecified                        | ICD-9-CM  | Diagnosis     |
| <b>Respiratory Disorder, Other Than Asthma or Chronic Obstructive Pulmonary Disease (COPD)</b> |   |           |               |
| 003.22   | Salmonella pneumonia  | ICD-9-CM  | Diagnosis     |
| 020.3  | Primary pneumonic plague                                    | ICD-9-CM  | Diagnosis     |
| 020.4  | Secondary pneumonic plague                                  | ICD-9-CM  | Diagnosis     |
| 020.5  | Pneumonic plague, unspecified                               | ICD-9-CM  | Diagnosis     |
| 021.2  | Pulmonary tularemia   | ICD-9-CM  | Diagnosis     |
| 022.1  | Pulmonary anthrax   | ICD-9-CM  | Diagnosis     |
| 031.0  | Pulmonary diseases due to other mycobacteria                | ICD-9-CM  | Diagnosis     |
| 032.0  | Faucial diphtheria  | ICD-9-CM  | Diagnosis     |
| 032.1  | Nasopharyngeal diphtheria                                   | ICD-9-CM  | Diagnosis     |
| 032.2  | Anterior nasal diphtheria                                   | ICD-9-CM  | Diagnosis     |
| 032.3  | Laryngeal diphtheria  | ICD-9-CM  | Diagnosis     |
| 034.0  | Streptococcal sore throat                                   | ICD-9-CM  | Diagnosis     |
| 039.1  | Pulmonary actinomycotic infection                           | ICD-9-CM  | Diagnosis     |
| 052.1  | Varicella (hemorrhagic) pneumonitis                         | ICD-9-CM  | Diagnosis     |
| 055.1  | Postmeasles pneumonia                                       | ICD-9-CM  | Diagnosis     |
| 073.0  | Ornithosis with pneumonia                                   | ICD-9-CM  | Diagnosis     |
| 083.0  | Q fever   | ICD-9-CM  | Diagnosis     |
| 112.4  | Candidiasis of lung   | ICD-9-CM  | Diagnosis     |
| 114.0  | Primary coccidioidomycosis (pulmonary)                      | ICD-9-CM  | Diagnosis     |
| 114.4  | Chronic pulmonary coccidioidomycosis                        | ICD-9-CM  | Diagnosis     |
| 114.5  | Unspecified pulmonary coccidioidomycosis                    | ICD-9-CM  | Diagnosis     |
| 115.05   | Histoplasma capsulatum pneumonia                            | ICD-9-CM  | Diagnosis     |
| 115.15   | Histoplasma duboisii pneumonia                              | ICD-9-CM  | Diagnosis     |
| 115.95   | Unspecified Histoplasmosis pneumonia                        | ICD-9-CM  | Diagnosis     |
| 122  | Echinococcosis  | ICD-9-CM  | Diagnosis     |
| 122.0  | Echinococcus granulosus infection of liver                  | ICD-9-CM  | Diagnosis     |
| 122.1  | Echinococcus granulosus infection of lung                   | ICD-9-CM  | Diagnosis     |
| 122.2  | Echinococcus granulosus infection of thyroid                | ICD-9-CM  | Diagnosis     |
| 122.3  | Other echinococcus granulosus infection                     | ICD-9-CM  | Diagnosis     |
| 122.4  | Unspecified echinococcus granulosus infection               | ICD-9-CM  | Diagnosis     |
| 122.5  | Echinococcus multilocularis infection of liver              | ICD-9-CM  | Diagnosis     |
| 122.6  | Other echinococcus multilocularis infection                 | ICD-9-CM  | Diagnosis     |
| 122.7  | Unspecified echinococcus multilocularis infection           | ICD-9-CM  | Diagnosis     |
| 122.8  | Unspecified echinococcus of liver                           | ICD-9-CM  | Diagnosis     |
| 122.9  | Other and unspecified echinococcosis                        | ICD-9-CM  | Diagnosis     |
| 123  | Other cestode infection                                     | ICD-9-CM  | Diagnosis     |
| 123.0  | Taenia solium infection, intestinal form                    | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code  | Description   | Code Type | Code Category |
|-------|---|-----------|---------------|
| 123.1 | Cysticercosis   | ICD-9-CM  | Diagnosis     |
| 123.2 | Taenia saginata infection   | ICD-9-CM  | Diagnosis     |
| 123.3 | Taeniasis, unspecified  | ICD-9-CM  | Diagnosis     |
| 123.4 | Diphyllobothriasis, intestinal                                      | ICD-9-CM  | Diagnosis     |
| 123.5 | Sparganosis (larval diphyllobothriasis)                             | ICD-9-CM  | Diagnosis     |
| 123.6 | Hymenolepiasis  | ICD-9-CM  | Diagnosis     |
| 123.8 | Other specified cestode infection                                   | ICD-9-CM  | Diagnosis     |
| 123.9 | Unspecified cestode infection                                       | ICD-9-CM  | Diagnosis     |
| 124   | Trichinosis   | ICD-9-CM  | Diagnosis     |
| 125   | Filarial infection and dracontiasis                                 | ICD-9-CM  | Diagnosis     |
| 125.0 | Bancroftian filariasis  | ICD-9-CM  | Diagnosis     |
| 125.1 | Malayan filariasis  | ICD-9-CM  | Diagnosis     |
| 125.2 | Loiasis   | ICD-9-CM  | Diagnosis     |
| 125.3 | Onchocerciasis  | ICD-9-CM  | Diagnosis     |
| 125.4 | Dipetalonemiasis  | ICD-9-CM  | Diagnosis     |
| 125.5 | Mansonella ozzardi infection  | ICD-9-CM  | Diagnosis     |
| 125.6 | Other specified filariasis  | ICD-9-CM  | Diagnosis     |
| 125.7 | Dracontiasis  | ICD-9-CM  | Diagnosis     |
| 125.9 | Unspecified filariasis  | ICD-9-CM  | Diagnosis     |
| 126   | Ancylostomiasis and necatoriasis                                    | ICD-9-CM  | Diagnosis     |
| 126.0 | Ancylostomiasis and necatoriasis due to ancylostoma duodenale       | ICD-9-CM  | Diagnosis     |
| 126.1 | Ancylostomiasis and necatoriasis due to necator americanus          | ICD-9-CM  | Diagnosis     |
| 126.2 | Ancylostomiasis and necatoriasis due to ancylostoma braziliense     | ICD-9-CM  | Diagnosis     |
| 126.3 | Ancylostomiasis and necatoriasis due to ancylostoma ceylanicum      | ICD-9-CM  | Diagnosis     |
| 126.8 | Ancylostomiasis and necatoriasis due to other specified ancylostoma | ICD-9-CM  | Diagnosis     |
| 126.9 | Unspecified ancylostomiasis and necatoriasis                        | ICD-9-CM  | Diagnosis     |
| 127   | Other intestinal helminthiasis                                      | ICD-9-CM  | Diagnosis     |
| 127.0 | Ascariasis  | ICD-9-CM  | Diagnosis     |
| 127.1 | Anisakiasis   | ICD-9-CM  | Diagnosis     |
| 127.2 | Strongyloidiasis  | ICD-9-CM  | Diagnosis     |
| 127.3 | Trichuriasis  | ICD-9-CM  | Diagnosis     |
| 127.4 | Enterobiasis  | ICD-9-CM  | Diagnosis     |
| 127.5 | Capillariasis   | ICD-9-CM  | Diagnosis     |
| 127.6 | Trichostrongyliasis   | ICD-9-CM  | Diagnosis     |
| 127.7 | Other specified intestinal helminthiasis                            | ICD-9-CM  | Diagnosis     |
| 127.8 | Mixed intestinal helminthiasis                                      | ICD-9-CM  | Diagnosis     |
| 127.9 | Unspecified intestinal helminthiasis                                | ICD-9-CM  | Diagnosis     |
| 128   | Other and unspecified helminthiasis                                 | ICD-9-CM  | Diagnosis     |
| 128.0 | Toxocariasis  | ICD-9-CM  | Diagnosis     |
| 128.1 | Gnathostomiasis   | ICD-9-CM  | Diagnosis     |
| 128.8 | Other specified helminthiasis                                       | ICD-9-CM  | Diagnosis     |
| 128.9 | Unspecified helminth infection                                      | ICD-9-CM  | Diagnosis     |
| 129   | Unspecified intestinal parasitism                                   | ICD-9-CM  | Diagnosis     |
| 130   | Toxoplasmosis   | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code   | Description                                | Code Type | Code Category |
|--------|--|-----------|---------------|
| 130.0  | Meningoencephalitis due to toxoplasmosis   | ICD-9-CM  | Diagnosis     |
| 130.1  | Conjunctivitis due to toxoplasmosis        | ICD-9-CM  | Diagnosis     |
| 130.2  | Chorioretinitis due to toxoplasmosis       | ICD-9-CM  | Diagnosis     |
| 130.3  | Myocarditis due to toxoplasmosis           | ICD-9-CM  | Diagnosis     |
| 130.4  | Pneumonitis due to toxoplasmosis           | ICD-9-CM  | Diagnosis     |
| 130.5  | Hepatitis due to toxoplasmosis             | ICD-9-CM  | Diagnosis     |
| 130.7  | Toxoplasmosis of other specified sites     | ICD-9-CM  | Diagnosis     |
| 130.8  | Multisystemic disseminated toxoplasmosis   | ICD-9-CM  | Diagnosis     |
| 130.9  | Unspecified toxoplasmosis                  | ICD-9-CM  | Diagnosis     |
| 131    | Trichomoniasis                             | ICD-9-CM  | Diagnosis     |
| 131.0  | Urogenital trichomoniasis                  | ICD-9-CM  | Diagnosis     |
| 131.00 | Unspecified urogenital trichomoniasis      | ICD-9-CM  | Diagnosis     |
| 131.01 | Trichomonal vulvovaginitis                 | ICD-9-CM  | Diagnosis     |
| 131.02 | Trichomonal urethritis                     | ICD-9-CM  | Diagnosis     |
| 131.03 | Trichomonal prostatitis                    | ICD-9-CM  | Diagnosis     |
| 131.09 | Other urogenital trichomoniasis            | ICD-9-CM  | Diagnosis     |
| 131.8  | Trichomoniasis of other specified sites    | ICD-9-CM  | Diagnosis     |
| 131.9  | Unspecified trichomoniasis                 | ICD-9-CM  | Diagnosis     |
| 132    | Pediculosis and phthirus infestation       | ICD-9-CM  | Diagnosis     |
| 132.0  | Pediculus capitis (head louse)             | ICD-9-CM  | Diagnosis     |
| 132.1  | Pediculus corporis (body louse)            | ICD-9-CM  | Diagnosis     |
| 132.2  | Phthirus pubis (pubic louse)               | ICD-9-CM  | Diagnosis     |
| 132.3  | Mixed pediculosis and phthirus infestation | ICD-9-CM  | Diagnosis     |
| 132.9  | Unspecified pediculosis                    | ICD-9-CM  | Diagnosis     |
| 133    | Acariasis                                  | ICD-9-CM  | Diagnosis     |
| 133.0  | Scabies                                    | ICD-9-CM  | Diagnosis     |
| 133.8  | Other acariasis                            | ICD-9-CM  | Diagnosis     |
| 133.9  | Unspecified acariasis                      | ICD-9-CM  | Diagnosis     |
| 134    | Other infestation                          | ICD-9-CM  | Diagnosis     |
| 134.0  | Myiasis                                    | ICD-9-CM  | Diagnosis     |
| 134.1  | Other arthropod infestation                | ICD-9-CM  | Diagnosis     |
| 134.2  | Hirudiniasis                               | ICD-9-CM  | Diagnosis     |
| 134.8  | Other specified infestations               | ICD-9-CM  | Diagnosis     |
| 134.9  | Unspecified infestation                    | ICD-9-CM  | Diagnosis     |
| 136.3  | Pneumocystosis                             | ICD-9-CM  | Diagnosis     |
| 460    | Acute nasopharyngitis (common cold)        | ICD-9-CM  | Diagnosis     |
| 461.0  | Acute maxillary sinusitis                  | ICD-9-CM  | Diagnosis     |
| 461.1  | Acute frontal sinusitis                    | ICD-9-CM  | Diagnosis     |
| 461.2  | Acute ethmoidal sinusitis                  | ICD-9-CM  | Diagnosis     |
| 461.3  | Acute sphenoidal sinusitis                 | ICD-9-CM  | Diagnosis     |
| 461.8  | Other acute sinusitis                      | ICD-9-CM  | Diagnosis     |
| 461.9  | Acute sinusitis, unspecified               | ICD-9-CM  | Diagnosis     |
| 462    | Acute pharyngitis                          | ICD-9-CM  | Diagnosis     |
| 463    | Acute tonsillitis                          | ICD-9-CM  | Diagnosis     |



**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code   | Description  | Code Type | Code Category |
|--------|--|-----------|---------------|
| 464.0  | Acute laryngitis   | ICD-9-CM  | Diagnosis     |
| 464.00 | Acute laryngitis, without mention of obstruction             | ICD-9-CM  | Diagnosis     |
| 464.01 | Acute laryngitis, with obstruction                           | ICD-9-CM  | Diagnosis     |
| 464.10 | Acute tracheitis without mention of obstruction              | ICD-9-CM  | Diagnosis     |
| 464.11 | Acute tracheitis with obstruction                            | ICD-9-CM  | Diagnosis     |
| 464.20 | Acute laryngotracheitis without mention of obstruction       | ICD-9-CM  | Diagnosis     |
| 464.21 | Acute laryngotracheitis with obstruction                     | ICD-9-CM  | Diagnosis     |
| 464.30 | Acute epiglottitis without mention of obstruction            | ICD-9-CM  | Diagnosis     |
| 464.31 | Acute epiglottitis with obstruction                          | ICD-9-CM  | Diagnosis     |
| 464.4  | Croup  | ICD-9-CM  | Diagnosis     |
| 464.50 | Unspecified supraglottis, without mention of obstruction     | ICD-9-CM  | Diagnosis     |
| 464.51 | Unspecified supraglottis, with obstruction                   | ICD-9-CM  | Diagnosis     |
| 465.0  | Acute laryngopharyngitis                                     | ICD-9-CM  | Diagnosis     |
| 465.8  | Acute upper respiratory infections of other multiple sites   | ICD-9-CM  | Diagnosis     |
| 465.9  | Acute upper respiratory infections of unspecified site       | ICD-9-CM  | Diagnosis     |
| 466.0  | Acute bronchitis   | ICD-9-CM  | Diagnosis     |
| 466.1  | Acute bronchiolitis  | ICD-9-CM  | Diagnosis     |
| 466.11 | Acute bronchiolitis due to respiratory syncytial virus (RSV) | ICD-9-CM  | Diagnosis     |
| 466.19 | Acute bronchiolitis due to other infectious organisms        | ICD-9-CM  | Diagnosis     |
| 470    | Deviated nasal septum  | ICD-9-CM  | Diagnosis     |
| 471.0  | Polyp of nasal cavity  | ICD-9-CM  | Diagnosis     |
| 471.1  | Polypoid sinus degeneration                                  | ICD-9-CM  | Diagnosis     |
| 471.8  | Other polyp of sinus   | ICD-9-CM  | Diagnosis     |
| 471.9  | Unspecified nasal polyp                                      | ICD-9-CM  | Diagnosis     |
| 472.0  | Chronic rhinitis   | ICD-9-CM  | Diagnosis     |
| 472.1  | Chronic pharyngitis  | ICD-9-CM  | Diagnosis     |
| 472.2  | Chronic nasopharyngitis                                      | ICD-9-CM  | Diagnosis     |
| 473.0  | Chronic maxillary sinusitis                                  | ICD-9-CM  | Diagnosis     |
| 473.1  | Chronic frontal sinusitis                                    | ICD-9-CM  | Diagnosis     |
| 473.2  | Chronic ethmoidal sinusitis                                  | ICD-9-CM  | Diagnosis     |
| 473.3  | Chronic sphenoidal sinusitis                                 | ICD-9-CM  | Diagnosis     |
| 473.8  | Other chronic sinusitis                                      | ICD-9-CM  | Diagnosis     |
| 473.9  | Unspecified sinusitis (chronic)                              | ICD-9-CM  | Diagnosis     |
| 474.0  | Chronic tonsillitis and adenoiditis                          | ICD-9-CM  | Diagnosis     |
| 474.00 | Chronic tonsillitis  | ICD-9-CM  | Diagnosis     |
| 474.01 | Chronic adenoiditis  | ICD-9-CM  | Diagnosis     |
| 474.02 | Chronic tonsillitis and adenoiditis                          | ICD-9-CM  | Diagnosis     |
| 474.10 | Hypertrophy of tonsil with adenoids                          | ICD-9-CM  | Diagnosis     |
| 474.11 | Hypertrophy of tonsils alone                                 | ICD-9-CM  | Diagnosis     |
| 474.12 | Hypertrophy of adenoids alone                                | ICD-9-CM  | Diagnosis     |
| 474.2  | Adenoid vegetations  | ICD-9-CM  | Diagnosis     |
| 474.8  | Other chronic disease of tonsils and adenoids                | ICD-9-CM  | Diagnosis     |
| 474.9  | Unspecified chronic disease of tonsils and adenoids          | ICD-9-CM  | Diagnosis     |
| 475    | Peritonsillar abscess  | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code   | Description   | Code Type | Code Category |
|--------|---|-----------|---------------|
| 476.0  | Chronic laryngitis  | ICD-9-CM  | Diagnosis     |
| 476.1  | Chronic laryngotracheitis   | ICD-9-CM  | Diagnosis     |
| 477.0  | Allergic rhinitis due to pollen                                     | ICD-9-CM  | Diagnosis     |
| 477.2  | Allergic rhinitis due to animal (cat) (dog) hair and dander         | ICD-9-CM  | Diagnosis     |
| 477.8  | Allergic rhinitis due to other allergen                             | ICD-9-CM  | Diagnosis     |
| 477.9  | Allergic rhinitis, cause unspecified                                | ICD-9-CM  | Diagnosis     |
| 478.0  | Hypertrophy of nasal turbinates                                     | ICD-9-CM  | Diagnosis     |
| 478.1  | Other diseases of nasal cavity and sinuses                          | ICD-9-CM  | Diagnosis     |
| 478.11 | Nasal mucositis (ulcerative)  | ICD-9-CM  | Diagnosis     |
| 478.19 | Other diseases of nasal cavity and sinuses                          | ICD-9-CM  | Diagnosis     |
| 478.20 | Unspecified disease of pharynx                                      | ICD-9-CM  | Diagnosis     |
| 478.21 | Cellulitis of pharynx or nasopharynx                                | ICD-9-CM  | Diagnosis     |
| 478.22 | Parapharyngeal abscess  | ICD-9-CM  | Diagnosis     |
| 478.24 | Retropharyngeal abscess   | ICD-9-CM  | Diagnosis     |
| 478.25 | Edema of pharynx or nasopharynx                                     | ICD-9-CM  | Diagnosis     |
| 478.26 | Cyst of pharynx or nasopharynx                                      | ICD-9-CM  | Diagnosis     |
| 478.29 | Other disease of pharynx or nasopharynx                             | ICD-9-CM  | Diagnosis     |
| 478.30 | Unspecified paralysis of vocal cords or larynx                      | ICD-9-CM  | Diagnosis     |
| 478.31 | Unilateral partial paralysis of vocal cords or larynx               | ICD-9-CM  | Diagnosis     |
| 478.32 | Unilateral complete paralysis of vocal cords or larynx              | ICD-9-CM  | Diagnosis     |
| 478.33 | Bilateral partial paralysis of vocal cords or larynx                | ICD-9-CM  | Diagnosis     |
| 478.34 | Bilateral complete paralysis of vocal cords or larynx               | ICD-9-CM  | Diagnosis     |
| 478.4  | Polyp of vocal cord or larynx                                       | ICD-9-CM  | Diagnosis     |
| 478.5  | Other diseases of vocal cords                                       | ICD-9-CM  | Diagnosis     |
| 478.6  | Edema of larynx   | ICD-9-CM  | Diagnosis     |
| 478.70 | Unspecified disease of larynx                                       | ICD-9-CM  | Diagnosis     |
| 478.71 | Cellulitis and perichondritis of larynx                             | ICD-9-CM  | Diagnosis     |
| 478.74 | Stenosis of larynx  | ICD-9-CM  | Diagnosis     |
| 478.75 | Laryngeal spasm   | ICD-9-CM  | Diagnosis     |
| 478.79 | Other diseases of larynx  | ICD-9-CM  | Diagnosis     |
| 478.8  | Upper respiratory tract hypersensitivity reaction, site unspecified | ICD-9-CM  | Diagnosis     |
| 478.9  | Other and unspecified diseases of upper respiratory tract           | ICD-9-CM  | Diagnosis     |
| 480.0  | Pneumonia due to adenovirus   | ICD-9-CM  | Diagnosis     |
| 480.1  | Pneumonia due to respiratory syncytial virus                        | ICD-9-CM  | Diagnosis     |
| 480.2  | Pneumonia due to parainfluenza virus                                | ICD-9-CM  | Diagnosis     |
| 480.3  | Pneumonia due to SARS-associated coronavirus                        | ICD-9-CM  | Diagnosis     |
| 480.8  | Pneumonia due to other virus not elsewhere classified               | ICD-9-CM  | Diagnosis     |
| 480.9  | Unspecified viral pneumonia   | ICD-9-CM  | Diagnosis     |
| 481    | Pneumococcal pneumonia (streptococcus pneumoniae pneumonia)         | ICD-9-CM  | Diagnosis     |
| 482.0  | Pneumonia due to Klebsiella pneumoniae                              | ICD-9-CM  | Diagnosis     |
| 482.1  | Pneumonia due to Pseudomonas  | ICD-9-CM  | Diagnosis     |
| 482.2  | Pneumonia due to Hemophilus influenzae (H. influenzae)              | ICD-9-CM  | Diagnosis     |
| 482.3  | Pneumonia due to Streptococcus                                      | ICD-9-CM  | Diagnosis     |
| 482.30 | Pneumonia due to unspecified Streptococcus                          | ICD-9-CM  | Diagnosis     |



**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code   | Description   | Code Type | Code Category |
|--------|---|-----------|---------------|
| 482.31 | Pneumonia due to Streptococcus, group A   | ICD-9-CM  | Diagnosis     |
| 482.32 | Pneumonia due to Streptococcus, group B   | ICD-9-CM  | Diagnosis     |
| 482.39 | Pneumonia due to other Streptococcus  | ICD-9-CM  | Diagnosis     |
| 482.4  | Pneumonia due to Staphylococcus   | ICD-9-CM  | Diagnosis     |
| 482.40 | Pneumonia due to Staphylococcus, unspecified  | ICD-9-CM  | Diagnosis     |
| 482.41 | Methicillin susceptible pneumonia due to Staphylococcus aureus                              | ICD-9-CM  | Diagnosis     |
| 482.42 | Methicillin resistant pneumonia due to Staphylococcus aureus                                | ICD-9-CM  | Diagnosis     |
| 482.49 | Other Staphylococcus pneumonia  | ICD-9-CM  | Diagnosis     |
| 482.8  | Pneumonia due to other specified bacteria   | ICD-9-CM  | Diagnosis     |
| 482.81 | Pneumonia due to anaerobes  | ICD-9-CM  | Diagnosis     |
| 482.82 | Pneumonia due to Escherichia coli (E. coli)   | ICD-9-CM  | Diagnosis     |
| 482.83 | Pneumonia due to other gram-negative bacteria   | ICD-9-CM  | Diagnosis     |
| 482.84 | Legionnaires' disease   | ICD-9-CM  | Diagnosis     |
| 482.89 | Pneumonia due to other specified bacteria   | ICD-9-CM  | Diagnosis     |
| 482.9  | Unspecified bacterial pneumonia   | ICD-9-CM  | Diagnosis     |
| 483    | Pneumonia due to other specified organism   | ICD-9-CM  | Diagnosis     |
| 483.0  | Pneumonia due to Mycoplasma pneumoniae  | ICD-9-CM  | Diagnosis     |
| 483.1  | Pneumonia due to Chlamydia  | ICD-9-CM  | Diagnosis     |
| 483.8  | Pneumonia due to other specified organism   | ICD-9-CM  | Diagnosis     |
| 484.1  | Pneumonia in cytomegalic inclusion disease  | ICD-9-CM  | Diagnosis     |
| 484.3  | Pneumonia in whooping cough   | ICD-9-CM  | Diagnosis     |
| 484.5  | Pneumonia in anthrax  | ICD-9-CM  | Diagnosis     |
| 484.6  | Pneumonia in aspergillosis  | ICD-9-CM  | Diagnosis     |
| 484.7  | Pneumonia in other systemic mycoses   | ICD-9-CM  | Diagnosis     |
| 484.8  | Pneumonia in other infectious diseases classified elsewhere                                 | ICD-9-CM  | Diagnosis     |
| 485    | Bronchopneumonia, organism unspecified  | ICD-9-CM  | Diagnosis     |
| 486    | Pneumonia, organism unspecified   | ICD-9-CM  | Diagnosis     |
| 487.0  | Influenza with pneumonia  | ICD-9-CM  | Diagnosis     |
| 487.1  | Influenza with other respiratory manifestations   | ICD-9-CM  | Diagnosis     |
| 487.8  | Influenza with other manifestations   | ICD-9-CM  | Diagnosis     |
| 488    | Influenza due to certain identified influenza viruses                                       | ICD-9-CM  | Diagnosis     |
| 488.0  | Influenza due to identified avian influenza virus   | ICD-9-CM  | Diagnosis     |
| 488.01 | Influenza due to identified avian influenza virus with pneumonia                            | ICD-9-CM  | Diagnosis     |
| 488.02 | Influenza due to identified avian influenza virus with other respiratory manifestations     | ICD-9-CM  | Diagnosis     |
| 488.09 | Influenza due to identified avian influenza virus with other manifestations                 | ICD-9-CM  | Diagnosis     |
| 488.1  | Influenza due to identified 2009 H1N1 influenza virus                                       | ICD-9-CM  | Diagnosis     |
| 488.11 | Influenza due to identified 2009 H1N1 influenza virus with pneumonia                        | ICD-9-CM  | Diagnosis     |
| 488.12 | Influenza due to identified 2009 H1N1 influenza virus with other respiratory manifestations | ICD-9-CM  | Diagnosis     |
| 488.19 | Influenza due to identified 2009 H1N1 influenza virus with other manifestations             | ICD-9-CM  | Diagnosis     |
| 488.81 | Influenza due to identified novel influenza A virus with pneumonia                          | ICD-9-CM  | Diagnosis     |
| 488.82 | Influenza due to identified novel influenza A virus with other respiratory manifestations   | ICD-9-CM  | Diagnosis     |
| 488.89 | Influenza due to identified novel influenza A virus with other manifestations               | ICD-9-CM  | Diagnosis     |
| 495.0  | Farmers' lung   | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code   | Description   | Code Type | Code Category |
|--------|---|-----------|---------------|
| 495.1  | Bagassosis  | ICD-9-CM  | Diagnosis     |
| 495.2  | Bird-fanciers' lung   | ICD-9-CM  | Diagnosis     |
| 495.3  | Suberosis   | ICD-9-CM  | Diagnosis     |
| 495.4  | Malt workers' lung  | ICD-9-CM  | Diagnosis     |
| 495.5  | Mushroom workers' lung  | ICD-9-CM  | Diagnosis     |
| 495.6  | Maple bark-strippers' lung  | ICD-9-CM  | Diagnosis     |
| 495.7  | Ventilation pneumonitis   | ICD-9-CM  | Diagnosis     |
| 495.8  | Other specified allergic alveolitis and pneumonitis                             | ICD-9-CM  | Diagnosis     |
| 495.9  | Unspecified allergic alveolitis and pneumonitis                                 | ICD-9-CM  | Diagnosis     |
| 496    | Chronic airway obstruction, not elsewhere classified                            | ICD-9-CM  | Diagnosis     |
| 500    | Coal workers' pneumoconiosis  | ICD-9-CM  | Diagnosis     |
| 501    | Asbestosis  | ICD-9-CM  | Diagnosis     |
| 502    | Pneumoconiosis due to other silica or silicates                                 | ICD-9-CM  | Diagnosis     |
| 503    | Pneumoconiosis due to other inorganic dust                                      | ICD-9-CM  | Diagnosis     |
| 504    | Pneumonopathy due to inhalation of other dust                                   | ICD-9-CM  | Diagnosis     |
| 505    | Unspecified pneumoconiosis  | ICD-9-CM  | Diagnosis     |
| 506.0  | Bronchitis and pneumonitis due to fumes and vapors                              | ICD-9-CM  | Diagnosis     |
| 506.1  | Acute pulmonary edema due to fumes and vapors                                   | ICD-9-CM  | Diagnosis     |
| 506.2  | Upper respiratory inflammation due to fumes and vapors                          | ICD-9-CM  | Diagnosis     |
| 506.3  | Other acute and subacute respiratory conditions due to fumes and vapors         | ICD-9-CM  | Diagnosis     |
| 506.4  | Chronic respiratory conditions due to fumes and vapors                          | ICD-9-CM  | Diagnosis     |
| 506.9  | Unspecified respiratory conditions due to fumes and vapors                      | ICD-9-CM  | Diagnosis     |
| 507.0  | Pneumonitis due to inhalation of food or vomitus                                | ICD-9-CM  | Diagnosis     |
| 507.1  | Pneumonitis due to inhalation of oils and essences                              | ICD-9-CM  | Diagnosis     |
| 507.8  | Pneumonitis due to other solids and liquids                                     | ICD-9-CM  | Diagnosis     |
| 508.0  | Acute pulmonary manifestations due to radiation                                 | ICD-9-CM  | Diagnosis     |
| 508.1  | Chronic and other pulmonary manifestations due to radiation                     | ICD-9-CM  | Diagnosis     |
| 508.2  | Respiratory conditions due to smoke inhalation                                  | ICD-9-CM  | Diagnosis     |
| 508.8  | Respiratory conditions due to other specified external agents                   | ICD-9-CM  | Diagnosis     |
| 508.9  | Respiratory conditions due to unspecified external agent                        | ICD-9-CM  | Diagnosis     |
| 510.0  | Empyema with fistula  | ICD-9-CM  | Diagnosis     |
| 510.9  | Empyema without mention of fistula  | ICD-9-CM  | Diagnosis     |
| 511.0  | Pleurisy without mention of effusion or current tuberculosis                    | ICD-9-CM  | Diagnosis     |
| 511.1  | Pleurisy with effusion, with mention of bacterial cause other than tuberculosis | ICD-9-CM  | Diagnosis     |
| 511.8  | Other specified forms of pleural effusion, except tuberculous                   | ICD-9-CM  | Diagnosis     |
| 511.89 | Other specified forms of effusion, except tuberculous                           | ICD-9-CM  | Diagnosis     |
| 511.9  | Unspecified pleural effusion  | ICD-9-CM  | Diagnosis     |
| 512.0  | Spontaneous tension pneumothorax  | ICD-9-CM  | Diagnosis     |
| 512.8  | Other pneumothorax and air leak   | ICD-9-CM  | Diagnosis     |
| 512.81 | Primary spontaneous pneumothorax  | ICD-9-CM  | Diagnosis     |
| 512.82 | Secondary spontaneous pneumothorax  | ICD-9-CM  | Diagnosis     |
| 512.83 | Chronic pneumothorax  | ICD-9-CM  | Diagnosis     |
| 512.84 | Other air leak  | ICD-9-CM  | Diagnosis     |
| 512.89 | Other pneumothorax  | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code   | Description   | Code Type | Code Category |
|--------|---|-----------|---------------|
| 513.0  | Abscess of lung   | ICD-9-CM  | Diagnosis     |
| 513.1  | Abscess of mediastinum  | ICD-9-CM  | Diagnosis     |
| 514    | Pulmonary congestion and hypostasis   | ICD-9-CM  | Diagnosis     |
| 515    | Postinflammatory pulmonary fibrosis   | ICD-9-CM  | Diagnosis     |
| 516.0  | Pulmonary alveolar proteinosis  | ICD-9-CM  | Diagnosis     |
| 516.1  | Idiopathic pulmonary hemosiderosis  | ICD-9-CM  | Diagnosis     |
| 516.2  | Pulmonary alveolar microlithiasis   | ICD-9-CM  | Diagnosis     |
| 516.3  | Idiopathic interstitial pneumonia   | ICD-9-CM  | Diagnosis     |
| 516.30 | Idiopathic interstitial pneumonia, not otherwise specified                            | ICD-9-CM  | Diagnosis     |
| 516.31 | Idiopathic pulmonary fibrosis   | ICD-9-CM  | Diagnosis     |
| 516.32 | Idiopathic non-specific interstitial pneumonitis                                      | ICD-9-CM  | Diagnosis     |
| 516.33 | Acute interstitial pneumonitis  | ICD-9-CM  | Diagnosis     |
| 516.34 | Respiratory bronchiolitis interstitial lung disease                                   | ICD-9-CM  | Diagnosis     |
| 516.35 | Idiopathic lymphoid interstitial pneumonia  | ICD-9-CM  | Diagnosis     |
| 516.36 | Cryptogenic organizing pneumonia  | ICD-9-CM  | Diagnosis     |
| 516.37 | Desquamative interstitial pneumonia   | ICD-9-CM  | Diagnosis     |
| 516.4  | Lymphangioleiomyomatosis  | ICD-9-CM  | Diagnosis     |
| 516.5  | Adult pulmonary Langerhans cell histiocytosis   | ICD-9-CM  | Diagnosis     |
| 516.61 | Neuroendocrine cell hyperplasia of infancy  | ICD-9-CM  | Diagnosis     |
| 516.62 | Pulmonary interstitial glycogenosis   | ICD-9-CM  | Diagnosis     |
| 516.63 | Surfactant mutations of the lung  | ICD-9-CM  | Diagnosis     |
| 516.64 | Alveolar capillary dysplasia with vein misalignment                                   | ICD-9-CM  | Diagnosis     |
| 516.69 | Other interstitial lung diseases of childhood   | ICD-9-CM  | Diagnosis     |
| 516.8  | Other specified alveolar and parietoalveolar pneumonopathies                          | ICD-9-CM  | Diagnosis     |
| 516.9  | Unspecified alveolar and parietoalveolar pneumonopathy                                | ICD-9-CM  | Diagnosis     |
| 517.1  | Rheumatic pneumonia   | ICD-9-CM  | Diagnosis     |
| 517.2  | Lung involvement in systemic sclerosis  | ICD-9-CM  | Diagnosis     |
| 517.3  | Acute chest syndrome  | ICD-9-CM  | Diagnosis     |
| 517.8  | Lung involvement in other diseases classified elsewhere                               | ICD-9-CM  | Diagnosis     |
| 518.0  | Pulmonary collapse  | ICD-9-CM  | Diagnosis     |
| 518.1  | Interstitial emphysema  | ICD-9-CM  | Diagnosis     |
| 518.2  | Compensatory emphysema  | ICD-9-CM  | Diagnosis     |
| 518.3  | Pulmonary eosinophilia  | ICD-9-CM  | Diagnosis     |
| 518.4  | Unspecified acute edema of lung   | ICD-9-CM  | Diagnosis     |
| 518.5  | Pulmonary insufficiency following trauma and surgery                                  | ICD-9-CM  | Diagnosis     |
| 518.51 | Acute respiratory failure following trauma and surgery                                | ICD-9-CM  | Diagnosis     |
| 518.52 | Other pulmonary insufficiency, not elsewhere classified, following trauma and surgery | ICD-9-CM  | Diagnosis     |
| 518.53 | Acute and chronic respiratory failure following trauma and surgery                    | ICD-9-CM  | Diagnosis     |
| 518.81 | Acute respiratory failure   | ICD-9-CM  | Diagnosis     |
| 518.82 | Other pulmonary insufficiency, not elsewhere classified                               | ICD-9-CM  | Diagnosis     |
| 518.83 | Chronic respiratory failure   | ICD-9-CM  | Diagnosis     |
| 518.84 | Acute and chronic respiratory failure   | ICD-9-CM  | Diagnosis     |
| 518.89 | Other diseases of lung, not elsewhere classified                                      | ICD-9-CM  | Diagnosis     |
| 519.1  | Other diseases of trachea and bronchus, not elsewhere classified                      | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code   | Description   | Code Type | Code Category |
|--------|---|-----------|---------------|
| 519.11 | Acute bronchospasm  | ICD-9-CM  | Diagnosis     |
| 519.19 | Other diseases of trachea and bronchus  | ICD-9-CM  | Diagnosis     |
| 519.2  | Mediastinitis   | ICD-9-CM  | Diagnosis     |
| 519.3  | Other diseases of mediastinum, not elsewhere classified   | ICD-9-CM  | Diagnosis     |
| 519.4  | Disorders of diaphragm  | ICD-9-CM  | Diagnosis     |
| 519.8  | Other diseases of respiratory system, not elsewhere classified                                      | ICD-9-CM  | Diagnosis     |
| 519.9  | Unspecified disease of respiratory system   | ICD-9-CM  | Diagnosis     |
| 782.5  | Cyanosis  | ICD-9-CM  | Diagnosis     |
| 784.1  | Throat pain   | ICD-9-CM  | Diagnosis     |
| 784.40 | Voice and resonance disorder, unspecified   | ICD-9-CM  | Diagnosis     |
| 784.41 | Aphonia   | ICD-9-CM  | Diagnosis     |
| 784.42 | Dysphonia   | ICD-9-CM  | Diagnosis     |
| 784.43 | Hypernasality   | ICD-9-CM  | Diagnosis     |
| 784.44 | Hyponasality  | ICD-9-CM  | Diagnosis     |
| 784.49 | Other voice and resonance disorders   | ICD-9-CM  | Diagnosis     |
| 784.7  | Epistaxis   | ICD-9-CM  | Diagnosis     |
| 784.8  | Hemorrhage from throat  | ICD-9-CM  | Diagnosis     |
| 784.9  | Other symptoms involving head and neck  | ICD-9-CM  | Diagnosis     |
| 784.91 | Postnasal drip  | ICD-9-CM  | Diagnosis     |
| 784.99 | Other symptoms involving head and neck  | ICD-9-CM  | Diagnosis     |
| 786.00 | Unspecified respiratory abnormality   | ICD-9-CM  | Diagnosis     |
| 786.01 | Hyperventilation  | ICD-9-CM  | Diagnosis     |
| 786.02 | Orthopnea   | ICD-9-CM  | Diagnosis     |
| 786.03 | Apnea   | ICD-9-CM  | Diagnosis     |
| 786.04 | Cheyne-Stokes respiration   | ICD-9-CM  | Diagnosis     |
| 786.05 | Shortness of breath   | ICD-9-CM  | Diagnosis     |
| 786.06 | Tachypnea   | ICD-9-CM  | Diagnosis     |
| 786.07 | Wheezing  | ICD-9-CM  | Diagnosis     |
| 786.09 | Other dyspnea and respiratory abnormalities   | ICD-9-CM  | Diagnosis     |
| 786.1  | Stridor   | ICD-9-CM  | Diagnosis     |
| 786.2  | Cough   | ICD-9-CM  | Diagnosis     |
| 786.3  | Hemoptysis  | ICD-9-CM  | Diagnosis     |
| 786.30 | Hemoptysis, unspecified   | ICD-9-CM  | Diagnosis     |
| 786.31 | Acute idiopathic pulmonary hemorrhage in infants [AIPHI]  | ICD-9-CM  | Diagnosis     |
| 786.39 | Other hemoptysis  | ICD-9-CM  | Diagnosis     |
| 786.4  | Abnormal sputum   | ICD-9-CM  | Diagnosis     |
| 786.52 | Painful respiration   | ICD-9-CM  | Diagnosis     |
| 786.6  | Swelling, mass, or lump in chest  | ICD-9-CM  | Diagnosis     |
| 786.7  | Abnormal chest sounds   | ICD-9-CM  | Diagnosis     |
| 786.8  | Hiccough  | ICD-9-CM  | Diagnosis     |
| 786.9  | Other symptoms involving respiratory system and chest   | ICD-9-CM  | Diagnosis     |
| 793.1  | Nonspecific (abnormal) findings on radiological and other examination of body structure, lung field | ICD-9-CM  | Diagnosis     |
| 793.11 | Solitary pulmonary nodule   | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code  | Description   | Code Type | Code Category |
|---|---|-----------|---------------|
| 793.19  | Other nonspecific abnormal finding of lung field                | ICD-9-CM  | Diagnosis     |
| 794.2   | Nonspecific abnormal results of pulmonary system function study | ICD-9-CM  | Diagnosis     |
| 799.1   | Respiratory arrest  | ICD-9-CM  | Diagnosis     |
| V12.6   | Personal history of diseases of respiratory system              | ICD-9-CM  | Diagnosis     |
| V12.60  | Personal history, unspecified disease of respiratory system     | ICD-9-CM  | Diagnosis     |
| V12.61  | Personal history, Pneumonia (recurrent)                         | ICD-9-CM  | Diagnosis     |
| V12.69  | Personal history, Other diseases of respiratory system          | ICD-9-CM  | Diagnosis     |
| V41.4   | Problems with voice production                                  | ICD-9-CM  | Diagnosis     |
| V42.6   | Lung replaced by transplant                                     | ICD-9-CM  | Diagnosis     |
| V44.0   | Tracheostomy status   | ICD-9-CM  | Diagnosis     |
| V46.1   | Dependence on Respirator [Ventilator]                           | ICD-9-CM  | Diagnosis     |
| V46.11  | Dependence on respirator, status                                | ICD-9-CM  | Diagnosis     |
| V46.12  | Encounter for respirator dependence during power failure        | ICD-9-CM  | Diagnosis     |
| V46.13  | Encounter for weaning from respirator [ventilator]              | ICD-9-CM  | Diagnosis     |
| V46.14  | Mechanical complication of respirator [ventilator]              | ICD-9-CM  | Diagnosis     |
| V46.2   | Dependence on machine for supplemental oxygen                   | ICD-9-CM  | Diagnosis     |
| V55.0   | Attention to tracheostomy                                       | ICD-9-CM  | Diagnosis     |
| <b>Psychiatric Events</b>                       |   |           |               |
| <i>Attention-deficit/hyperactivity disorder</i> |   |           |               |
| 314   | Hyperkinetic syndrome of childhood                              | ICD-9-CM  | Diagnosis     |
| 314.0   | Attention deficit disorder of childhood                         | ICD-9-CM  | Diagnosis     |
| 314.00  | Attention deficit disorder without mention of hyperactivity     | ICD-9-CM  | Diagnosis     |
| 314.01  | Attention deficit disorder with hyperactivity                   | ICD-9-CM  | Diagnosis     |
| 314.1   | Hyperkinesis with developmental delay                           | ICD-9-CM  | Diagnosis     |
| 314.2   | Hyperkinetic conduct disorder                                   | ICD-9-CM  | Diagnosis     |
| 314.8   | Other specified manifestations of hyperkinetic syndrome         | ICD-9-CM  | Diagnosis     |
| 314.9   | Unspecified hyperkinetic syndrome                               | ICD-9-CM  | Diagnosis     |
| <i>Akathisia</i>                                |   |           |               |
| 333.99  | Other extrapyramidal disease and abnormal movement disorder     | ICD-9-CM  | Diagnosis     |
| <i>Anxiety</i>                                  |   |           |               |
| 300.02  | Generalized anxiety disorder                                    | ICD-9-CM  | Diagnosis     |
| 300.0   | Anxiety states  | ICD-9-CM  | Diagnosis     |
| 300.00  | Anxiety state, unspecified                                      | ICD-9-CM  | Diagnosis     |
| 300.09  | Other anxiety states  | ICD-9-CM  | Diagnosis     |
| 300.2   | Phobic disorders  | ICD-9-CM  | Diagnosis     |
| 300.20  | Phobia, unspecified   | ICD-9-CM  | Diagnosis     |
| 300.22  | Agoraphobia without mention of panic attacks                    | ICD-9-CM  | Diagnosis     |
| 300.29  | Other isolated or specific phobias                              | ICD-9-CM  | Diagnosis     |
| 300.01  | Panic disorder without agoraphobia                              | ICD-9-CM  | Diagnosis     |
| 300.21  | Agoraphobia with panic disorder                                 | ICD-9-CM  | Diagnosis     |
| <i>Bipolar disorder</i>                         |   |           |               |
| 296.0   | Bipolar I disorder, single manic episode                        | ICD-9-CM  | Diagnosis     |
| 296.00  | Bipolar I disorder, single manic episode, unspecified           | ICD-9-CM  | Diagnosis     |
| 296.01  | Bipolar I disorder, single manic episode, mild                  | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code   | Description   | Code Type | Code Category |
|--------|---|-----------|---------------|
| 296.02 | Bipolar I disorder, single manic episode, moderate  | ICD-9-CM  | Diagnosis     |
| 296.03 | Bipolar I disorder, single manic episode, severe, without mention of psychotic behavior                       | ICD-9-CM  | Diagnosis     |
| 296.04 | Bipolar I disorder, single manic episode, severe, specified as with psychotic behavior                        | ICD-9-CM  | Diagnosis     |
| 296.05 | Bipolar I disorder, single manic episode, in partial or unspecified remission                                 | ICD-9-CM  | Diagnosis     |
| 296.06 | Bipolar I disorder, single manic episode, in full remission   | ICD-9-CM  | Diagnosis     |
| 296.1  | Manic disorder, recurrent episode   | ICD-9-CM  | Diagnosis     |
| 296.10 | Manic disorder, recurrent episode, unspecified  | ICD-9-CM  | Diagnosis     |
| 296.11 | Manic disorder, recurrent episode, mild   | ICD-9-CM  | Diagnosis     |
| 296.12 | Manic disorder, recurrent episode, moderate   | ICD-9-CM  | Diagnosis     |
| 296.13 | Manic disorder, recurrent episode, severe, without mention of psychotic behavior                              | ICD-9-CM  | Diagnosis     |
| 296.14 | Manic disorder, recurrent episode, severe, specified as with psychotic behavior                               | ICD-9-CM  | Diagnosis     |
| 296.15 | Manic disorder, recurrent episode, in partial or unspecified remission  | ICD-9-CM  | Diagnosis     |
| 296.16 | Manic disorder, recurrent episode, in full remission  | ICD-9-CM  | Diagnosis     |
| 296.4  | Bipolar I disorder, most recent episode (or current) manic  | ICD-9-CM  | Diagnosis     |
| 296.40 | Bipolar I disorder, most recent episode (or current) manic, unspecified                                       | ICD-9-CM  | Diagnosis     |
| 296.41 | Bipolar I disorder, most recent episode (or current) manic, mild  | ICD-9-CM  | Diagnosis     |
| 296.42 | Bipolar I disorder, most recent episode (or current) manic, moderate  | ICD-9-CM  | Diagnosis     |
| 296.43 | Bipolar I disorder, most recent episode (or current) manic, severe, without mention of psychotic behavior     | ICD-9-CM  | Diagnosis     |
| 296.44 | Bipolar I disorder, most recent episode (or current) manic, severe, specified as with psychotic behavior      | ICD-9-CM  | Diagnosis     |
| 296.45 | Bipolar I disorder, most recent episode (or current) manic, in partial or unspecified remission               | ICD-9-CM  | Diagnosis     |
| 296.46 | Bipolar I disorder, most recent episode (or current) manic, in full remission                                 | ICD-9-CM  | Diagnosis     |
| 296.5  | Bipolar I disorder, most recent episode (or current), depressed   | ICD-9-CM  | Diagnosis     |
| 296.50 | Bipolar I disorder, most recent episode (or current) depressed, unspecified                                   | ICD-9-CM  | Diagnosis     |
| 296.51 | Bipolar I disorder, most recent episode (or current) depressed, mild  | ICD-9-CM  | Diagnosis     |
| 296.52 | Bipolar I disorder, most recent episode (or current) depressed, moderate                                      | ICD-9-CM  | Diagnosis     |
| 296.53 | Bipolar I disorder, most recent episode (or current) depressed, severe, without mention of psychotic behavior | ICD-9-CM  | Diagnosis     |
| 296.54 | Bipolar I disorder, most recent episode (or current) depressed, severe, specified as with psychotic behavior  | ICD-9-CM  | Diagnosis     |
| 296.55 | Bipolar I disorder, most recent episode (or current) depressed, in partial or unspecified remission           | ICD-9-CM  | Diagnosis     |
| 296.56 | Bipolar I disorder, most recent episode (or current) depressed, in full remission                             | ICD-9-CM  | Diagnosis     |
| 296.6  | Bipolar I disorder, most recent episode (or current), mixed   | ICD-9-CM  | Diagnosis     |
| 296.60 | Bipolar I disorder, most recent episode (or current) mixed, unspecified                                       | ICD-9-CM  | Diagnosis     |
| 296.61 | Bipolar I disorder, most recent episode (or current) mixed, mild  | ICD-9-CM  | Diagnosis     |
| 296.62 | Bipolar I disorder, most recent episode (or current) mixed, moderate  | ICD-9-CM  | Diagnosis     |
| 296.63 | Bipolar I disorder, most recent episode (or current) mixed, severe, without mention of psychotic behavior     | ICD-9-CM  | Diagnosis     |
| 296.64 | Bipolar I disorder, most recent episode (or current) mixed, severe, specified as with psychotic behavior      | ICD-9-CM  | Diagnosis     |



**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code                                    | Description   | Code Type | Code Category |
|---|---|-----------|---------------|
| 296.65                                  | Bipolar I disorder, most recent episode (or current) mixed, in partial or unspecified remission | ICD-9-CM  | Diagnosis     |
| 296.66                                  | Bipolar I disorder, most recent episode (or current) mixed, in full remission                   | ICD-9-CM  | Diagnosis     |
| 296.7                                   | Bipolar I disorder, most recent episode (or current) unspecified                                | ICD-9-CM  | Diagnosis     |
| 296.8                                   | Other and unspecified bipolar disorders   | ICD-9-CM  | Diagnosis     |
| 296.80                                  | Bipolar disorder, unspecified   | ICD-9-CM  | Diagnosis     |
| 296.81                                  | Atypical manic disorder   | ICD-9-CM  | Diagnosis     |
| 296.82                                  | Atypical depressive disorder  | ICD-9-CM  | Diagnosis     |
| 296.89                                  | Other and unspecified bipolar disorders   | ICD-9-CM  | Diagnosis     |
| 296.99                                  | Other specified episodic mood disorder  | ICD-9-CM  | Diagnosis     |
| <i>Childhood cerebral degenerations</i> |   |           |               |
| 330                                     | Cerebral degenerations usually manifest in childhood  | ICD-9-CM  | Diagnosis     |
| 330.0                                   | Leukodystrophy  | ICD-9-CM  | Diagnosis     |
| 330.1                                   | Cerebral lipidoses  | ICD-9-CM  | Diagnosis     |
| 330.2                                   | Cerebral degeneration in generalized lipidoses  | ICD-9-CM  | Diagnosis     |
| 330.3                                   | Cerebral degeneration of childhood in other diseases classified elsewhere                       | ICD-9-CM  | Diagnosis     |
| 330.8                                   | Other specified cerebral degenerations in childhood   | ICD-9-CM  | Diagnosis     |
| 330.9                                   | Unspecified cerebral degeneration in childhood  | ICD-9-CM  | Diagnosis     |
| <i>Conduct disorder</i>                 |   |           |               |
| 312                                     | Disturbance of conduct not elsewhere classified   | ICD-9-CM  | Diagnosis     |
| 312.0                                   | Undersocialized conduct disorder aggressive type  | ICD-9-CM  | Diagnosis     |
| 312.00                                  | Undersocialized conduct disorder aggressive type, unspecified                                   | ICD-9-CM  | Diagnosis     |
| 312.01                                  | Undersocialized conduct disorder aggressive type, mild  | ICD-9-CM  | Diagnosis     |
| 312.02                                  | Undersocialized conduct disorder aggressive type, moderate                                      | ICD-9-CM  | Diagnosis     |
| 312.03                                  | Undersocialized conduct disorder aggressive, severe   | ICD-9-CM  | Diagnosis     |
| 312.1                                   | Undersocialized conduct disorder unaggressive type  | ICD-9-CM  | Diagnosis     |
| 312.10                                  | Undersocialized conduct disorder unaggressive type, unspecified                                 | ICD-9-CM  | Diagnosis     |
| 312.11                                  | Undersocialized conduct disorder unaggressive type, mild  | ICD-9-CM  | Diagnosis     |
| 312.12                                  | Undersocialized conduct disorder unaggressive type, moderate                                    | ICD-9-CM  | Diagnosis     |
| 312.13                                  | Undersocialized conduct disorder unaggressive, severe   | ICD-9-CM  | Diagnosis     |
| 312.2                                   | Socialized conduct disorder   | ICD-9-CM  | Diagnosis     |
| 312.20                                  | Socialized conduct disorder, unspecified  | ICD-9-CM  | Diagnosis     |
| 312.21                                  | Socialized conduct disorder, mild   | ICD-9-CM  | Diagnosis     |
| 312.22                                  | Socialized conduct disorder, moderate   | ICD-9-CM  | Diagnosis     |
| 312.23                                  | Socialized conduct disorder, severe   | ICD-9-CM  | Diagnosis     |
| 312.3                                   | Disorders of impulse control not elsewhere classified   | ICD-9-CM  | Diagnosis     |
| 312.30                                  | Impulse control disorder, unspecified   | ICD-9-CM  | Diagnosis     |
| 312.31                                  | Pathological gambling   | ICD-9-CM  | Diagnosis     |
| 312.32                                  | Kleptomania   | ICD-9-CM  | Diagnosis     |
| 312.33                                  | Pyromania   | ICD-9-CM  | Diagnosis     |
| 312.34                                  | Intermittent explosive disorder   | ICD-9-CM  | Diagnosis     |
| 312.35                                  | Isolated explosive disorder   | ICD-9-CM  | Diagnosis     |
| 312.39                                  | Other disorders of impulse control  | ICD-9-CM  | Diagnosis     |
| 312.4                                   | Mixed disturbance of conduct and emotions   | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code              | Description   | Code Type | Code Category |
|-------------------|---|-----------|---------------|
| 312.8             | Other specified disturbances of conduct not elsewhere classified                            | ICD-9-CM  | Diagnosis     |
| 312.81            | Conduct disorder, childhood onset type  | ICD-9-CM  | Diagnosis     |
| 312.82            | Conduct disorder, adolescent onset type   | ICD-9-CM  | Diagnosis     |
| 312.89            | Other conduct disorder  | ICD-9-CM  | Diagnosis     |
| 312.9             | Unspecified disturbance of conduct  | ICD-9-CM  | Diagnosis     |
| <b>Delirium</b>   |   |           |               |
| 291.0             | Alcohol withdrawal delirium   | ICD-9-CM  | Diagnosis     |
| 292.81            | Drug-induced delirium   | ICD-9-CM  | Diagnosis     |
| 293               | Transient mental disorders due to conditions classified elsewhere                           | ICD-9-CM  | Diagnosis     |
| 293.0             | Delirium due to conditions classified elsewhere   | ICD-9-CM  | Diagnosis     |
| 293.1             | Subacute delirium   | ICD-9-CM  | Diagnosis     |
| 293.8             | Other specified transient mental disorders due to conditions classified elsewhere           | ICD-9-CM  | Diagnosis     |
| 293.81            | Psychotic disorder with delusions in conditions classified elsewhere                        | ICD-9-CM  | Diagnosis     |
| 293.82            | Psychotic disorder with hallucinations in conditions classified elsewhere                   | ICD-9-CM  | Diagnosis     |
| 293.83            | Mood disorder in conditions classified elsewhere  | ICD-9-CM  | Diagnosis     |
| 293.84            | Anxiety disorder in conditions classified elsewhere   | ICD-9-CM  | Diagnosis     |
| 293.89            | Other specified transient mental disorders due to conditions classified elsewhere           | ICD-9-CM  | Diagnosis     |
| 293.9             | Unspecified transient mental disorder in conditions classified elsewhere                    | ICD-9-CM  | Diagnosis     |
| 348.3             | Encephalopathy, not elsewhere classified  | ICD-9-CM  | Diagnosis     |
| 348.30            | Encephalopathy, unspecified   | ICD-9-CM  | Diagnosis     |
| 348.31            | Metabolic encephalopathy  | ICD-9-CM  | Diagnosis     |
| 348.39            | Other encephalopathy  | ICD-9-CM  | Diagnosis     |
| <b>Depression</b> |   |           |               |
| 311               | Depressive disorder, not elsewhere classified   | ICD-9-CM  | Diagnosis     |
| 296.2             | Major depressive disorder, single episode   | ICD-9-CM  | Diagnosis     |
| 296.20            | Major depressive disorder, single episode, unspecified                                      | ICD-9-CM  | Diagnosis     |
| 296.21            | Major depressive disorder, single episode, mild   | ICD-9-CM  | Diagnosis     |
| 296.22            | Major depressive disorder, single episode, moderate   | ICD-9-CM  | Diagnosis     |
| 296.23            | Major depressive disorder, single episode, severe, without mention of psychotic behavior    | ICD-9-CM  | Diagnosis     |
| 296.24            | Major depressive disorder, single episode, severe, specified as with psychotic behavior     | ICD-9-CM  | Diagnosis     |
| 296.25            | Major depressive disorder, single episode, in partial or unspecified remission              | ICD-9-CM  | Diagnosis     |
| 296.26            | Major depressive disorder, single episode in full remission                                 | ICD-9-CM  | Diagnosis     |
| 296.3             | Major depressive disorder, recurrent episode  | ICD-9-CM  | Diagnosis     |
| 296.30            | Major depressive disorder, recurrent episode, unspecified                                   | ICD-9-CM  | Diagnosis     |
| 296.31            | Major depressive disorder, recurrent episode, mild  | ICD-9-CM  | Diagnosis     |
| 296.32            | Major depressive disorder, recurrent episode, moderate                                      | ICD-9-CM  | Diagnosis     |
| 296.33            | Major depressive disorder, recurrent episode, severe, without mention of psychotic behavior | ICD-9-CM  | Diagnosis     |
| 296.34            | Major depressive disorder, recurrent episode, severe, specified as with psychotic behavior  | ICD-9-CM  | Diagnosis     |
| 296.35            | Major depressive disorder, recurrent episode, in partial or unspecified remission           | ICD-9-CM  | Diagnosis     |
| 296.36            | Major depressive disorder, recurrent episode, in full remission                             | ICD-9-CM  | Diagnosis     |
| 296.90            | Unspecified episodic mood disorder  | ICD-9-CM  | Diagnosis     |



**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code                                 | Description   | Code Type | Code Category |
|--------------------------------------|---|-----------|---------------|
| 300.4                                | Dysthymic disorder  | ICD-9-CM  | Diagnosis     |
| 309.0                                | Adjustment disorder with depressed mood   | ICD-9-CM  | Diagnosis     |
| 309.1                                | Prolonged depressive reaction as adjustment reaction                                  | ICD-9-CM  | Diagnosis     |
| <i>Electroconvulsive therapy</i>     |   |           |               |
| 90870                                | Electroconvulsive therapy (includes necessary monitoring)                             | CPT-4     | Procedure     |
| 90871                                | Electroconvulsive therapy (includes necessary monitoring); multiple seizures, per day | CPT-4     | Procedure     |
| <i>Hallucination</i>                 |   |           |               |
| 780.1                                | Hallucinations  | ICD-9-CM  | Diagnosis     |
| <i>Obsessive-compulsive disorder</i> |   |           |               |
| 300.3                                | Obsessive-compulsive disorders  | ICD-9-CM  | Diagnosis     |
| <i>Other cerebral degenerations</i>  |   |           |               |
| 331                                  | Other cerebral degenerations  | ICD-9-CM  | Diagnosis     |
| 331.0                                | Alzheimer's disease   | ICD-9-CM  | Diagnosis     |
| 331.1                                | Frontotemporal dementia   | ICD-9-CM  | Diagnosis     |
| 331.11                               | Pick's disease  | ICD-9-CM  | Diagnosis     |
| 331.19                               | Other frontotemporal dementia   | ICD-9-CM  | Diagnosis     |
| 331.2                                | Senile degeneration of brain  | ICD-9-CM  | Diagnosis     |
| 331.3                                | Communicating hydrocephalus   | ICD-9-CM  | Diagnosis     |
| 331.4                                | Obstructive hydrocephalus   | ICD-9-CM  | Diagnosis     |
| 331.5                                | Idiopathic normal pressure hydrocephalus (INPH)                                       | ICD-9-CM  | Diagnosis     |
| 331.6                                | Corticobasal degeneration   | ICD-9-CM  | Diagnosis     |
| 331.7                                | Cerebral degeneration in diseases classified elsewhere                                | ICD-9-CM  | Diagnosis     |
| 331.8                                | Other cerebral degeneration   | ICD-9-CM  | Diagnosis     |
| 331.81                               | Reye's syndrome   | ICD-9-CM  | Diagnosis     |
| 331.82                               | Dementia with lewy bodies   | ICD-9-CM  | Diagnosis     |
| 331.83                               | Mild cognitive impairment, so stated  | ICD-9-CM  | Diagnosis     |
| 331.89                               | Other cerebral degeneration   | ICD-9-CM  | Diagnosis     |
| 331.9                                | Cerebral degeneration, unspecified  | ICD-9-CM  | Diagnosis     |
| <i>Other mental disorders</i>        |   |           |               |
| 300.1                                | Dissociative, conversion and factitious disorders                                     | ICD-9-CM  | Diagnosis     |
| 300.10                               | Hysteria unspecified  | ICD-9-CM  | Diagnosis     |
| 300.11                               | conversion disorder   | ICD-9-CM  | Diagnosis     |
| 300.12                               | Dissociative amnesia  | ICD-9-CM  | Diagnosis     |
| 300.13                               | Dissociative fugue  | ICD-9-CM  | Diagnosis     |
| 300.14                               | Dissociative identity disorder  | ICD-9-CM  | Diagnosis     |
| 300.15                               | Dissociative disorder or reaction, unspecified  | ICD-9-CM  | Diagnosis     |
| 300.16                               | Factitious disorder with predominantly psychological signs and symptoms               | ICD-9-CM  | Diagnosis     |
| 300.19                               | Other and unspecified factitious illness  | ICD-9-CM  | Diagnosis     |
| 300.5                                | Neurasthenia  | ICD-9-CM  | Diagnosis     |
| 300.6                                | Depersonalization disorder  | ICD-9-CM  | Diagnosis     |
| 300.7                                | Hypochondriasis   | ICD-9-CM  | Diagnosis     |
| 300.8                                | Somatoform disorders  | ICD-9-CM  | Diagnosis     |
| 300.81                               | Somatization disorder   | ICD-9-CM  | Diagnosis     |
| 300.82                               | Undifferentiated somatoform disorder  | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code   | Description   | Code Type | Code Category |
|--------|---|-----------|---------------|
| 300.89 | Other somatoform disorders  | ICD-9-CM  | Diagnosis     |
| 300.9  | Unspecified nonpsychotic mental disorder                                | ICD-9-CM  | Diagnosis     |
| 302    | Sexual and gender identity disorders                                    | ICD-9-CM  | Diagnosis     |
| 302.0  | Ego-dystonic sexual orientation   | ICD-9-CM  | Diagnosis     |
| 302.1  | Zoophilia   | ICD-9-CM  | Diagnosis     |
| 302.2  | Pedophilia  | ICD-9-CM  | Diagnosis     |
| 302.3  | Transvestic fetishism   | ICD-9-CM  | Diagnosis     |
| 302.4  | Exhibitionism   | ICD-9-CM  | Diagnosis     |
| 302.5  | Trans-sexualism   | ICD-9-CM  | Diagnosis     |
| 302.50 | Trans-sexualism with unspecified sexual history                         | ICD-9-CM  | Diagnosis     |
| 302.51 | Trans-sexualism with asexual history                                    | ICD-9-CM  | Diagnosis     |
| 302.52 | Trans-sexualism with homosexual history                                 | ICD-9-CM  | Diagnosis     |
| 302.53 | Trans-sexualism with heterosexual history                               | ICD-9-CM  | Diagnosis     |
| 302.6  | Gender identity disorder in children                                    | ICD-9-CM  | Diagnosis     |
| 302.7  | Psychosexual dysfunction  | ICD-9-CM  | Diagnosis     |
| 302.70 | Psychosexual dysfunction, unspecified                                   | ICD-9-CM  | Diagnosis     |
| 302.71 | Hypoactive sexual desire disorder                                       | ICD-9-CM  | Diagnosis     |
| 302.72 | Psychosexual dysfunction with inhibited sexual excitement               | ICD-9-CM  | Diagnosis     |
| 302.73 | Female orgasmic disorder  | ICD-9-CM  | Diagnosis     |
| 302.74 | Male orgasmic disorder  | ICD-9-CM  | Diagnosis     |
| 302.75 | Premature ejaculation   | ICD-9-CM  | Diagnosis     |
| 302.76 | Dyspareunia, psychogenic  | ICD-9-CM  | Diagnosis     |
| 302.79 | Psychosexual dysfunction with other specified psychosexual dysfunctions | ICD-9-CM  | Diagnosis     |
| 302.8  | Other specified psychosexual disorders                                  | ICD-9-CM  | Diagnosis     |
| 302.81 | Fetishism   | ICD-9-CM  | Diagnosis     |
| 302.82 | Voyeurism   | ICD-9-CM  | Diagnosis     |
| 302.83 | Sexual masochism  | ICD-9-CM  | Diagnosis     |
| 302.84 | Sexual sadism   | ICD-9-CM  | Diagnosis     |
| 302.85 | Gender identity disorder in adolescents or adults                       | ICD-9-CM  | Diagnosis     |
| 302.89 | Other specified psychosexual disorders                                  | ICD-9-CM  | Diagnosis     |
| 302.9  | Unspecified psychosexual disorders                                      | ICD-9-CM  | Diagnosis     |
| 306    | Physiological malfunction arising from mental factors                   | ICD-9-CM  | Diagnosis     |
| 306.0  | Musculoskeletal malfunction arising from mental factors                 | ICD-9-CM  | Diagnosis     |
| 306.1  | Respiratory malfunction arising from mental factors                     | ICD-9-CM  | Diagnosis     |
| 306.2  | Cardiovascular malfunction arising from mental factors                  | ICD-9-CM  | Diagnosis     |
| 306.3  | Skin disorder arising from mental factors                               | ICD-9-CM  | Diagnosis     |
| 306.4  | Gastrointestinal malfunction arising from mental factors                | ICD-9-CM  | Diagnosis     |
| 306.5  | Genitourinary malfunction arising from mental factors                   | ICD-9-CM  | Diagnosis     |
| 306.50 | Psychogenic genitourinary malfunction, unspecified                      | ICD-9-CM  | Diagnosis     |
| 306.51 | psychogenic vaginismus  | ICD-9-CM  | Diagnosis     |
| 306.52 | psychogenic dysmenorrhea  | ICD-9-CM  | Diagnosis     |
| 306.53 | psychogenic dysuria   | ICD-9-CM  | Diagnosis     |
| 306.59 | Other genitourinary malfunction arising from mental factors             | ICD-9-CM  | Diagnosis     |
| 306.6  | Endocrine disorder arising from mental factors                          | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code   | Description   | Code Type | Code Category |
|--------|---|-----------|---------------|
| 306.7  | Disorder of organs of special sense arising from mental factors               | ICD-9-CM  | Diagnosis     |
| 306.8  | Other specified psychophysiological malfunction                               | ICD-9-CM  | Diagnosis     |
| 306.9  | Unspecified psychophysiological malfunction                                   | ICD-9-CM  | Diagnosis     |
| 307    | Special symptoms or syndromes not elsewhere classified                        | ICD-9-CM  | Diagnosis     |
| 307.0  | Adult onset fluency disorder  | ICD-9-CM  | Diagnosis     |
| 307.1  | Anorexia nervosa  | ICD-9-CM  | Diagnosis     |
| 307.2  | Tics  | ICD-9-CM  | Diagnosis     |
| 307.20 | Tic disorder, unspecified   | ICD-9-CM  | Diagnosis     |
| 307.21 | Transient tic disorder  | ICD-9-CM  | Diagnosis     |
| 307.22 | Chronic motor or vocal tic disorder   | ICD-9-CM  | Diagnosis     |
| 307.23 | Tourette's disorder   | ICD-9-CM  | Diagnosis     |
| 307.3  | Stereotypic movement disorder   | ICD-9-CM  | Diagnosis     |
| 307.5  | Other unspecified disorder of eating  | ICD-9-CM  | Diagnosis     |
| 307.50 | Eating disorder, unspecified  | ICD-9-CM  | Diagnosis     |
| 307.51 | Bulimia nervosa   | ICD-9-CM  | Diagnosis     |
| 307.52 | Pica  | ICD-9-CM  | Diagnosis     |
| 307.53 | Rumination disorder   | ICD-9-CM  | Diagnosis     |
| 307.54 | Psychogenic vomiting  | ICD-9-CM  | Diagnosis     |
| 307.59 | Other disorders of eating   | ICD-9-CM  | Diagnosis     |
| 307.6  | Enuresis  | ICD-9-CM  | Diagnosis     |
| 307.7  | Encopresis  | ICD-9-CM  | Diagnosis     |
| 307.8  | pain disorder related to psychological factors                                | ICD-9-CM  | Diagnosis     |
| 307.80 | psychogenic pain, site unspecified  | ICD-9-CM  | Diagnosis     |
| 307.81 | Tension headache  | ICD-9-CM  | Diagnosis     |
| 307.89 | Other pain disorders related to psychological factors                         | ICD-9-CM  | Diagnosis     |
| 307.9  | Other and unspecified special symptoms or syndromes, not elsewhere classified | ICD-9-CM  | Diagnosis     |
| 308    | Acute reaction to stress  | ICD-9-CM  | Diagnosis     |
| 308.0  | Predominant disturbance of emotions   | ICD-9-CM  | Diagnosis     |
| 308.1  | Predominant disturbance of consciousness                                      | ICD-9-CM  | Diagnosis     |
| 308.2  | Predominant psychomotor disturbance   | ICD-9-CM  | Diagnosis     |
| 308.3  | Other acute reactions to stress   | ICD-9-CM  | Diagnosis     |
| 308.4  | Mixed disorders as reaction to stress   | ICD-9-CM  | Diagnosis     |
| 308.9  | Unspecified acute reaction to stress  | ICD-9-CM  | Diagnosis     |
| 309.2  | Adjustment reaction with predominant disturbance of other emotions            | ICD-9-CM  | Diagnosis     |
| 309.21 | Separation anxiety disorder   | ICD-9-CM  | Diagnosis     |
| 309.22 | Emancipation disorder of adolescence and early adult life                     | ICD-9-CM  | Diagnosis     |
| 309.23 | Specific academic or work inhibition  | ICD-9-CM  | Diagnosis     |
| 309.24 | Adjustment disorder with anxiety  | ICD-9-CM  | Diagnosis     |
| 309.28 | Adjustment disorder with mixed anxiety and depressed mo                       | ICD-9-CM  | Diagnosis     |
| 309.29 | Other adjustment reactions with predominant disturbance of other emotions     | ICD-9-CM  | Diagnosis     |
| 309.3  | Adjustment disorder with disturbance of conduct                               | ICD-9-CM  | Diagnosis     |
| 309.4  | Adjustment disorder with mixed disturbance of emotions and conduct            | ICD-9-CM  | Diagnosis     |
| 309.8  | Other specified adjustment reactions  | ICD-9-CM  | Diagnosis     |
| 309.82 | Adjustment reaction with physical symptoms                                    | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code   | Description  | Code Type | Code Category |
|--------|--|-----------|---------------|
| 309.83 | Adjustment reaction with withdrawal  | ICD-9-CM  | Diagnosis     |
| 309.89 | Other specified adjustment reactions   | ICD-9-CM  | Diagnosis     |
| 309.9  | Unspecified adjustment reaction  | ICD-9-CM  | Diagnosis     |
| 310    | Specific nonpsychotic mental disorders due to brain damage                               | ICD-9-CM  | Diagnosis     |
| 310.0  | Frontal lobe syndrome  | ICD-9-CM  | Diagnosis     |
| 310.1  | Personality change due to conditions classified elsewhere                                | ICD-9-CM  | Diagnosis     |
| 310.2  | Postconcussion syndrome  | ICD-9-CM  | Diagnosis     |
| 310.8  | Other specified nonpsychotic mental disorders following organic brain damage             | ICD-9-CM  | Diagnosis     |
| 310.81 | Pseudobulbar affect  | ICD-9-CM  | Diagnosis     |
| 310.89 | Other specified nonpsychotic mental disorders following organic brain damage             | ICD-9-CM  | Diagnosis     |
| 310.9  | Unspecified nonpsychotic mental disorder following organic brain damage                  | ICD-9-CM  | Diagnosis     |
| 313    | Disturbance of emotions specific to childhood and adolescence                            | ICD-9-CM  | Diagnosis     |
| 313.0  | Overanxious disorder specific to childhood and adolescence                               | ICD-9-CM  | Diagnosis     |
| 313.1  | Misery and unhappiness disorder specific to childhood and adolescence                    | ICD-9-CM  | Diagnosis     |
| 313.2  | Sensitivity shyness and social withdrawal disorder specific to childhood and adolescence | ICD-9-CM  | Diagnosis     |
| 313.21 | Shyness disorder of childhood  | ICD-9-CM  | Diagnosis     |
| 313.22 | Introverted disorder of childhood  | ICD-9-CM  | Diagnosis     |
| 313.23 | Selective mutism   | ICD-9-CM  | Diagnosis     |
| 313.3  | Relationship problems specific to childhood and adolescence                              | ICD-9-CM  | Diagnosis     |
| 313.8  | Other or mixed emotional disturbances of childhood or adolescence                        | ICD-9-CM  | Diagnosis     |
| 313.81 | Oppositional defiant disorder  | ICD-9-CM  | Diagnosis     |
| 313.82 | Identity disorder of childhood or adolescence  | ICD-9-CM  | Diagnosis     |
| 313.83 | Academic underachievement disorder of childhood or adolescence                           | ICD-9-CM  | Diagnosis     |
| 313.89 | Other emotional disturbances of childhood or adolescence                                 | ICD-9-CM  | Diagnosis     |
| 313.9  | Unspecified emotional disturbance of childhood or adolescence                            | ICD-9-CM  | Diagnosis     |
| 315    | Specific delays in development   | ICD-9-CM  | Diagnosis     |
| 315.0  | Developmental reading disorder   | ICD-9-CM  | Diagnosis     |
| 315.00 | Developmental reading disorder, unspecified  | ICD-9-CM  | Diagnosis     |
| 315.01 | Alexia   | ICD-9-CM  | Diagnosis     |
| 315.02 | Developmental dyslexia   | ICD-9-CM  | Diagnosis     |
| 315.09 | Other specific developmental reading disorder  | ICD-9-CM  | Diagnosis     |
| 315.1  | Mathematics disorder   | ICD-9-CM  | Diagnosis     |
| 315.2  | Other specific developmental learning difficulties                                       | ICD-9-CM  | Diagnosis     |
| 315.3  | Developmental speech or language disorder  | ICD-9-CM  | Diagnosis     |
| 315.31 | Expressive language disorder   | ICD-9-CM  | Diagnosis     |
| 315.32 | Mixed receptive-expressive language disorder   | ICD-9-CM  | Diagnosis     |
| 315.34 | Speech and language developmental delay due to hearing loss                              | ICD-9-CM  | Diagnosis     |
| 315.35 | Childhood onset fluency disorder   | ICD-9-CM  | Diagnosis     |
| 315.39 | Other developmental speech or language disorder  | ICD-9-CM  | Diagnosis     |
| 315.4  | Developmental coordination disorder  | ICD-9-CM  | Diagnosis     |
| 315.5  | Mixed development disorder   | ICD-9-CM  | Diagnosis     |
| 315.8  | Other specified delays in development  | ICD-9-CM  | Diagnosis     |
| 315.9  | Unspecified delay in development   | ICD-9-CM  | Diagnosis     |
| 316    | Psychic factors associated with diseases classified elsewhere                            | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code  | Description  | Code Type | Code Category |
|---|--|-----------|---------------|
| <i>Persistent mental disorders due to conditions classified elsewhere</i> |  |           |               |
| 294   | Persistent mental disorders due to conditions classified elsewhere             | ICD-9-CM  | Diagnosis     |
| 294.0   | Amnestic disorder in conditions classified elsewhere                           | ICD-9-CM  | Diagnosis     |
| 294.1   | Dementia in conditions classified elsewhere                                    | ICD-9-CM  | Diagnosis     |
| 294.10  | Dementia in conditions classified elsewhere without behavioral disturbance     | ICD-9-CM  | Diagnosis     |
| 294.11  | Dementia in conditions classified elsewhere with behavioral disturbance        | ICD-9-CM  | Diagnosis     |
| 294.2   | Dementia, unspecified  | ICD-9-CM  | Diagnosis     |
| 294.20  | Dementia, unspecified, without behavioral disturbance                          | ICD-9-CM  | Diagnosis     |
| 294.21  | Dementia, unspecified, with behavioral disturbance                             | ICD-9-CM  | Diagnosis     |
| 294.8   | Other persistent mental disorders due to conditions classified elsewhere       | ICD-9-CM  | Diagnosis     |
| 294.9   | Unspecified persistent mental disorders due to conditions classified elsewhere | ICD-9-CM  | Diagnosis     |
| <i>Personality disorders</i>  |  |           |               |
| 301   | Personality disorders  | ICD-9-CM  | Diagnosis     |
| 301.0   | Paranoid personality disorder  | ICD-9-CM  | Diagnosis     |
| 301.1   | Affective personality disorder   | ICD-9-CM  | Diagnosis     |
| 301.10  | Affective personality disorder, unspecified                                    | ICD-9-CM  | Diagnosis     |
| 301.11  | Chronic hypomanic personality disorder   | ICD-9-CM  | Diagnosis     |
| 301.12  | Chronic depressive personality disorder  | ICD-9-CM  | Diagnosis     |
| 301.13  | Cyclothymic disorder   | ICD-9-CM  | Diagnosis     |
| 301.2   | Schizoid personality disorder  | ICD-9-CM  | Diagnosis     |
| 301.20  | Schizoid personality disorder, unspecified                                     | ICD-9-CM  | Diagnosis     |
| 301.21  | Introverted personality  | ICD-9-CM  | Diagnosis     |
| 301.22  | Schizotypal personality disorder   | ICD-9-CM  | Diagnosis     |
| 301.3   | Explosive personality disorder   | ICD-9-CM  | Diagnosis     |
| 301.4   | Obsessive-compulsive personality disorder                                      | ICD-9-CM  | Diagnosis     |
| 301.5   | Histrionic personality disorder  | ICD-9-CM  | Diagnosis     |
| 301.50  | Histrionic personality disorder, unspecified                                   | ICD-9-CM  | Diagnosis     |
| 301.51  | Chronic factitious illness with physical symptoms                              | ICD-9-CM  | Diagnosis     |
| 301.59  | Other histrionic personality disorder  | ICD-9-CM  | Diagnosis     |
| 301.6   | Dependent personality disorder   | ICD-9-CM  | Diagnosis     |
| 301.7   | Antisocial personality disorder  | ICD-9-CM  | Diagnosis     |
| 301.8   | Other personality disorders  | ICD-9-CM  | Diagnosis     |
| 301.81  | Narcissistic personality disorder  | ICD-9-CM  | Diagnosis     |
| 301.82  | Avoidant personality disorder  | ICD-9-CM  | Diagnosis     |
| 301.83  | Borderline personality disorder  | ICD-9-CM  | Diagnosis     |
| 301.84  | Passive-aggressive personality   | ICD-9-CM  | Diagnosis     |
| 301.89  | Other personality disorders  | ICD-9-CM  | Diagnosis     |
| 301.9   | Unspecified personality disorder   | ICD-9-CM  | Diagnosis     |
| <i>Pervasive developmental disorders</i>                                  |  |           |               |
| 299   | Pervasive developmental disorders  | ICD-9-CM  | Diagnosis     |
| 299.0   | Autistic disorder  | ICD-9-CM  | Diagnosis     |
| 299.00  | Autistic disorder, current or active state                                     | ICD-9-CM  | Diagnosis     |
| 299.01  | Autistic disorder, residual state  | ICD-9-CM  | Diagnosis     |
| 299.1   | Childhood disintegrative disorder  | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code                                  | Description  | Code Type | Code Category |
|---------------------------------------|--|-----------|---------------|
| 299.10                                | Childhood disintegrative disorder, current or active state                 | ICD-9-CM  | Diagnosis     |
| 299.11                                | Childhood disintegrative disorder, residual state                          | ICD-9-CM  | Diagnosis     |
| 299.8                                 | Other specified pervasive developmental disorders                          | ICD-9-CM  | Diagnosis     |
| 299.80                                | Other specified pervasive developmental disorders, current or active state | ICD-9-CM  | Diagnosis     |
| 299.81                                | Other specified pervasive developmental disorders, residual state          | ICD-9-CM  | Diagnosis     |
| 299.9                                 | Unspecified pervasive developmental disorder                               | ICD-9-CM  | Diagnosis     |
| 299.90                                | Unspecified pervasive developmental disorder, current or active state      | ICD-9-CM  | Diagnosis     |
| 299.91                                | Unspecified pervasive developmental disorder, residual state               | ICD-9-CM  | Diagnosis     |
| <i>Post-traumatic stress disorder</i> |  |           |               |
| 309.81                                | Posttraumatic stress disorder  | ICD-9-CM  | Diagnosis     |
| <i>Psychotic conditions</i>           |  |           |               |
| 290.8                                 | Other specified senile psychotic conditions                                | ICD-9-CM  | Diagnosis     |
| 290.9                                 | Unspecified senile psychotic condition                                     | ICD-9-CM  | Diagnosis     |
| 297                                   | Delusional disorders   | ICD-9-CM  | Diagnosis     |
| 297.0                                 | Paranoid state, simple   | ICD-9-CM  | Diagnosis     |
| 297.1                                 | Delusional disorders   | ICD-9-CM  | Diagnosis     |
| 297.2                                 | Paraphrenia  | ICD-9-CM  | Diagnosis     |
| 297.3                                 | Shared psychotic disorder  | ICD-9-CM  | Diagnosis     |
| 297.8                                 | Other specified paranoid states  | ICD-9-CM  | Diagnosis     |
| 297.9                                 | unspecified paranoid state   | ICD-9-CM  | Diagnosis     |
| 298                                   | Other nonorganic psychosis   | ICD-9-CM  | Diagnosis     |
| 298.0                                 | Depressive type psychosis  | ICD-9-CM  | Diagnosis     |
| 298.1                                 | Excitatory type psychosis  | ICD-9-CM  | Diagnosis     |
| 298.2                                 | Reactive confusion   | ICD-9-CM  | Diagnosis     |
| 298.3                                 | Acute paranoid reaction  | ICD-9-CM  | Diagnosis     |
| 298.4                                 | Psychogenic paranoid psychosis   | ICD-9-CM  | Diagnosis     |
| 298.8                                 | Other and unspecified reactive psychosis                                   | ICD-9-CM  | Diagnosis     |
| 298.9                                 | Unspecified psychosis  | ICD-9-CM  | Diagnosis     |
| <i>Schizophrenia</i>                  |  |           |               |
| 295                                   | Schizophrenic disorders  | ICD-9-CM  | Diagnosis     |
| 295.0                                 | Simple type schizophrenia  | ICD-9-CM  | Diagnosis     |
| 295.00                                | Simple schizophrenia, unspecified condition                                | ICD-9-CM  | Diagnosis     |
| 295.01                                | Simple schizophrenia, subchronic condition                                 | ICD-9-CM  | Diagnosis     |
| 295.02                                | Simple schizophrenia, chronic condition                                    | ICD-9-CM  | Diagnosis     |
| 295.03                                | Simple schizophrenia, subchronic condition with acute exacerbation         | ICD-9-CM  | Diagnosis     |
| 295.04                                | Simple schizophrenia, chronic condition with acute exacerbation            | ICD-9-CM  | Diagnosis     |
| 295.05                                | Simple schizophrenia, in remission   | ICD-9-CM  | Diagnosis     |
| 295.1                                 | Disorganized type schizophrenia  | ICD-9-CM  | Diagnosis     |
| 295.10                                | Disorganized schizophrenia, unspecified condition                          | ICD-9-CM  | Diagnosis     |
| 295.11                                | Disorganized schizophrenia, subchronic condition                           | ICD-9-CM  | Diagnosis     |
| 295.12                                | Disorganized schizophrenia, chronic condition                              | ICD-9-CM  | Diagnosis     |
| 295.13                                | Disorganized schizophrenia, subchronic condition with acute exacerbation   | ICD-9-CM  | Diagnosis     |
| 295.14                                | Disorganized schizophrenia, chronic condition with acute exacerbation      | ICD-9-CM  | Diagnosis     |
| 295.15                                | Disorganized schizophrenia, in remission                                   | ICD-9-CM  | Diagnosis     |



**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code   | Description  | Code Type | Code Category |
|--------|--|-----------|---------------|
| 295.2  | Catatonic type schizophrenia   | ICD-9-CM  | Diagnosis     |
| 295.20 | Catatonic schizophrenia, unspecified condition                             | ICD-9-CM  | Diagnosis     |
| 295.21 | Catatonic schizophrenia, subchronic condition                              | ICD-9-CM  | Diagnosis     |
| 295.22 | Catatonic schizophrenia, chronic condition                                 | ICD-9-CM  | Diagnosis     |
| 295.23 | Catatonic schizophrenia, subchronic condition with acute exacerbation      | ICD-9-CM  | Diagnosis     |
| 295.24 | Catatonic schizophrenia, chronic condition with acute exacerbation         | ICD-9-CM  | Diagnosis     |
| 295.25 | Catatonic schizophrenia, in remission                                      | ICD-9-CM  | Diagnosis     |
| 295.3  | Paranoid type schizophrenia  | ICD-9-CM  | Diagnosis     |
| 295.30 | Paranoid schizophrenia, unspecified condition                              | ICD-9-CM  | Diagnosis     |
| 295.31 | Paranoid schizophrenia, subchronic condition                               | ICD-9-CM  | Diagnosis     |
| 295.32 | Paranoid schizophrenia, chronic condition                                  | ICD-9-CM  | Diagnosis     |
| 295.33 | Paranoid schizophrenia, subchronic condition with acute exacerbation       | ICD-9-CM  | Diagnosis     |
| 295.34 | Paranoid schizophrenia, chronic condition with acute exacerbation          | ICD-9-CM  | Diagnosis     |
| 295.35 | Paranoid schizophrenia, in remission                                       | ICD-9-CM  | Diagnosis     |
| 295.4  | Schizophreniform disorder  | ICD-9-CM  | Diagnosis     |
| 295.40 | Schizophreniform disorder, unspecified                                     | ICD-9-CM  | Diagnosis     |
| 295.41 | Schizophreniform disorder, subchronic                                      | ICD-9-CM  | Diagnosis     |
| 295.42 | Schizophreniform disorder, chronic   | ICD-9-CM  | Diagnosis     |
| 295.43 | Schizophreniform disorder, subchronic with acute exacerbation              | ICD-9-CM  | Diagnosis     |
| 295.44 | Schizophreniform disorder, chronic with acute exacerbation                 | ICD-9-CM  | Diagnosis     |
| 295.45 | Schizophreniform disorder, in remission                                    | ICD-9-CM  | Diagnosis     |
| 295.5  | Latent schizophrenia   | ICD-9-CM  | Diagnosis     |
| 295.50 | Latent schizophrenia, unspecified condition                                | ICD-9-CM  | Diagnosis     |
| 295.51 | Latent schizophrenia, subchronic condition                                 | ICD-9-CM  | Diagnosis     |
| 295.52 | Latent schizophrenia, chronic condition                                    | ICD-9-CM  | Diagnosis     |
| 295.53 | Latent schizophrenia, subchronic condition with acute exacerbation         | ICD-9-CM  | Diagnosis     |
| 295.54 | Latent schizophrenia, chronic condition with acute exacerbation            | ICD-9-CM  | Diagnosis     |
| 295.55 | Latent schizophrenia, in remission   | ICD-9-CM  | Diagnosis     |
| 295.6  | Schizophrenic disorders, residual type                                     | ICD-9-CM  | Diagnosis     |
| 295.60 | Schizophrenic disorders, residual type, unspecified                        | ICD-9-CM  | Diagnosis     |
| 295.61 | Schizophrenic disorders, residual type, subchronic                         | ICD-9-CM  | Diagnosis     |
| 295.62 | Schizophrenic disorders, residual type, chronic                            | ICD-9-CM  | Diagnosis     |
| 295.63 | Schizophrenic disorders, residual type, subchronic with acute exacerbation | ICD-9-CM  | Diagnosis     |
| 295.64 | Schizophrenic disorders, residual type, chronic with acute exacerbation    | ICD-9-CM  | Diagnosis     |
| 295.65 | Schizophrenic disorders, residual type, in remission                       | ICD-9-CM  | Diagnosis     |
| 295.7  | Schizoaffective disorder   | ICD-9-CM  | Diagnosis     |
| 295.70 | Schizoaffective disorder, unspecified                                      | ICD-9-CM  | Diagnosis     |
| 295.71 | Schizoaffective disorder, subchronic                                       | ICD-9-CM  | Diagnosis     |
| 295.72 | Schizoaffective disorder, chronic  | ICD-9-CM  | Diagnosis     |
| 295.73 | Schizoaffective disorder, subchronic with acute exacerbation               | ICD-9-CM  | Diagnosis     |
| 295.74 | Schizoaffective disorder, chronic with acute exacerbation                  | ICD-9-CM  | Diagnosis     |
| 295.75 | Schizoaffective disorder, in remission                                     | ICD-9-CM  | Diagnosis     |
| 295.8  | Other specified types of schizophrenia                                     | ICD-9-CM  | Diagnosis     |
| 295.80 | Other specified types of schizophrenia, unspecified condition              | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code                           | Description  | Code Type | Code Category |
|--------------------------------|--|-----------|---------------|
| 295.81                         | Other specified types of schizophrenia, subchronic condition                         | ICD-9-CM  | Diagnosis     |
| 295.82                         | Other specified types of schizophrenia, chronic condition                            | ICD-9-CM  | Diagnosis     |
| 295.83                         | Other specified types of schizophrenia, subchronic condition with acute exacerbation | ICD-9-CM  | Diagnosis     |
| 295.84                         | Other specified types of schizophrenia, chronic condition with acute exacerbation    | ICD-9-CM  | Diagnosis     |
| 295.85                         | Other specified types of schizophrenia, in remission                                 | ICD-9-CM  | Diagnosis     |
| 295.9                          | Unspecified schizophrenia  | ICD-9-CM  | Diagnosis     |
| 295.90                         | Unspecified schizophrenia, unspecified condition                                     | ICD-9-CM  | Diagnosis     |
| 295.91                         | Unspecified schizophrenia, subchronic condition                                      | ICD-9-CM  | Diagnosis     |
| 295.92                         | Unspecified schizophrenia, chronic condition   | ICD-9-CM  | Diagnosis     |
| 295.93                         | Unspecified schizophrenia, subchronic condition with acute exacerbation              | ICD-9-CM  | Diagnosis     |
| 295.94                         | Unspecified schizophrenia, chronic condition with acute exacerbation                 | ICD-9-CM  | Diagnosis     |
| 295.95                         | Unspecified schizophrenia, in remission  | ICD-9-CM  | Diagnosis     |
| <i>Sleep disorder</i>          |  |           |               |
| 307.4                          | Specific disorders of sleep of nonorganic origin                                     | ICD-9-CM  | Diagnosis     |
| 307.40                         | Nonorganic sleep disorder, unspecified   | ICD-9-CM  | Diagnosis     |
| 307.41                         | Transient disorder of initiating or maintaining sleep                                | ICD-9-CM  | Diagnosis     |
| 307.42                         | Persistent disorder of initiating or maintaining sleep                               | ICD-9-CM  | Diagnosis     |
| 307.43                         | Transient disorder of initiating or maintaining wakefulness                          | ICD-9-CM  | Diagnosis     |
| 307.44                         | Persistent disorder of initiating or maintaining wakefulness                         | ICD-9-CM  | Diagnosis     |
| 307.45                         | Circadian rhythm sleep disorder of nonorganic origin                                 | ICD-9-CM  | Diagnosis     |
| 307.46                         | Sleep arousal disorder   | ICD-9-CM  | Diagnosis     |
| 307.47                         | Other dysfunctions of sleep stages or arousal from sleep                             | ICD-9-CM  | Diagnosis     |
| 307.48                         | Repetitive intrusions of sleep   | ICD-9-CM  | Diagnosis     |
| 307.49                         | Other specific disorders of sleep of nonorganic origin                               | ICD-9-CM  | Diagnosis     |
| 347                            | Cataplexy and narcolepsy   | ICD-9-CM  | Diagnosis     |
| 347.0                          | Narcolepsy   | ICD-9-CM  | Diagnosis     |
| 347.00                         | Narcolepsy, without cataplexy  | ICD-9-CM  | Diagnosis     |
| 347.01                         | Narcolepsy, with cataplexy   | ICD-9-CM  | Diagnosis     |
| 347.1                          | Narcolepsy in conditions classified elsewhere  | ICD-9-CM  | Diagnosis     |
| 347.10                         | Narcolepsy in conditions classified elsewhere, without cataplexy                     | ICD-9-CM  | Diagnosis     |
| 347.11                         | Narcolepsy in conditions classified elsewhere, with cataplexy                        | ICD-9-CM  | Diagnosis     |
| 780.5                          | Sleep disturbances   | ICD-9-CM  | Diagnosis     |
| 780.50                         | Sleep disturbances, unspecified  | ICD-9-CM  | Diagnosis     |
| 780.51                         | Insomnia with sleep apnea, unspecified   | ICD-9-CM  | Diagnosis     |
| 780.52                         | Insomnia, unspecified  | ICD-9-CM  | Diagnosis     |
| 780.53                         | Hypersomnia, with sleep apnea, unspecified   | ICD-9-CM  | Diagnosis     |
| 780.54                         | Hypersomnia, unspecified   | ICD-9-CM  | Diagnosis     |
| 780.55                         | Disruption of 24 hour sleep wake cycle, unspecified                                  | ICD-9-CM  | Diagnosis     |
| 780.56                         | Dysfunctions associated with sleep stages or arousal from sleep                      | ICD-9-CM  | Diagnosis     |
| 780.57                         | Unspecified sleep apnea  | ICD-9-CM  | Diagnosis     |
| 780.58                         | Sleep related movement disorder, unspecified   | ICD-9-CM  | Diagnosis     |
| 780.59                         | Other sleep disturbances   | ICD-9-CM  | Diagnosis     |
| <i>Social anxiety disorder</i> |  |           |               |
| 300.23                         | Social phobia  | ICD-9-CM  | Diagnosis     |



**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code                             | Description   | Code Type | Code Category |
|----------------------------------|---|-----------|---------------|
| <i>Substance abuse disorders</i> |   |           |               |
| 291                              | Alcohol withdrawal delirium                               | ICD-9-CM  | Diagnosis     |
| 291.1                            | Alcohol-induced persisting amnestic disorder              | ICD-9-CM  | Diagnosis     |
| 291.2                            | Alcohol-induced persisting dementia                       | ICD-9-CM  | Diagnosis     |
| 291.3                            | Alcohol-induced psychotic disorder with hallucinations    | ICD-9-CM  | Diagnosis     |
| 291.4                            | Idiosyncratic alcohol intoxication                        | ICD-9-CM  | Diagnosis     |
| 291.5                            | Alcohol-induced psychotic disorder with delusions         | ICD-9-CM  | Diagnosis     |
| 291.8                            | Other specified alcohol-induced mental disorders          | ICD-9-CM  | Diagnosis     |
| 291.81                           | Alcohol withdrawal  | ICD-9-CM  | Diagnosis     |
| 291.82                           | Alcohol induced sleep disorders                           | ICD-9-CM  | Diagnosis     |
| 291.89                           | Other specified alcohol-induced mental disorders          | ICD-9-CM  | Diagnosis     |
| 291.9                            | Unspecified alcohol-induced mental disorders              | ICD-9-CM  | Diagnosis     |
| 292.0                            | Drug withdrawal   | ICD-9-CM  | Diagnosis     |
| 292.1                            | Drug-induced psychotic disorder                           | ICD-9-CM  | Diagnosis     |
| 292.11                           | Drug-induced psychotic disorder with delusions            | ICD-9-CM  | Diagnosis     |
| 292.12                           | Drug-induced psychotic disorder with hallucinations       | ICD-9-CM  | Diagnosis     |
| 292.2                            | Pathological drug intoxication                            | ICD-9-CM  | Diagnosis     |
| 292.8                            | Other specified drug-induced mental disorders             | ICD-9-CM  | Diagnosis     |
| 292.89                           | Other specified drug-induced mental disorder              | ICD-9-CM  | Diagnosis     |
| 292.9                            | Unspecified drug-induced mental disorder                  | ICD-9-CM  | Diagnosis     |
| 303.0                            | Acute alcoholic intoxication                              | ICD-9-CM  | Diagnosis     |
| 303.00                           | Acute alcoholic intoxication, unspecified                 | ICD-9-CM  | Diagnosis     |
| 303.01                           | Acute alcoholic intoxication, continuous                  | ICD-9-CM  | Diagnosis     |
| 303.02                           | Acute alcoholic intoxication, episodic                    | ICD-9-CM  | Diagnosis     |
| 303.03                           | Acute alcoholic intoxication, in remission                | ICD-9-CM  | Diagnosis     |
| 303.9                            | Other and unspecified alcohol dependence                  | ICD-9-CM  | Diagnosis     |
| 303.90                           | Other and unspecified alcohol dependence, unspecified     | ICD-9-CM  | Diagnosis     |
| 303.91                           | Other and unspecified alcohol dependence, continuous      | ICD-9-CM  | Diagnosis     |
| 303.92                           | Other and unspecified alcohol dependence, episodic        | ICD-9-CM  | Diagnosis     |
| 303.93                           | Other and unspecified alcohol dependence, in remission    | ICD-9-CM  | Diagnosis     |
| 304.0                            | Opioid type dependence                                    | ICD-9-CM  | Diagnosis     |
| 304.00                           | Opioid type dependence, unspecified                       | ICD-9-CM  | Diagnosis     |
| 304.01                           | Opioid type dependence, continuous                        | ICD-9-CM  | Diagnosis     |
| 304.02                           | Opioid type dependence, episodic                          | ICD-9-CM  | Diagnosis     |
| 304.03                           | Opioid type dependence, in remission                      | ICD-9-CM  | Diagnosis     |
| 304.1                            | Sedative, hypnotic or anxiolytic dependence               | ICD-9-CM  | Diagnosis     |
| 304.10                           | Sedative, hypnotic or anxiolytic dependence, unspecified  | ICD-9-CM  | Diagnosis     |
| 304.11                           | Sedative, hypnotic or anxiolytic dependence, continuous   | ICD-9-CM  | Diagnosis     |
| 304.12                           | Sedative, hypnotic or anxiolytic dependence, episodic     | ICD-9-CM  | Diagnosis     |
| 304.13                           | Sedative, hypnotic or anxiolytic dependence, in remission | ICD-9-CM  | Diagnosis     |
| 304.2                            | Cocaine dependence  | ICD-9-CM  | Diagnosis     |
| 304.20                           | Cocaine dependence, unspecified                           | ICD-9-CM  | Diagnosis     |
| 304.21                           | Cocaine dependence, continuous                            | ICD-9-CM  | Diagnosis     |
| 304.22                           | Cocaine dependence, episodic                              | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code   | Description   | Code Type | Code Category |
|--------|---|-----------|---------------|
| 304.23 | Cocaine dependence, in remission  | ICD-9-CM  | Diagnosis     |
| 304.3  | Cannabis dependence   | ICD-9-CM  | Diagnosis     |
| 304.30 | Cannabis dependence, unspecified  | ICD-9-CM  | Diagnosis     |
| 304.31 | Cannabis dependence, continuous   | ICD-9-CM  | Diagnosis     |
| 304.32 | Cannabis dependence, episodic   | ICD-9-CM  | Diagnosis     |
| 304.33 | Cannabis dependence, in remission   | ICD-9-CM  | Diagnosis     |
| 304.4  | Amphetamine and other psychostimulant dependence                              | ICD-9-CM  | Diagnosis     |
| 304.40 | Amphetamine and other psychostimulant dependence, unspecified                 | ICD-9-CM  | Diagnosis     |
| 304.41 | Amphetamine and other psychostimulant dependence, continuous                  | ICD-9-CM  | Diagnosis     |
| 304.42 | Amphetamine and other psychostimulant dependence, episodic                    | ICD-9-CM  | Diagnosis     |
| 304.43 | Amphetamine and other psychostimulant dependence, in remission                | ICD-9-CM  | Diagnosis     |
| 304.5  | Hallucinogen dependence   | ICD-9-CM  | Diagnosis     |
| 304.50 | Hallucinogen dependence, unspecified  | ICD-9-CM  | Diagnosis     |
| 304.51 | Hallucinogen dependence, continuous   | ICD-9-CM  | Diagnosis     |
| 304.52 | Hallucinogen dependence, episodic   | ICD-9-CM  | Diagnosis     |
| 304.53 | Hallucinogen dependence, in remission   | ICD-9-CM  | Diagnosis     |
| 304.6  | Other specified drug dependence   | ICD-9-CM  | Diagnosis     |
| 304.60 | Other specified drug dependence, unspecified                                  | ICD-9-CM  | Diagnosis     |
| 304.61 | Other specified drug dependence, continuous                                   | ICD-9-CM  | Diagnosis     |
| 304.62 | Other specified drug dependence, episodic                                     | ICD-9-CM  | Diagnosis     |
| 304.63 | Other specified drug dependence, in remission                                 | ICD-9-CM  | Diagnosis     |
| 304.7  | Combinations of opioid type drug with any other drug dependence               | ICD-9-CM  | Diagnosis     |
| 304.70 | Combinations of opioid type drug with any other drug dependence, unspecified  | ICD-9-CM  | Diagnosis     |
| 304.71 | Combinations of opioid type drug with any other drug dependence, continuous   | ICD-9-CM  | Diagnosis     |
| 304.72 | Combinations of opioid type drug with any other drug dependence, episodic     | ICD-9-CM  | Diagnosis     |
| 304.73 | Combinations of opioid type drug with any other drug dependence, in remission | ICD-9-CM  | Diagnosis     |
| 304.8  | Combinations of drug dependence excluding opioid type drug                    | ICD-9-CM  | Diagnosis     |
| 304.80 | Combinations of drug dependence excluding opioid type drug, unspecified       | ICD-9-CM  | Diagnosis     |
| 304.81 | Combinations of drug dependence excluding opioid type drug, continuous        | ICD-9-CM  | Diagnosis     |
| 304.82 | Combinations of drug dependence excluding opioid type drug, episodic          | ICD-9-CM  | Diagnosis     |
| 304.83 | Combinations of drug dependence excluding opioid type drug, in remission      | ICD-9-CM  | Diagnosis     |
| 304.9  | Unspecified drug dependence   | ICD-9-CM  | Diagnosis     |
| 304.90 | Unspecified drug dependence, unspecified                                      | ICD-9-CM  | Diagnosis     |
| 304.91 | Unspecified drug dependence, continuous                                       | ICD-9-CM  | Diagnosis     |
| 304.92 | Unspecified drug dependence, episodic   | ICD-9-CM  | Diagnosis     |
| 304.93 | Unspecified drug dependence, in remission                                     | ICD-9-CM  | Diagnosis     |
| 305.0  | Nondependent alcohol abuse  | ICD-9-CM  | Diagnosis     |
| 305.00 | Nondependent alcohol abuse, unspecified                                       | ICD-9-CM  | Diagnosis     |
| 305.01 | Nondependent alcohol abuse, continuous  | ICD-9-CM  | Diagnosis     |
| 305.02 | Nondependent alcohol abuse, episodic  | ICD-9-CM  | Diagnosis     |
| 305.03 | Nondependent alcohol abuse, in remission                                      | ICD-9-CM  | Diagnosis     |
| 305.2  | Nondependent cannabis abuse   | ICD-9-CM  | Diagnosis     |
| 305.20 | Nondependent cannabis abuse, unspecified                                      | ICD-9-CM  | Diagnosis     |
| 305.21 | Nondependent cannabis abuse, continuous                                       | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code                            | Description  | Code Type | Code Category |
|---------------------------------|--|-----------|---------------|
| 305.22                          | Nondependent cannabis abuse, episodic  | ICD-9-CM  | Diagnosis     |
| 305.23                          | Nondependent cannabis abuse, in remission                                      | ICD-9-CM  | Diagnosis     |
| 305.3                           | Nondependent hallucinogen abuse  | ICD-9-CM  | Diagnosis     |
| 305.30                          | Nondependent hallucinogen abuse, unspecified                                   | ICD-9-CM  | Diagnosis     |
| 305.31                          | Nondependent hallucinogen abuse, continuous                                    | ICD-9-CM  | Diagnosis     |
| 305.32                          | Nondependent hallucinogen abuse, episodic                                      | ICD-9-CM  | Diagnosis     |
| 305.33                          | Nondependent hallucinogen abuse, in remission                                  | ICD-9-CM  | Diagnosis     |
| 305.4                           | Nondependent sedative, hypnotic or anxiolytic abuse                            | ICD-9-CM  | Diagnosis     |
| 305.40                          | Nondependent sedative, hypnotic or anxiolytic abuse, unspecified               | ICD-9-CM  | Diagnosis     |
| 305.41                          | Nondependent sedative hypnotic or anxiolytic abuse, continuous                 | ICD-9-CM  | Diagnosis     |
| 305.42                          | Nondependent sedative, hypnotic or anxiolytic abuse, episodic                  | ICD-9-CM  | Diagnosis     |
| 305.43                          | Nondependent sedative, hypnotic or anxiolytic abuse, in remission              | ICD-9-CM  | Diagnosis     |
| 305.5                           | Nondependent opioid abuse  | ICD-9-CM  | Diagnosis     |
| 305.50                          | Nondependent opioid abuse, unspecified   | ICD-9-CM  | Diagnosis     |
| 305.51                          | Nondependent opioid abuse, continuous  | ICD-9-CM  | Diagnosis     |
| 305.52                          | Nondependent opioid abuse, episodic  | ICD-9-CM  | Diagnosis     |
| 305.53                          | Nondependent opioid abuse, in remission  | ICD-9-CM  | Diagnosis     |
| 305.6                           | Nondependent cocaine abuse   | ICD-9-CM  | Diagnosis     |
| 305.60                          | Nondependent cocaine abuse, unspecified  | ICD-9-CM  | Diagnosis     |
| 305.61                          | Nondependent cocaine abuse, continuous   | ICD-9-CM  | Diagnosis     |
| 305.62                          | Nondependent cocaine abuse, episodic   | ICD-9-CM  | Diagnosis     |
| 305.63                          | Nondependent cocaine abuse, in remission                                       | ICD-9-CM  | Diagnosis     |
| 305.7                           | Nondependent amphetamine or related acting sympathomimetic abuse               | ICD-9-CM  | Diagnosis     |
| 305.70                          | Nondependent amphetamine or related acting sympathomimetic abuse, unspecified  | ICD-9-CM  | Diagnosis     |
| 305.71                          | Nondependent amphetamine or related acting sympathomimetic abuse, continuous   | ICD-9-CM  | Diagnosis     |
| 305.72                          | Nondependent amphetamine or related acting sympathomimetic abuse, episodic     | ICD-9-CM  | Diagnosis     |
| 305.73                          | Nondependent amphetamine or related acting sympathomimetic abuse, in remission | ICD-9-CM  | Diagnosis     |
| 305.8                           | Nondependent antidepressant type abuse   | ICD-9-CM  | Diagnosis     |
| 305.80                          | Nondependent antidepressant type abuse, unspecified                            | ICD-9-CM  | Diagnosis     |
| 305.81                          | Nondependent antidepressant type abuse, continuous                             | ICD-9-CM  | Diagnosis     |
| 305.82                          | Nondependent antidepressant type abuse, episodic                               | ICD-9-CM  | Diagnosis     |
| 305.83                          | Nondependent antidepressant type abuse, in remission                           | ICD-9-CM  | Diagnosis     |
| 305.9                           | Other, mixed, or unspecified nondependent drug abuse                           | ICD-9-CM  | Diagnosis     |
| 305.90                          | Other, mixed, or unspecified nondependent drug abuse, unspecified              | ICD-9-CM  | Diagnosis     |
| 305.91                          | Other, mixed, or unspecified nondependent drug abuse, continuous               | ICD-9-CM  | Diagnosis     |
| 305.92                          | Other, mixed, or unspecified nondependent drug abuse, episodic                 | ICD-9-CM  | Diagnosis     |
| 305.93                          | Other, mixed, or unspecified nondependent drug abuse, in remission             | ICD-9-CM  | Diagnosis     |
| <b><i>Suicidal behavior</i></b> |  |           |               |
| 960                             | Poisoning by antibiotics   | ICD-9-CM  | Diagnosis     |
| 960.0                           | Poisoning by penicillins   | ICD-9-CM  | Diagnosis     |
| 960.1                           | Poisoning by antifungal antibiotics  | ICD-9-CM  | Diagnosis     |
| 960.2                           | Poisoning by chloramphenicol group   | ICD-9-CM  | Diagnosis     |
| 960.3                           | Poisoning by erythromycin and other macrolides                                 | ICD-9-CM  | Diagnosis     |
| 960.4                           | Poisoning by tetracycline group  | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code  | Description   | Code Type | Code Category |
|-------|---|-----------|---------------|
| 960.5 | Poisoning of cephalosporin group                                      | ICD-9-CM  | Diagnosis     |
| 960.6 | Poisoning of antimycobacterial antibiotics                            | ICD-9-CM  | Diagnosis     |
| 960.7 | Poisoning by antineoplastic antibiotics                               | ICD-9-CM  | Diagnosis     |
| 960.8 | Poisoning by other specified antibiotics                              | ICD-9-CM  | Diagnosis     |
| 960.9 | Poisoning by unspecified antibiotic                                   | ICD-9-CM  | Diagnosis     |
| 961   | Poisoning by other anti-infectives                                    | ICD-9-CM  | Diagnosis     |
| 961.0 | Poisoning by sulfonamides   | ICD-9-CM  | Diagnosis     |
| 961.1 | Poisoning by arsenical anti-infectives                                | ICD-9-CM  | Diagnosis     |
| 961.2 | Poisoning by heavy metal anti-infectives                              | ICD-9-CM  | Diagnosis     |
| 961.3 | Poisoning by quinoline and hydroxyquinoline derivatives               | ICD-9-CM  | Diagnosis     |
| 961.4 | Poisoning by antimalarials and drugs acting on other blood protozoa   | ICD-9-CM  | Diagnosis     |
| 961.5 | Poisoning by other antiprotozoal drugs                                | ICD-9-CM  | Diagnosis     |
| 961.6 | Poisoning by anthelmintics  | ICD-9-CM  | Diagnosis     |
| 961.7 | Poisoning by antiviral drugs  | ICD-9-CM  | Diagnosis     |
| 961.8 | Poisoning by other antimycobacterial drugs                            | ICD-9-CM  | Diagnosis     |
| 961.9 | Poisoning by other and unspecified anti-infectives                    | ICD-9-CM  | Diagnosis     |
| 962   | Poisoning by hormones and synthetic substitutes                       | ICD-9-CM  | Diagnosis     |
| 962.0 | Poisoning by adrenal cortical steroids                                | ICD-9-CM  | Diagnosis     |
| 962.1 | Poisoning by androgens and anabolic congeners                         | ICD-9-CM  | Diagnosis     |
| 962.2 | Poisoning by ovarian hormones and synthetic substitutes               | ICD-9-CM  | Diagnosis     |
| 962.3 | Poisoning by insulins and antidiabetic agents                         | ICD-9-CM  | Diagnosis     |
| 962.4 | Poisoning by anterior pituitary hormones                              | ICD-9-CM  | Diagnosis     |
| 962.5 | Poisoning by posterior pituitary hormones                             | ICD-9-CM  | Diagnosis     |
| 962.6 | Poisoning by parathyroid and parathyroid derivatives                  | ICD-9-CM  | Diagnosis     |
| 962.7 | Poisoning by thyroid and thyroid derivatives                          | ICD-9-CM  | Diagnosis     |
| 962.8 | Poisoning by antithyroid agents                                       | ICD-9-CM  | Diagnosis     |
| 962.9 | Poisoning by other and unspecified hormones and synthetic substitutes | ICD-9-CM  | Diagnosis     |
| 963   | Poisoning by primarily systemic agents                                | ICD-9-CM  | Diagnosis     |
| 963.0 | Poisoning by antiallergic and antiemetic drugs                        | ICD-9-CM  | Diagnosis     |
| 963.1 | Poisoning by antineoplastic and immunosuppressive drugs               | ICD-9-CM  | Diagnosis     |
| 963.2 | Poisoning by acidifying agents  | ICD-9-CM  | Diagnosis     |
| 963.3 | Poisoning by alkalizing agents  | ICD-9-CM  | Diagnosis     |
| 963.4 | Poisoning by enzymes, not elsewhere classified                        | ICD-9-CM  | Diagnosis     |
| 963.5 | Poisoning by vitamins, not elsewhere classified                       | ICD-9-CM  | Diagnosis     |
| 963.8 | Poisoning by other specified systemic agents                          | ICD-9-CM  | Diagnosis     |
| 963.9 | Poisoning by unspecified systemic agent                               | ICD-9-CM  | Diagnosis     |
| 964   | Poisoning by agents primarily affecting blood constituents            | ICD-9-CM  | Diagnosis     |
| 964.0 | Poisoning by iron and its compounds                                   | ICD-9-CM  | Diagnosis     |
| 964.1 | Poisoning by liver preparations and other antianemic agents           | ICD-9-CM  | Diagnosis     |
| 964.2 | Poisoning by anticoagulants   | ICD-9-CM  | Diagnosis     |
| 964.3 | Poisoning by vitamin K (phytonadione)                                 | ICD-9-CM  | Diagnosis     |
| 964.4 | Poisoning by fibrinolysis-affecting drugs                             | ICD-9-CM  | Diagnosis     |
| 964.5 | Poisoning by anticoagulant antagonists and other coagulants           | ICD-9-CM  | Diagnosis     |
| 964.6 | Poisoning by gamma globulin   | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code   | Description  | Code Type | Code Category |
|--------|--|-----------|---------------|
| 964.7  | Poisoning by natural blood and blood products  | ICD-9-CM  | Diagnosis     |
| 964.8  | Poisoning by other specified agents affecting blood constituents                         | ICD-9-CM  | Diagnosis     |
| 964.9  | Poisoning by unspecified agent affecting blood constituents                              | ICD-9-CM  | Diagnosis     |
| 965    | Poisoning by analgesics, antipyretics, and antirheumatics                                | ICD-9-CM  | Diagnosis     |
| 965.0  | Poisoning by opiates and related narcotics   | ICD-9-CM  | Diagnosis     |
| 965.00 | Poisoning by opium (alkaloids), unspecified  | ICD-9-CM  | Diagnosis     |
| 965.01 | Poisoning by heroin  | ICD-9-CM  | Diagnosis     |
| 965.02 | Poisoning by methadone   | ICD-9-CM  | Diagnosis     |
| 965.09 | Poisoning by opiates and related narcotics, other  | ICD-9-CM  | Diagnosis     |
| 965.1  | Poisoning by salicylates   | ICD-9-CM  | Diagnosis     |
| 965.4  | Poisoning by aromatic analgesics, not elsewhere classified                               | ICD-9-CM  | Diagnosis     |
| 965.5  | Poisoning by pyrazole derivatives  | ICD-9-CM  | Diagnosis     |
| 965.6  | Poisoning by antirheumatics (antiphlogistics)  | ICD-9-CM  | Diagnosis     |
| 965.61 | Poisoning by propionic acid derivatives  | ICD-9-CM  | Diagnosis     |
| 965.69 | Poisoning by other antirheumatics  | ICD-9-CM  | Diagnosis     |
| 965.7  | Poisoning by other non-narcotic analgesics   | ICD-9-CM  | Diagnosis     |
| 965.8  | Poisoning by other specified analgesics and antipyretics                                 | ICD-9-CM  | Diagnosis     |
| 965.9  | Poisoning by unspecified analgesic and antipyretic                                       | ICD-9-CM  | Diagnosis     |
| 966    | Poisoning by anticonvulsants and anti-Parkinsonism drugs                                 | ICD-9-CM  | Diagnosis     |
| 966.0  | Poisoning by oxazolidine derivatives   | ICD-9-CM  | Diagnosis     |
| 966.1  | Poisoning by hydantoin derivatives   | ICD-9-CM  | Diagnosis     |
| 966.2  | Poisoning by succinimides  | ICD-9-CM  | Diagnosis     |
| 966.3  | Poisoning by other and unspecified anticonvulsants                                       | ICD-9-CM  | Diagnosis     |
| 966.4  | Poisoning by anti-Parkinsonism drugs   | ICD-9-CM  | Diagnosis     |
| 967    | Poisoning by sedatives and hypnotics   | ICD-9-CM  | Diagnosis     |
| 967.0  | Poisoning by barbiturates  | ICD-9-CM  | Diagnosis     |
| 967.1  | Poisoning by chloral hydrate group   | ICD-9-CM  | Diagnosis     |
| 967.2  | Poisoning by paraldehyde   | ICD-9-CM  | Diagnosis     |
| 967.3  | Poisoning by bromine compounds   | ICD-9-CM  | Diagnosis     |
| 967.4  | Poisoning by methaqualone compounds  | ICD-9-CM  | Diagnosis     |
| 967.5  | Poisoning by glutethimide group  | ICD-9-CM  | Diagnosis     |
| 967.6  | Poisoning by mixed sedatives, not elsewhere classified                                   | ICD-9-CM  | Diagnosis     |
| 967.8  | Poisoning by other sedatives and hypnotics   | ICD-9-CM  | Diagnosis     |
| 967.9  | Poisoning by unspecified sedative or hypnotic  | ICD-9-CM  | Diagnosis     |
| 968    | Poisoning by other central nervous system depressants and anesthetics                    | ICD-9-CM  | Diagnosis     |
| 968.0  | Poisoning by central nervous system muscle-tone depressants                              | ICD-9-CM  | Diagnosis     |
| 968.1  | Poisoning by halothane   | ICD-9-CM  | Diagnosis     |
| 968.2  | Poisoning by other gaseous anesthetics   | ICD-9-CM  | Diagnosis     |
| 968.3  | Poisoning by intravenous anesthetics   | ICD-9-CM  | Diagnosis     |
| 968.4  | Poisoning by other and unspecified general anesthetics                                   | ICD-9-CM  | Diagnosis     |
| 968.5  | Poisoning by other central nervous system depressants and anesthetics, Surface (topical) | ICD-9-CM  | Diagnosis     |
| 968.6  | Poisoning by peripheral nerve- and plexus-blocking anesthetics                           | ICD-9-CM  | Diagnosis     |
| 968.7  | Poisoning by spinal anesthetics  | ICD-9-CM  | Diagnosis     |
| 968.9  | Poisoning by other and unspecified local anesthetics                                     | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code   | Description  | Code Type | Code Category |
|--------|--|-----------|---------------|
| 969    | Poisoning by psychotropic agents   | ICD-9-CM  | Diagnosis     |
| 969.0  | Poisoning by antidepressants   | ICD-9-CM  | Diagnosis     |
| 969.00 | Poisoning by antidepressant, unspecified                                 | ICD-9-CM  | Diagnosis     |
| 969.01 | Poisoning by monoamine oxidase inhibitors                                | ICD-9-CM  | Diagnosis     |
| 969.02 | Poisoning by selective serotonin and norepinephrine reuptake inhibitors  | ICD-9-CM  | Diagnosis     |
| 969.03 | Poisoning by selective serotonin reuptake inhibitors                     | ICD-9-CM  | Diagnosis     |
| 969.04 | Poisoning by tetracyclic antidepressants                                 | ICD-9-CM  | Diagnosis     |
| 969.05 | Poisoning by tricyclic antidepressants                                   | ICD-9-CM  | Diagnosis     |
| 969.09 | Poisoning by other antidepressants                                       | ICD-9-CM  | Diagnosis     |
| 969.1  | Poisoning by phenothiazine-based tranquilizers                           | ICD-9-CM  | Diagnosis     |
| 969.2  | Poisoning by butyrophenone-based tranquilizers                           | ICD-9-CM  | Diagnosis     |
| 969.3  | Poisoning by other antipsychotics, neuroleptics, and major tranquilizers | ICD-9-CM  | Diagnosis     |
| 969.4  | Poisoning by benzodiazepine-based tranquilizers                          | ICD-9-CM  | Diagnosis     |
| 969.5  | Poisoning by other tranquilizers   | ICD-9-CM  | Diagnosis     |
| 969.6  | Poisoning by psychodysleptics (hallucinogens)                            | ICD-9-CM  | Diagnosis     |
| 969.7  | Poisoning by psychostimulants  | ICD-9-CM  | Diagnosis     |
| 969.70 | Poisoning by psychostimulant, unspecified                                | ICD-9-CM  | Diagnosis     |
| 969.71 | Poisoning by caffeine  | ICD-9-CM  | Diagnosis     |
| 969.72 | Poisoning by amphetamines  | ICD-9-CM  | Diagnosis     |
| 969.73 | Poisoning by methylphenidate   | ICD-9-CM  | Diagnosis     |
| 969.79 | Poisoning by other psychostimulants                                      | ICD-9-CM  | Diagnosis     |
| 969.8  | Poisoning by other specified psychotropic agents                         | ICD-9-CM  | Diagnosis     |
| 969.9  | Poisoning by unspecified psychotropic agent                              | ICD-9-CM  | Diagnosis     |
| 881    | Open wound of elbow, forearm, and wrist                                  | ICD-9-CM  | Diagnosis     |
| 980    | Toxic effect of alcohol  | ICD-9-CM  | Diagnosis     |
| 980.0  | Toxic effect of ethyl alcohol  | ICD-9-CM  | Diagnosis     |
| 980.1  | Toxic effect of methyl alcohol   | ICD-9-CM  | Diagnosis     |
| 980.2  | Toxic effect of isopropyl alcohol  | ICD-9-CM  | Diagnosis     |
| 980.3  | Toxic effect of fusel oil  | ICD-9-CM  | Diagnosis     |
| 980.8  | Toxic effect of other specified alcohols                                 | ICD-9-CM  | Diagnosis     |
| 980.9  | Toxic effect of unspecified alcohol                                      | ICD-9-CM  | Diagnosis     |
| 981    | Toxic effect of petroleum products                                       | ICD-9-CM  | Diagnosis     |
| 982    | Toxic effect of solvents other than petroleum-based                      | ICD-9-CM  | Diagnosis     |
| 982.0  | Toxic effect of benzene and homologues                                   | ICD-9-CM  | Diagnosis     |
| 982.1  | Toxic effect of carbon tetrachloride                                     | ICD-9-CM  | Diagnosis     |
| 982.2  | Toxic effect of carbon disulfide   | ICD-9-CM  | Diagnosis     |
| 982.3  | Toxic effect of other chlorinated hydrocarbon solvents                   | ICD-9-CM  | Diagnosis     |
| 982.4  | Toxic effect of nitroglycol  | ICD-9-CM  | Diagnosis     |
| 982.8  | Toxic effect of other nonpetroleum-based solvents                        | ICD-9-CM  | Diagnosis     |
| 983    | Toxic effect of corrosive aromatics, acids, and caustic alkalis          | ICD-9-CM  | Diagnosis     |
| 983.0  | Toxic effect of corrosive aromatics                                      | ICD-9-CM  | Diagnosis     |
| 983.1  | Toxic effect of acids  | ICD-9-CM  | Diagnosis     |
| 983.2  | Toxic effect of caustic alkalis  | ICD-9-CM  | Diagnosis     |
| 983.9  | Toxic effect of caustic, unspecified                                     | ICD-9-CM  | Diagnosis     |



**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code   | Description   | Code Type | Code Category |
|--------|---|-----------|---------------|
| 984    | Toxic effect of lead and its compounds (including fumes)            | ICD-9-CM  | Diagnosis     |
| 984.0  | Toxic effect of inorganic lead compounds                            | ICD-9-CM  | Diagnosis     |
| 984.1  | Toxic effect of organic lead compounds                              | ICD-9-CM  | Diagnosis     |
| 984.8  | Toxic effect of other lead compounds                                | ICD-9-CM  | Diagnosis     |
| 984.9  | Toxic effect of unspecified lead compound                           | ICD-9-CM  | Diagnosis     |
| 985    | Toxic effect of other metals  | ICD-9-CM  | Diagnosis     |
| 985.0  | Toxic effect of mercury and its compounds                           | ICD-9-CM  | Diagnosis     |
| 985.1  | Toxic effect of arsenic and its compounds                           | ICD-9-CM  | Diagnosis     |
| 985.2  | Toxic effect of manganese and its compounds                         | ICD-9-CM  | Diagnosis     |
| 985.3  | Toxic effect of beryllium and its compounds                         | ICD-9-CM  | Diagnosis     |
| 985.4  | Toxic effect of antimony and its compounds                          | ICD-9-CM  | Diagnosis     |
| 985.5  | Toxic effect of cadmium and its compounds                           | ICD-9-CM  | Diagnosis     |
| 985.6  | Toxic effect of chromium  | ICD-9-CM  | Diagnosis     |
| 985.8  | Toxic effect of other specified metals                              | ICD-9-CM  | Diagnosis     |
| 985.9  | Toxic effect of unspecified metal                                   | ICD-9-CM  | Diagnosis     |
| 986    | Toxic effect of carbon monoxide                                     | ICD-9-CM  | Diagnosis     |
| 987    | Toxic effect of other gases, fumes, or vapors                       | ICD-9-CM  | Diagnosis     |
| 987.0  | Toxic effect of liquefied petroleum gases                           | ICD-9-CM  | Diagnosis     |
| 987.1  | Toxic effect of other hydrocarbon gas                               | ICD-9-CM  | Diagnosis     |
| 987.2  | Toxic effect of nitrogen oxides                                     | ICD-9-CM  | Diagnosis     |
| 987.3  | Toxic effect of sulfur dioxide                                      | ICD-9-CM  | Diagnosis     |
| 987.4  | Toxic effect of freon   | ICD-9-CM  | Diagnosis     |
| 987.5  | Toxic effect of lacrimogenic gas                                    | ICD-9-CM  | Diagnosis     |
| 987.6  | Toxic effect of chlorine gas  | ICD-9-CM  | Diagnosis     |
| 987.7  | Toxic effect of hydrocyanic acid gas                                | ICD-9-CM  | Diagnosis     |
| 987.8  | Toxic effect of other specified gases, fumes, or vapors             | ICD-9-CM  | Diagnosis     |
| 987.9  | Toxic effect of unspecified gas, fume, or vapor                     | ICD-9-CM  | Diagnosis     |
| 988    | Toxic effect of noxious substances eaten as food                    | ICD-9-CM  | Diagnosis     |
| 988.0  | Toxic effect of fish and shellfish                                  | ICD-9-CM  | Diagnosis     |
| 988.1  | Toxic effect of mushrooms   | ICD-9-CM  | Diagnosis     |
| 988.2  | Toxic effect of berries and other plants                            | ICD-9-CM  | Diagnosis     |
| 988.8  | Toxic effect of other specified noxious substances                  | ICD-9-CM  | Diagnosis     |
| 988.9  | Toxic effect of unspecified noxious substance                       | ICD-9-CM  | Diagnosis     |
| 989    | Toxic effect of other substances, chiefly nonmedicinal as to source | ICD-9-CM  | Diagnosis     |
| 989.0  | Toxic effect of hydrocyanic acid and cyanides                       | ICD-9-CM  | Diagnosis     |
| 989.1  | Toxic effect of strychnine and salts                                | ICD-9-CM  | Diagnosis     |
| 989.2  | Toxic effect of chlorinated hydrocarbons                            | ICD-9-CM  | Diagnosis     |
| 989.3  | Toxic effect of organophosphate and carbamate                       | ICD-9-CM  | Diagnosis     |
| 989.4  | Toxic effect of other pesticides, not elsewhere classified          | ICD-9-CM  | Diagnosis     |
| 989.5  | Toxic effect of venom   | ICD-9-CM  | Diagnosis     |
| 989.6  | Toxic effect of soaps and detergents                                | ICD-9-CM  | Diagnosis     |
| 989.7  | Toxic effect of aflatoxin and other mycotoxin (food contaminants)   | ICD-9-CM  | Diagnosis     |
| 989.8  | Toxic effect of other substances, chiefly nonmedicinal as to source | ICD-9-CM  | Diagnosis     |
| 989.81 | Toxic effect of asbestos  | ICD-9-CM  | Diagnosis     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code                                     | Description  | Code Type | Code Category |
|--|--|-----------|---------------|
| 989.82                                   | Toxic effect of latex  | ICD-9-CM  | Diagnosis     |
| 989.83                                   | Toxic effect of silicone   | ICD-9-CM  | Diagnosis     |
| 989.84                                   | Toxic effect of tobacco  | ICD-9-CM  | Diagnosis     |
| 989.89                                   | Toxic effect of other substances   | ICD-9-CM  | Diagnosis     |
| 989.9                                    | Toxic effect of unspecified substance, chiefly nonmedicinal as to source   | ICD-9-CM  | Diagnosis     |
| 994.7                                    | Asphyxiation and strangulation   | ICD-9-CM  | Diagnosis     |
| <i>Transcranial magnetic stimulation</i> |  |           |               |
| 90867                                    | Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management  | CPT-4     | Procedure     |
| 90868                                    | Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session  | CPT-4     | Procedure     |
| 90869                                    | Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management   | CPT-4     | Procedure     |
| <i>Vagus nerve stimulation</i>           |  |           |               |
| 61885                                    | Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array   | CPT-4     | Procedure     |
| 61886                                    | Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays   | CPT-4     | Procedure     |
| 61888                                    | Revision or removal of cranial neurostimulator pulse generator or receiver   | CPT-4     | Procedure     |
| 64553                                    | Percutaneous implantation of neurostimulator electrode array; cranial nerve  | CPT-4     | Procedure     |
| 64568                                    | Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator   | CPT-4     | Procedure     |
| 64569                                    | Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator   | CPT-4     | Procedure     |
| 64570                                    | Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator   | CPT-4     | Procedure     |
| 64585                                    | Revision or removal of peripheral neurostimulator electrode array  | CPT-4     | Procedure     |
| 95970                                    | Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (ie, cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming | CPT-4     | Procedure     |
| 95971                                    | Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming          | CPT-4     | Procedure     |



**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| Code                                      | Description  | Code Type | Code Category |
|---|--|-----------|---------------|
| 95974                                     | Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour   | CPT-4     | Procedure     |
| 95975                                     | Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure) | CPT-4     | Procedure     |
| L8679                                     | Implantable neurostimulator, pulse generator, any type   | HCPCS     | Procedure     |
| L8680                                     | Implantable neurostimulator electrode, each  | HCPCS     | Procedure     |
| L8681                                     | Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only  | HCPCS     | Procedure     |
| L8682                                     | Implantable neurostimulator radiofrequency receiver  | HCPCS     | Procedure     |
| L8683                                     | Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver   | HCPCS     | Procedure     |
| L8685                                     | Implantable neurostimulator pulse generator, single array, rechargeable, includes extension  | HCPCS     | Procedure     |
| L8686                                     | Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension   | HCPCS     | Procedure     |
| L8687                                     | Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension  | HCPCS     | Procedure     |
| L8688                                     | Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension   | HCPCS     | Procedure     |
| L8689                                     | External recharging system for battery (internal) for use with implantable neurostimulator, replacement only   | HCPCS     | Procedure     |
| <b>Psychiatric and Psychotropic Drugs</b> |  |           |               |
| C9035                                     | Injection, aripiprazole lauroxil (Aristada Initio), 1 mg   | HCPCS     | Procedure     |
| C9037                                     | Injection, risperidone (Perseris), 0.5 mg  | HCPCS     | Procedure     |
| C9125                                     | Injection, risperidone, per 12.5 mg  | HCPCS     | Procedure     |
| C9204                                     | Injection, ziprasidone mesylate injection, per 20 mg   | HCPCS     | Procedure     |
| C9255                                     | Injection, paliperidone palmitate, 1 mg  | HCPCS     | Procedure     |
| C9470                                     | Injection, aripiprazole lauroxil, 1 mg   | HCPCS     | Procedure     |
| C9497                                     | Loxapine, inhalation powder, 10 mg   | HCPCS     | Procedure     |
| J0400                                     | Injection, aripiprazole, intramuscular, 0.25 mg  | HCPCS     | Procedure     |
| J0401                                     | Injection, aripiprazole, extended release, 1 mg  | HCPCS     | Procedure     |
| J1320                                     | Injection, amitriptyline HCl, up to 20 mg  | HCPCS     | Procedure     |
| J1630                                     | Injection, haloperidol, up to 5 mg   | HCPCS     | Procedure     |
| J1631                                     | Injection, haloperidol decanoate, per 50 mg  | HCPCS     | Procedure     |
| J1790                                     | Injection, droperidol, up to 5 mg  | HCPCS     | Procedure     |
| J1810                                     | Injection, droperidol and fentanyl citrate, up to 2 ml ampule  | HCPCS     | Procedure     |

**Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Covariates in this Request**

| <b>Code</b> | <b>Description</b>                                       | <b>Code Type</b> | <b>Code Category</b> |
|-------------|--|------------------|----------------------|
| J1942       | Injection, aripiprazole lauroxil, 1 mg                   | HCPCS            | Procedure            |
| J1990       | Injection, chlordiazepoxide HCl, up to 100 mg            | HCPCS            | Procedure            |
| J2060       | Injection, lorazepam, 2 mg                               | HCPCS            | Procedure            |
| J2062       | Loxapine for inhalation, 1 mg                            | HCPCS            | Procedure            |
| J2330       | Injection, thiothixene, up to 4 mg                       | HCPCS            | Procedure            |
| J2358       | Injection, olanzapine, long-acting, 1 mg                 | HCPCS            | Procedure            |
| J2426       | Injection, paliperidone palmitate extended release, 1 mg | HCPCS            | Procedure            |
| J2515       | Injection, pentobarbital sodium, per 50 mg               | HCPCS            | Procedure            |
| J2680       | Injection, fluphenazine decanoate, up to 25 mg           | HCPCS            | Procedure            |
| J2794       | Injection, risperidone, long acting, 0.5 mg              | HCPCS            | Procedure            |
| J3230       | Injection, chlorpromazine HCl, up to 50 mg               | HCPCS            | Procedure            |
| J3270       | Injection, imipramine hcl, up to 25 mg                   | HCPCS            | Procedure            |
| J3310       | Injection, perphenazine, up to 5 mg                      | HCPCS            | Procedure            |
| J3360       | Injection, diazepam, up to 5 mg                          | HCPCS            | Procedure            |
| J3486       | Injection, ziprasidone mesylate, 10 mg                   | HCPCS            | Procedure            |
| S0136       | Clozapine, 25 mg   | HCPCS            | Procedure            |
| S0160       | Dextroamphetamine sulfate, 5 mg                          | HCPCS            | Procedure            |
| S0163       | Injection, risperidone, long acting, 12.5 mg             | HCPCS            | Procedure            |
| S0166       | Injection, olanzapine, 2.5 mg                            | HCPCS            | Procedure            |

## Appendix J. List of Generic and Brand Drug Names Used to Define Covariates in this Request

| Generic Name   | Brand Name                  |
|--|-----------------------------|
| <b>Short-Acting Beta Agonists (SABAs)</b>              |                             |
| albuterol  | Proventil                   |
| albuterol  | Albuterol                   |
| albuterol  | Respirol                    |
| albuterol  | Albuterol (refill)          |
| albuterol  | Proventil (Refill)          |
| albuterol  | Ventolin                    |
| albuterol  | Ventolin Refill             |
| albuterol sulfate                                      | ProAir RespiClick           |
| albuterol sulfate                                      | Ventolin Rotacaps           |
| albuterol sulfate                                      | Ventolin Rotahaler/Rotacaps |
| albuterol sulfate                                      | Ventolin HFA                |
| albuterol sulfate                                      | Albuterol sulfate           |
| albuterol sulfate                                      | ProAir HFA                  |
| albuterol sulfate                                      | Proventil HFA               |
| albuterol sulfate                                      | Airet                       |
| albuterol sulfate                                      | Ventolin                    |
| albuterol sulfate                                      | Proventil                   |
| albuterol sulfate                                      | AccuNeb                     |
| albuterol sulfate                                      | Vospire ER                  |
| albuterol sulfate                                      | Volmax                      |
| ipratropium bromide/albuterol sulfate                  | Combivent                   |
| ipratropium bromide/albuterol sulfate                  | Combivent Respimat          |
| ipratropium bromide/albuterol sulfate                  | DuoNeb                      |
| ipratropium bromide/albuterol sulfate                  | Ipratropium-albuterol       |
| levalbuterol HCl                                       | Xopenex                     |
| levalbuterol HCl                                       | Levalbuterol HCl            |
| levalbuterol HCl                                       | Xopenex Concentrate         |
| levalbuterol tartrate                                  | Xopenex HFA                 |
| levalbuterol tartrate                                  | Levalbuterol tartrate       |
| metaproterenol sulfate                                 | Alupent                     |
| metaproterenol sulfate                                 | Metaproterenol              |
| pirbuterol acetate                                     | Maxair                      |
| pirbuterol acetate                                     | Maxair Autohaler            |
| terbutaline sulfate                                    | Brethaire                   |
| terbutaline sulfate                                    | Brethine                    |
| terbutaline sulfate                                    | Terbutaline                 |
| <b>Anticholinergic agents</b>                          |                             |
| tiotropium bromide                                     | Spiriva with HandiHaler     |
| tiotropium bromide                                     | Spiriva Respimat            |
| <b>Phosphodiesterase Inhibitors</b>                    |                             |
| aminophylline  | Aminophylline               |
| aminophylline/ephedrine/potassium iodide/phenobarbital | Dainite-KI                  |
| dyphylline   | Dilor                       |
| dyphylline   | Lufyllin                    |
| dyphylline   | Dylix                       |

## Appendix J. List of Generic and Brand Drug Names Used to Define Covariates in this Request

| Generic Name                                       | Brand Name             |
|--|------------------------|
| guaifenesin/dyphylline                             | Lufyllin-GG            |
| guaifenesin/dyphylline                             | Dyphylline-guaifenesin |
| guaifenesin/dyphylline                             | Dilor-G                |
| guaifenesin/dyphylline                             | Panfil-G               |
| guaifenesin/dyphylline                             | Dyline-GG              |
| guaifenesin/dyphylline                             | D-G Liquid             |
| guaifenesin/dyphylline                             | Dyphyl-G               |
| guaifenesin/dyphylline                             | Dyphylline-GG          |
| guaifenesin/dyphylline                             | DG 200                 |
| guaifenesin/dyphylline                             | COPD                   |
| guaifenesin/dyphylline                             | Difil-G 400            |
| guaifenesin/dyphylline                             | Difil G Forte          |
| guaifenesin/dyphylline                             | Dyflex-G               |
| guaifenesin/dyphylline                             | Dyflex                 |
| guaifenesin/dyphylline                             | Bi-Filin G             |
| guaifenesin/dyphylline                             | Difil-G                |
| guaifenesin/dyphylline                             | Dyfilin-GG             |
| guaifenesin/dyphylline                             | Dilex-G                |
| guaifenesin/dyphylline                             | Dilex-G 200            |
| guaifenesin/dyphylline                             | DILEX-G 400            |
| guaifenesin/dyphylline                             | Dyphylline GG ES       |
| guaifenesin/dyphylline                             | Jay-Phyl               |
| guaifenesin/dyphylline                             | Bronkophylline GG      |
| guaifenesin/dyphylline                             | Brondil                |
| guaifenesin/dyphylline                             | Dy-G                   |
| guaifenesin/dyphylline                             | Dyphysin               |
| guaifenesin/dyphylline/ephedrine/phenobarbital     | Lufyllin-EPG           |
| guaifenesin/theophylline                           | Slo-Phyllin GG         |
| guaifenesin/theophylline                           | MYCI BRON-G            |
| guaifenesin/theophylline                           | Elixophyllin GG        |
| guaifenesin/theophylline                           | Theolate               |
| guaifenesin/theophylline                           | Ed-Bron G              |
| guaifenesin/theophylline                           | Theomar GG             |
| guaifenesin/theophylline                           | Quibron                |
| guaifenesin/theophylline                           | Quibron-300            |
| guaifenesin/theophylline                           | Broncodur              |
| guaifenesin/theophylline                           | Broncap                |
| guaifenesin/theophylline anhydrous/pseudoephedrine | Broncomar-1            |
| theophylline anhydrous                             | Uniphyll               |
| theophylline anhydrous                             | T-Phyl                 |
| theophylline anhydrous                             | theophylline           |
| theophylline anhydrous                             | Slo-Bid Gyrocaps       |
| theophylline anhydrous                             | Slo-Phyllin            |
| theophylline anhydrous                             | Slo-Phyllin 80         |
| theophylline anhydrous                             | Theo-Dur               |
| theophylline anhydrous                             | Uni-Dur                |

## Appendix J. List of Generic and Brand Drug Names Used to Define Covariates in this Request

| Generic Name   | Brand Name                    |
|--|-------------------------------|
| theophylline anhydrous                                       | Theo-X                        |
| theophylline anhydrous                                       | Theolair                      |
| theophylline anhydrous                                       | Theolair-SR                   |
| theophylline anhydrous                                       | Aerolate Jr                   |
| theophylline anhydrous                                       | Aerolate Sr                   |
| theophylline anhydrous                                       | Aerolate III TD               |
| theophylline anhydrous                                       | Elixophyllin                  |
| theophylline anhydrous                                       | TheoCap                       |
| theophylline anhydrous                                       | Theochron                     |
| theophylline anhydrous                                       | Truxophyllin                  |
| theophylline anhydrous                                       | Theo-24                       |
| theophylline anhydrous                                       | Quibron-T                     |
| theophylline anhydrous                                       | Quibron-T/SR                  |
| theophylline in dextrose 5 % in water                        | theophylline in dextrose 5 %  |
| theophylline/cafeine/AA no.13/cinnamon/herbal 135            | Pulmophylline-Pulmona         |
| theophylline/dietary supplement,misc.comb.no.9               | Senophylline                  |
| theophylline/ephedrine HCl/phenobarbital                     | theophylline-ephed-phenobarb  |
| theophylline/ephedrine HCl/phenobarbital                     | Asthma                        |
| theophylline/ephedrine/potassium iodide/phenobarbital        | Quadrinal                     |
| theophylline/potassium iodide                                | Elixophyllin-KI               |
| Psychiatric and Psychotropic Drugs                           |                               |
| <i>Attention-deficit/hyperactivity disorder</i>              |                               |
| atomoxetine HCl  | Atomoxetine                   |
| atomoxetine HCl  | Strattera                     |
| dexmethylphenidate HCl                                       | Dexmethylphenidate            |
| dexmethylphenidate HCl                                       | Focalin                       |
| dexmethylphenidate HCl                                       | Focalin XR                    |
| dextroamphetamine sulfate                                    | Dexedrine                     |
| dextroamphetamine sulfate                                    | Dexedrine Spansule            |
| dextroamphetamine sulfate                                    | Dextroamphetamine             |
| dextroamphetamine sulfate                                    | DextroStat                    |
| dextroamphetamine sulfate                                    | Liquadd                       |
| dextroamphetamine sulfate                                    | ProCentra                     |
| dextroamphetamine sulfate                                    | Zenzedi                       |
| dextroamphetamine sulf-saccharate/amphetamine sulf-aspartate | Adderall                      |
| dextroamphetamine sulf-saccharate/amphetamine sulf-aspartate | Adderall XR                   |
| dextroamphetamine sulf-saccharate/amphetamine sulf-aspartate | Dextroamphetamine-amphetamine |
| guanfacine HCl   | Guanfacine                    |
| guanfacine HCl   | Intuniv ER                    |
| guanfacine HCl   | Tenex                         |
| lisdexamfetamine dimesylate                                  | Vyvanse                       |
| methamphetamine HCl  | Desoxyn                       |
| methamphetamine HCl  | Methamphetamine               |
| methylphenidate  | Daytrana                      |
| methylphenidate HCl  | Aptensio XR                   |
| methylphenidate HCl  | Concerta                      |

## Appendix J. List of Generic and Brand Drug Names Used to Define Covariates in this Request

| Generic Name                                       | Brand Name                     |
|--|--------------------------------|
| methylphenidate HCl                                | Metadate CD                    |
| methylphenidate HCl                                | Metadate ER                    |
| methylphenidate HCl                                | Methylin                       |
| methylphenidate HCl                                | Methylin ER                    |
| methylphenidate HCl                                | Methylphenidate HCl            |
| methylphenidate HCl                                | QuilliChew ER                  |
| methylphenidate HCl                                | Quillivant XR                  |
| methylphenidate HCl                                | Relexxii                       |
| methylphenidate HCl                                | Ritalin                        |
| methylphenidate HCl                                | Ritalin LA                     |
| methylphenidate HCl                                | Ritalin SR                     |
| pemoline   | Cylert                         |
| pemoline   | Pemoline                       |
| <b>Antidepressants</b>                             |                                |
| amitriptyline HCl                                  | Elavil                         |
| amitriptyline HCl                                  | Amitriptyline                  |
| amitriptyline HCl                                  | Vanatrip                       |
| amitriptyline HCl                                  | EnovaRx-Amitriptyline          |
| amitriptyline HCl/chlordiazepoxide                 | Amitriptyline-chlordiazepoxide |
| amitriptyline HCl/chlordiazepoxide                 | Limbitrol                      |
| amitriptyline HCl/chlordiazepoxide                 | Limbitrol DS                   |
| amoxapine  | Amoxapine                      |
| bupropion HBr                                      | Aplenzin                       |
| bupropion HCl                                      | Budeprion SR                   |
| bupropion HCl                                      | Budeprion XL                   |
| bupropion HCl                                      | Buproban                       |
| bupropion HCl                                      | Bupropion HCl                  |
| bupropion HCl                                      | Bupropion HCl (smoking deter)  |
| bupropion HCl                                      | Forfivo XL                     |
| bupropion HCl                                      | Wellbutrin                     |
| bupropion HCl                                      | Wellbutrin SR                  |
| bupropion HCl                                      | Wellbutrin XL                  |
| bupropion HCl                                      | Zyban                          |
| bupropion HCl/dietary supplement combination no.15 | Appbutamone-D                  |
| bupropion HCl/dietary supplement combination no.16 | Appbutamone                    |
| citalopram hydrobromide                            | Celexa                         |
| citalopram hydrobromide                            | Citalopram                     |
| clomipramine HCl                                   | Anafranil                      |
| clomipramine HCl                                   | Clomipramine                   |
| desipramine HCl                                    | Desipramine                    |
| desipramine HCl                                    | Norpramin                      |
| desvenlafaxine                                     | Desvenlafaxine                 |
| desvenlafaxine                                     | Khedeza                        |
| desvenlafaxine fumarate                            | Desvenlafaxine fumarate        |
| desvenlafaxine succinate                           | Desvenlafaxine succinate       |
| desvenlafaxine succinate                           | Pristiq                        |

# Appendix J. List of Generic and Brand Drug Names Used to Define Covariates in this Request

| Generic Name                            | Brand Name                     |
|---|--------------------------------|
| doxepin HCl                             | Doxepin                        |
| doxepin HCl                             | Silenor                        |
| doxepin HCl                             | Sinequan                       |
| doxepin HCl                             | Prudoxin                       |
| doxepin HCl                             | Zonalon                        |
| duloxetine HCl                          | Cymbalta                       |
| duloxetine HCl                          | Duloxetine                     |
| duloxetine HCl                          | Irenka                         |
| escitalopram oxalate                    | escitalopram oxalate           |
| escitalopram oxalate                    | Lexapro                        |
| fluoxetine HCl                          | Fluoxetine                     |
| fluoxetine HCl                          | Prozac                         |
| fluoxetine HCl                          | Prozac Weekly                  |
| fluoxetine HCl                          | Rapiflux                       |
| fluoxetine HCl                          | Sarafem                        |
| fluoxetine HCl                          | Selfemra                       |
| fluoxetine HCl/dietary supplement no.17 | Gaboxetine                     |
| fluoxetine HCl/dietary supplement no.8  | Sentroxatine                   |
| fluvoxamine maleate                     | Fluvoxamine                    |
| fluvoxamine maleate                     | Luvox                          |
| fluvoxamine maleate                     | Luvox CR                       |
| imipramine HCl                          | Imipramine HCl                 |
| imipramine HCl                          | Tofranil                       |
| imipramine pamoate                      | Imipramine pamoate             |
| imipramine pamoate                      | Tofranil-PM                    |
| isocarboxazid                           | Marplan                        |
| levomilnacipran HCl                     | Fetzima                        |
| maprotiline HCl                         | Ludiomil                       |
| maprotiline HCl                         | Maprotiline                    |
| mirtazapine                             | Mirtazapine                    |
| mirtazapine                             | Remeron                        |
| mirtazapine                             | Remeron SolTab                 |
| naltrexone HCl/bupropion HCl            | Contrave                       |
| nefazodone HCl                          | Nefazodone                     |
| nefazodone HCl                          | Serzone                        |
| nortriptyline HCl                       | Aventyl                        |
| nortriptyline HCl                       | Nortriptyline                  |
| nortriptyline HCl                       | Pamelor                        |
| olanzapine/fluoxetine HCl               | Olanzapine-fluoxetine          |
| olanzapine/fluoxetine HCl               | Symbyax                        |
| paroxetine HCl                          | Paroxetine HCl                 |
| paroxetine HCl                          | Paxil                          |
| paroxetine HCl                          | Paxil CR                       |
| paroxetine mesylate                     | Brisdelle                      |
| paroxetine mesylate                     | Paroxetine mesylate(menop.sym) |
| paroxetine mesylate                     | Pexeva                         |

## Appendix J. List of Generic and Brand Drug Names Used to Define Covariates in this Request

| Generic Name                          | Brand Name                 |
|---------------------------------------|----------------------------|
| perphenazine/amitriptyline HCl        | Duo-Vil 2-10               |
| perphenazine/amitriptyline HCl        | Duo-Vil 2-25               |
| perphenazine/amitriptyline HCl        | Etrafon 2-10               |
| perphenazine/amitriptyline HCl        | Etrafon 2-25               |
| perphenazine/amitriptyline HCl        | Etrafon Forte 4-25         |
| perphenazine/amitriptyline HCl        | Perphenazine-amitriptyline |
| perphenazine/amitriptyline HCl        | Triavil 2-10               |
| perphenazine/amitriptyline HCl        | Triavil 2-25               |
| perphenazine/amitriptyline HCl        | Triavil 4-25               |
| phenelzine sulfate                    | Nardil                     |
| phenelzine sulfate                    | Phenelzine                 |
| selegiline                            | Emsam                      |
| selegiline HCl                        | Carbex                     |
| selegiline HCl                        | Eldepryl                   |
| selegiline HCl                        | Selegiline HCl             |
| selegiline HCl                        | Zelapar                    |
| sertraline HCl                        | Sertraline                 |
| sertraline HCl                        | Zoloft                     |
| tranylcypromine sulfate               | Parnate                    |
| tranylcypromine sulfate               | Tranylcypromine            |
| trazodone HCl/dietary supplement no.8 | Trazamine                  |
| trimipramine maleate                  | Surmontil                  |
| trimipramine maleate                  | Trimipramine               |
| venlafaxine HCl                       | Effexor                    |
| venlafaxine HCl                       | Effexor XR                 |
| venlafaxine HCl                       | Venlafaxine                |
| vilazodone HCl                        | Viibryd                    |
| vortioxetine hydrobromide             | Brintellix                 |
| vortioxetine hydrobromide             | Trintellix                 |
| <b>Antipsychotics</b>                 |                            |
| aripiprazole                          | Abilify                    |
| aripiprazole                          | Abilify Maintena           |
| aripiprazole                          | Abilify Discmelt           |
| aripiprazole                          | Abilify MyCite             |
| aripiprazole                          | Aripiprazole               |
| asenapine maleate                     | Saphris                    |
| asenapine maleate                     | Saphris (black cherry)     |
| brexpiprazole                         | Rexulti                    |
| carbamazepine                         | Atretol                    |
| carbamazepine                         | Carbamazepine              |
| carbamazepine                         | Carbatrol                  |
| carbamazepine                         | Epitol                     |
| carbamazepine                         | Equetro                    |
| carbamazepine                         | Tegretol                   |
| carbamazepine                         | Tegretol XR                |
| cariprazine HCl                       | Vraylar                    |



## Appendix J. List of Generic and Brand Drug Names Used to Define Covariates in this Request

| Generic Name           | Brand Name                     |
|------------------------|--------------------------------|
| chlorpromazine HCl     | Chlorpromazine                 |
| chlorpromazine HCl     | Thorazine                      |
| clonazepam             | Ceberclon                      |
| clonazepam             | Clonazepam                     |
| clonazepam             | Klonopin                       |
| clozapine              | Clozapine                      |
| clozapine              | Clozaril                       |
| clozapine              | FazaClo                        |
| clozapine              | Versacloz                      |
| divalproex sodium      | Depakote                       |
| divalproex sodium      | Depakote ER                    |
| divalproex sodium      | Depakote Sprinkles             |
| divalproex sodium      | Divalproex                     |
| fluphenazine decanoate | Fluphenazine decanoate         |
| fluphenazine decanoate | Prolixin Decanoate             |
| fluphenazine enanthate | Prolixin                       |
| fluphenazine HCl       | Fluphenazine HCl               |
| fluphenazine HCl       | Prolixin                       |
| fluphenazine HCl       | Permitil                       |
| haloperidol            | Haloperidol                    |
| haloperidol decanoate  | Haldol Decanoate               |
| haloperidol decanoate  | Haloperidol decanoate          |
| haloperidol lactate    | Haldol                         |
| haloperidol lactate    | Haloperidol lactate            |
| iloperidone            | Fanapt                         |
| lamotrigine            | Lamictal                       |
| lamotrigine            | Lamictal ODT                   |
| lamotrigine            | Lamictal ODT Starter (Blue)    |
| lamotrigine            | Lamictal ODT Starter (Green)   |
| lamotrigine            | Lamictal ODT Starter (Orange)  |
| lamotrigine            | Lamictal Starter (Blue) Kit    |
| lamotrigine            | Lamictal Starter (Green) Kit   |
| lamotrigine            | Lamictal Starter (Orange) Kit  |
| lamotrigine            | Lamictal XR                    |
| lamotrigine            | Lamictal XR Starter (Blue)     |
| lamotrigine            | Lamictal XR Starter (Green)    |
| lamotrigine            | Lamictal XR Starter (Orange)   |
| lamotrigine            | Lamotrigine                    |
| lamotrigine            | Subvenite                      |
| lamotrigine            | Subvenite Starter (Blue) Kit   |
| lamotrigine            | Subvenite Starter (Green) Kit  |
| lamotrigine            | Subvenite Starter (Orange) Kit |
| lithium carbonate      | Eskalith                       |
| lithium carbonate      | Eskalith CR                    |
| lithium carbonate      | Lithium carbonate              |
| lithium carbonate      | Lithobid                       |

## Appendix J. List of Generic and Brand Drug Names Used to Define Covariates in this Request

| Generic Name                                      | Brand Name         |
|---|--------------------|
| lithium citrate                                   | Lithium citrate    |
| loxapine  | Adasuve            |
| loxapine HCl                                      | Loxitane           |
| loxapine HCl                                      | Loxitane-C         |
| loxapine succinate                                | Loxapine succinate |
| loxapine succinate                                | Loxitane           |
| lurasidone HCl                                    | Latuda             |
| mesoridazine besylate                             | Serentil           |
| molindone HCl                                     | Moban              |
| molindone HCl                                     | Molindone          |
| olanzapine  | Olanzapine         |
| olanzapine  | Zyprexa            |
| olanzapine  | Zyprexa Zydis      |
| olanzapine pamoate                                | Zyprexa Relprevv   |
| oxcarbazepine                                     | Oxcarbazepine      |
| oxcarbazepine                                     | Oxtellar XR        |
| oxcarbazepine                                     | Trileptal          |
| paliperidone                                      | Invega             |
| paliperidone                                      | Paliperidone       |
| paliperidone palmitate                            | Invega Sustenna    |
| paliperidone palmitate                            | Invega Trinza      |
| perphenazine                                      | Trilafon           |
| perphenazine                                      | Perphenazine       |
| pimozide  | Orap               |
| pimozide  | Pimozide           |
| quetiapine fumarate                               | Quetiapine         |
| quetiapine fumarate                               | Seroquel           |
| quetiapine fumarate                               | Seroquel XR        |
| risperidone                                       | Perseris           |
| risperidone                                       | Risperdal          |
| risperidone                                       | Risperdal M-TAB    |
| risperidone                                       | Risperidone        |
| risperidone microspheres                          | Risperdal Consta   |
| thioridazine HCl                                  | Mellaril           |
| thioridazine HCl                                  | Mellaril-S         |
| thioridazine HCl                                  | Thioridazine       |
| thiothixene                                       | Navane             |
| thiothixene                                       | Thiothixene        |
| thiothixene HCl                                   | Navane             |
| thiothixene HCl                                   | Thiothixene HCl    |
| trifluoperazine HCl                               | Stelazine          |
| trifluoperazine HCl                               | Trifluoperazine    |
| valproic acid                                     | Depakene           |
| valproic acid                                     | Stavzor            |
| valproic acid                                     | Valproic acid      |
| valproic acid (as sodium salt) (valproate sodium) | Depacon            |

## Appendix J. List of Generic and Brand Drug Names Used to Define Covariates in this Request

| Generic Name                                      | Brand Name                     |
|---|--------------------------------|
| valproic acid (as sodium salt) (valproate sodium) | Valproate sodium               |
| valproic acid (as sodium salt) (valproate sodium) | Depakene                       |
| valproic acid (as sodium salt) (valproate sodium) | Valproic acid (as sodium salt) |
| ziprasidone HCl                                   | Geodon                         |
| ziprasidone HCl                                   | Ziprasidone HCl                |
| ziprasidone mesylate                              | Geodon                         |
| <b>Anxiety agents</b>                             |                                |
| alprazolam  | Alprazolam                     |
| alprazolam  | Alprazolam Intensol            |
| alprazolam  | Niravam                        |
| alprazolam  | Xanax                          |
| alprazolam  | Xanax XR                       |
| alprazolam/dietary supplement,misc combo no.17    | Gabazolamine                   |
| aspirin/meprobamate                               | Equagesic                      |
| aspirin/meprobamate                               | Meprobamate-aspirin            |
| aspirin/meprobamate                               | Micrainin                      |
| bupirone HCl                                      | BuSpar                         |
| bupirone HCl                                      | Buspirone                      |
| bupirone HCl                                      | Vanspar                        |
| chlordiazepoxide HCl                              | Librium                        |
| chlordiazepoxide HCl                              | Chlordiazepoxide HCl           |
| chlordiazepoxide HCl                              | Poxi                           |
| chlordiazepoxide HCl/methscopolamine nitrate      | Librax (with methscopolamine)  |
| chlordiazepoxide/clidinium bromide                | Chlordiazepoxide-clidinium     |
| chlordiazepoxide/clidinium bromide                | Librax (with clidinium)        |
| clorazepate dipotassium                           | Clorazepate dipotassium        |
| clorazepate dipotassium                           | Gen-XENE                       |
| clorazepate dipotassium                           | Tranxene-SD                    |
| clorazepate dipotassium                           | Tranxene T-Tab                 |
| diazepam  | Diazepam                       |
| diazepam  | Valium                         |
| diazepam  | Diazepam Intensol              |
| diazepam  | Diastat                        |
| diazepam  | Diastat AcuDial                |
| diazepam  | Diastat Pediatric              |
| diazepam  | Diastat Universal              |
| diazepam (in soybean oil)                         | Dizac                          |
| droperidol  | Droperidol                     |
| droperidol  | Inapsine                       |
| halazepam   | Paxipam                        |
| lorazepam   | Ativan                         |
| lorazepam   | Lorazepam                      |
| lorazepam   | Lorazepam Intensol             |
| lorazepam in 0.9 % sodium chloride                | Lorazepam in 0.9% sod chloride |
| lorazepam in 5 % dextrose and water               | Lorazepam in dextrose 5 %      |
| meprobamate                                       | Equanil                        |

## Appendix J. List of Generic and Brand Drug Names Used to Define Covariates in this Request

| Generic Name                           | Brand Name           |
|--|----------------------|
| meprobamate                            | MB-Tab               |
| meprobamate                            | Meprobamate          |
| meprobamate                            | Miltown              |
| oxazepam                               | Oxazepam             |
| oxazepam                               | Serax                |
| <i>Sedative hypnotics</i>              |                      |
| amobarbital sodium/secobarbital sodium | Tuinal               |
| butabarbital sodium                    | Butisol              |
| chloral hydrate                        | Chloral hydrate      |
| chloral hydrate                        | Somnote              |
| chloral hydrate                        | Aquachloral          |
| estazolam                              | Estazolam            |
| estazolam                              | Prosom               |
| eszopiclone                            | Eszopiclone          |
| eszopiclone                            | Lunesta              |
| ethchlorvynol                          | Placidyl             |
| flurazepam HCl                         | Dalmane              |
| flurazepam HCl                         | Flurazepam           |
| mephobarbital                          | Mebaral              |
| mephobarbital                          | Mephobarbital        |
| pentobarbital sodium                   | Nembutal Sodium      |
| pentobarbital sodium                   | Pentobarbital sodium |
| pentobarbital sodium                   | Nembutal             |
| quazepam                               | Doral                |
| quazepam                               | Quazepam             |
| ramelteon                              | Rozerem              |
| secobarbital sodium                    | Seconal              |
| secobarbital sodium                    | Seconal Sodium       |
| suvorexant                             | Belsomra             |
| temazepam                              | Restoril             |
| temazepam                              | Temazepam            |
| temazepam/dietary supplement no.8      | Strazepam            |
| triazolam                              | Halcion              |
| triazolam                              | Triazolam            |
| zaleplon                               | Sonata               |
| zaleplon                               | Zaleplon             |
| zolpidem tartrate                      | Ambien               |
| zolpidem tartrate                      | Ambien CR            |
| zolpidem tartrate                      | AMBIEN PAK           |
| zolpidem tartrate                      | Zolpidem             |
| zolpidem tartrate                      | Zolpimist            |
| zolpidem tartrate                      | Edluar               |
| zolpidem tartrate                      | Intermezzo           |

# Appendix K. Specifications for Parameters for this Request, Part 1

This request utilized the Cohort Identification and Descriptive Analysis (CIDA) tool, version 7.3.5, to identify individuals with asthma and without chronic obstructive pulmonary disease (COPD) who were dispensed either montelukast or inhaled corticosteroids (ICS) in the Sentinel Distributed Database (SDD). We examined the association between montelukast versus ICS use and inpatient depression, outpatient depressive disorder, and self-harm.

|   |  |  |  |  |  |  |
|---|--|--|--|--|--|--|
| <p><b>Query Period:</b> January 1, 2000 - September 30, 2015</p> <p><b>Coverage Requirement:</b> Medical and Drug Coverage</p> <p><b>Pre-index Enrollment Requirement:</b> 183 days</p> <p><b>Post-index Enrollment Requirement:</b> None</p> <p><b>Restrictions:</b> Male and Female only</p> <p><b>Age:</b> 6-11, 12-17, 18+ years</p> <p><b>Enrollment Gap:</b> 45 days</p> <p><b>Envelope Macro:</b> *On: Reclassify encounters during inpatient stay as inpatient;</p> <p><b>Never-exposed Cohort:</b> None</p> <p><b>Additional Output (Dist of Index, MFU):</b> Censoring</p> <p><b>Freeze Data:</b> Yes</p> |  |  |  |  |  |  |
|---|--|--|--|--|--|--|

|   | Comparison 1  |  | Comparison 2   |  | Comparison 3   |  |
|---|---|--|--|--|--|--|
| Logic   | Inpatient Depression  |  | Inpatient Depression;<br>Sensitivity for ICS 30 day extension/gap        |  | Inpatient Depression;<br>Sensitivity for 0 day extension                 |  |
| Group   | Mon_IPDep   | ICS_IPDep  | Mon_IPDep  | ICS_IPDep_30day  | Mon_IPDep_Ext0   | ICS_IPDep_Ext0   |
| Drug/Exposure                                   |   |  |  |  |  |  |
| Exposure/Comparator                             | Montelukast   | ICS monotherapy  | Montelukast  | ICS monotherapy  | Montelukast  | ICS monotherapy  |
| Stockpiling                                     | Generic Name  | Generic Name   | Generic Name   | Generic Name   | Generic Name   | Generic Name   |
| Care Setting/Principal Diagnosis Position (PDX) | Any   | Any  | Any  | Any  | Any  | Any  |
| Episode Gap                                     | 15 days   | 15 days  | 15 days  | 30 days  | 15 days  | 15 days  |
| Episode Extension                               | 15 days   | 15 days  | 15 days  | 30 days  | 0 days   | 0 days   |
| Incident with Respect to:                       | Montelukast, ICS monotherapy, long-acting beta-adrenoceptor agonist (LABAs), ICS combination therapies, or leukotriene receptor antagonists (LTRAs) | Montelukast, ICS monotherapy, LABAs, ICS combination therapies, or LTRAs | Montelukast, ICS monotherapy, LABAs, ICS combination therapies, or LTRAs | Montelukast, ICS monotherapy, LABAs, ICS combination therapies, or LTRAs | Montelukast, ICS monotherapy, LABAs, ICS combination therapies, or LTRAs | Montelukast, ICS monotherapy, LABAs, ICS combination therapies, or LTRAs |
| Incidence Criteria Care Setting/PDX             | Any   | Any  | Any  | Any  | Any  | Any  |
| Washout   | -183 days   | -183 days  | -183 days  | -183 days  | -183 days  | -183 days  |
| Cohort Definition                               | First valid incident treatment episode during the query period  | First valid incident treatment episode during the query period           | First valid incident treatment episode during the query period           | First valid incident treatment episode during the query period           | First valid incident treatment episode during the query period           | First valid incident treatment episode during the query period           |

**Appendix K. Specifications for Parameters for this Request, Part 1**

| Inclusion/Exclusion Criteria             |   |   |   |   |   |   |
|--|---|---|---|---|---|---|
| <b>Criteria</b>                          | Asthma  | Asthma  | Asthma  | Asthma  | Asthma  | Asthma  |
| <b>Type</b>                              | Inclusion   | Inclusion   | Inclusion   | Inclusion   | Inclusion   | Inclusion   |
| <b>Evaluation Window</b>                 | -183, 0   | -183, 0   | -183, 0   | -183, 0   | -183, 0   | -183, 0   |
| <b>Care Setting/PDX</b>                  | Any   | Any   | Any   | Any   | Any   | Any   |
| <b>Criteria</b>                          | Chronic obstructive pulmonary disease (COPD)  | COPD  | COPD  | COPD  | COPD  | COPD  |
| <b>Type</b>                              | Exclusion   | Exclusion   | Exclusion   | Exclusion   | Exclusion   | Exclusion   |
| <b>Evaluation Window</b>                 | -183, 0   | -183, 0   | -183, 0   | -183, 0   | -183, 0   | -183, 0   |
| <b>Care Setting/PDX</b>                  | Any   | Any   | Any   | Any   | Any   | Any   |
| <b>Criteria</b>                          | ICS Monotherapy   | Montelukast   | ICS Monotherapy   | Montelukast   | ICS Monotherapy   | Montelukast   |
| <b>Type</b>                              | Exclusion   | Exclusion   | Exclusion   | Exclusion   | Exclusion   | Exclusion   |
| <b>Evaluation Window</b>                 | 0,0   | 0,0   | 0,0   | 0,0   | 0,0   | 0,0   |
| <b>Care Setting/PDX</b>                  | Any   | Any   | Any   | Any   | Any   | Any   |
| <b>Criteria</b>                          | Primary outcomes: Inpatient Primary Depressive Disorder, Outpatient Depressive Disorder, Self-harm hospitalizations (Patrick et al.), E-codes for Self-Harm | Primary outcomes: Inpatient Primary Depressive Disorder, Outpatient Depressive Disorder, Self-harm hospitalizations (Patrick et al.), E-codes for Self-Harm | Primary outcomes: Inpatient Primary Depressive Disorder, Outpatient Depressive Disorder, Self-harm hospitalizations (Patrick et al.), E-codes for Self-Harm | Primary outcomes: Inpatient Primary Depressive Disorder, Outpatient Depressive Disorder, Self-harm hospitalizations (Patrick et al.), E-codes for Self-Harm | Primary outcomes: Inpatient Primary Depressive Disorder, Outpatient Depressive Disorder, Self-harm hospitalizations (Patrick et al.), E-codes for Self-Harm | Primary outcomes: Inpatient Primary Depressive Disorder, Outpatient Depressive Disorder, Self-harm hospitalizations (Patrick et al.), E-codes for Self-Harm |
| <b>Type</b>                              | Exclusion   | Exclusion   | Exclusion   | Exclusion   | Exclusion   | Exclusion   |
| <b>Evaluation Window</b>                 | 0,0   | 0,0   | 0,0   | 0,0   | 0,0   | 0,0   |
| <b>At Risk Time</b>                      |   |   |   |   |   |   |
| <b>Minimum exposure episode duration</b> | ----  | ----  | ----  | ----  | ----  | ----  |
| <b>Maximum exposure episode duration</b> | ----  | ----  | ----  | ----  | ----  | ----  |

**Appendix K. Specifications for Parameters for this Request, Part 1**

|   |  |  |  |  |  |  |
|---|--|--|--|--|--|--|
| <b>Truncation Criteria</b>                            | (1) Dispensing of ICS monotherapy, LABAs, ICS combination therapies, or LTRAs<br>(2) Dispensing of oral corticosteroid<br>(3) Asthma-related hospitalization in the primary position<br>(4) Death<br>(5) DP End Date<br>(6) Query End Date<br>(7) Disenrollment<br>(8) Outcome<br>(9) End of treatment episode | (1) Dispensing of montelukast, LABAs, ICS combination therapies, or LTRAs<br>(2) Dispensing of oral corticosteroid<br>(3) Asthma-related hospitalization in the primary position<br>(4) Death<br>(5) DP End Date<br>(6) Query End Date<br>(7) Disenrollment<br>(8) Outcome<br>(9) End of treatment episode | (1) Dispensing of ICS monotherapy, LABAs, ICS combination therapies, or LTRAs<br>(2) Dispensing of oral corticosteroid<br>(3) Asthma-related hospitalization in the primary position<br>(4) Death<br>(5) DP End Date<br>(6) Query End Date<br>(7) Disenrollment<br>(8) Outcome<br>(9) End of treatment episode | (1) Dispensing of montelukast, LABAs, ICS combination therapies, or LTRAs<br>(2) Dispensing of oral corticosteroid<br>(3) Asthma-related hospitalization in the primary position<br>(4) Death<br>(5) DP End Date<br>(6) Query End Date<br>(7) Disenrollment<br>(8) Outcome<br>(9) End of treatment episode | (1) Dispensing of ICS monotherapy, LABAs, ICS combination therapies, or LTRAs<br>(2) Dispensing of oral corticosteroid<br>(3) Asthma-related hospitalization in the primary position<br>(4) Death<br>(5) DP End Date<br>(6) Query End Date<br>(7) Disenrollment<br>(8) Outcome<br>(9) End of treatment episode | (1) Dispensing of montelukast, LABAs, ICS combination therapies, or LTRAs<br>(2) Dispensing of oral corticosteroid<br>(3) Asthma-related hospitalization in the primary position<br>(4) Death<br>(5) DP End Date<br>(6) Query End Date<br>(7) Disenrollment<br>(8) Outcome<br>(9) End of treatment episode |
| <b>Blackout Period</b>                                | 1 (no same day exposure outcome, minimum 2 day episode)  | 1 (no same day exposure outcome, minimum 2 day episode)  | 1 (no same day exposure outcome, minimum 2 day episode)  | 1 (no same day exposure outcome, minimum 2 day episode)  | 1 (no same day exposure outcome, minimum 2 day episode)  | 1 (no same day exposure outcome, minimum 2 day episode)  |
| <b>Event/Outcome</b>                                  |  |  |  |  |  |  |
| <b>Event/Outcome</b><br><i>See Appendices D and E</i> | Inpatient Primary Depressive Disorder  | Inpatient Primary Depressive Disorder  | Inpatient Primary Depressive Disorder  | Inpatient Primary Depressive Disorder  | Inpatient Primary Depressive Disorder  | Inpatient Primary Depressive Disorder  |
| <b>Propensity Score Matching</b>                      |  |  |  |  |  |  |
| <b>Covariates</b>                                     | See Appendices I and J   | See Appendices I and J   | See Appendices I and J   | See Appendices I and J   | See Appendices I and J   | See Appendices I and J   |
| <b>Matching Ratio</b>                                 | 1:1  | 1:1  | 1:1  | 1:1  | 1:1  | 1:1  |
| <b>Matching Caliper Settings</b>                      | 0.050  | 0.050  | 0.050  | 0.050  | 0.050  | 0.050  |
| <b>Analysis Type</b>                                  | Unconditional, Conditional   | Unconditional, Conditional   | Unconditional, Conditional   | Unconditional, Conditional   | Unconditional, Conditional   | Unconditional, Conditional   |
| <b>Additional Covariates to Adjust for</b>            | -----  | -----  | -----  | -----  | -----  | -----  |

| Appendix K. Specifications for Parameters for this Request, Part 1   |   |   |   |   |   |   |
|--|---|---|---|---|---|---|
| <b>Subgroup Analysis</b>   | (1) Label change via dichotomous periods (2000-2007, 2008-2015) | (1) Label change via dichotomous periods (2000-2007, 2008-2015) | (1) Label change via dichotomous periods (2000-2007, 2008-2015) | (1) Label change via dichotomous periods (2000-2007, 2008-2015) | (1) Label change via dichotomous periods (2000-2007, 2008-2015) | (1) Label change via dichotomous periods (2000-2007, 2008-2015) |
|  | (2) Sex (Male and Female)                                       | (2) Sex (Male and Female)                                       | (2) Sex (Male and Female)                                       | (2) Sex (Male and Female)                                       | (2) Sex (Male and Female)                                       | (2) Sex (Male and Female)                                       |
|  | (3) Age (6-11, 12-17, 18+)                                      | (3) Age (6-11, 12-17, 18+)                                      | (3) Age (6-11, 12-17, 18+)                                      | (3) Age (6-11, 12-17, 18+)                                      | (3) Age (6-11, 12-17, 18+)                                      | (3) Age (6-11, 12-17, 18+)                                      |
|  | (4) History of psych disorder (y/n)                             | (4) History of psych disorder (y/n)                             | (4) History of psych disorder (y/n)                             | (4) History of psych disorder (y/n)                             | (4) History of psych disorder (y/n)                             | (4) History of psych disorder (y/n)                             |
| <b>Re-matching within subgroup</b>   | From Matched  | From Matched  | From Matched  | From Matched  | From Matched  | From Matched  |
| <b>Effect Estimation</b>   | Risk set level  | Risk set level  | Risk set level  | Risk set level  | Risk set level  | Risk set level  |
| <b>Kaplan Meier Plot</b>   | Yes   | Yes   | Yes   | Yes   | Yes   | Yes   |
| International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) codes are provided by Optum360. National Drug Codes (NDCs) are checked against First Data Bank's "National Drug Data File (NDDF®) Plus." |   |   |   |   |   |   |



| Appendix L. Specifications for Parameters for this Request, Part 2 |  |  |  |  |  |  |
|--|--|--|--|--|--|--|
|  | Comparison 4   |  | Comparison 5   |  | Comparison 6   |  |
| Logic  | Outpatient Depressive Disorder   |  | Self-harm, Patrick et al. algorithm                                      |  | Self-harm, Patrick et al. algorithm<br>OR a self-harm E-code             |  |
| Group  | Mon_OutDep   | ICS_OutDep   | Mon_SelfHarm   | ICS_SelfHarm   | Mon_SelfHarm_Ecode   | ICS_SelfHarm_Ecode   |
| Drug/Exposure  |  |  |  |  |  |  |
| Exposure/Comparator  | Montelukast  | ICS monotherapy  | Montelukast  | ICS monotherapy  | Montelukast  | ICS monotherapy  |
| Stockpiling  | Generic Name   | Generic Name   | Generic Name   | Generic Name   | Generic Name   | Generic Name   |
| Care Setting/PDX   | Any  | Any  | Any  | Any  | Any  | Any  |
| Episode Gap  | 30 days  | 30 days  | 15 days  | 15 days  | 15 days  | 15 days  |
| Episode Extension  | 30 days  | 30 days  | 15 days  | 15 days  | 15 days  | 15 days  |
| Incident with Respect to:  | Montelukast, ICS monotherapy, LABAs, ICS combination therapies, or LTRAs | Montelukast, ICS monotherapy, LABAs, ICS combination therapies, or LTRAs | Montelukast, ICS monotherapy, LABAs, ICS combination therapies, or LTRAs | Montelukast, ICS monotherapy, LABAs, ICS combination therapies, or LTRAs | Montelukast, ICS monotherapy, LABAs, ICS combination therapies, or LTRAs | Montelukast, ICS monotherapy, LABAs, ICS combination therapies, or LTRAs |
| Incidence Criteria Care Setting/PDX                                | Any  | Any  | Any  | Any  | Any  | Any  |
| Washout  | -183 days  | -183 days  | -183 days  | -183 days  | -183 days  | -183 days  |
| Cohort Definition  | First valid incident treatment episode during the query period           | First valid incident treatment episode during the query period           | First valid incident treatment episode during the query period           | First valid incident treatment episode during the query period           | First valid incident treatment episode during the query period           | First valid incident treatment episode during the query period           |
| Inclusion/Exclusion Criteria                                       |  |  |  |  |  |  |
| Criteria   | Asthma   | Asthma   | Asthma   | Asthma   | Asthma   | Asthma   |
| Type   | Inclusion  | Inclusion  | Inclusion  | Inclusion  | Inclusion  | Inclusion  |
| Evaluation Window  | -183, 0  | -183, 0  | -183, 0  | -183, 0  | -183, 0  | -183, 0  |
| Care Setting/PDX   | Any  | Any  | Any  | Any  | Any  | Any  |
| Criteria   | COPD   | COPD   | COPD   | COPD   | COPD   | COPD   |
| Type   | Exclusion  | Exclusion  | Exclusion  | Exclusion  | Exclusion  | Exclusion  |
| Evaluation Window  | -183, 0  | -183, 0  | -183, 0  | -183, 0  | -183, 0  | -183, 0  |
| Care Setting/PDX   | Any  | Any  | Any  | Any  | Any  | Any  |
| Criteria   | ICS Monotherapy  | Montelukast  | ICS Monotherapy  | Montelukast  | ICS Monotherapy  | Montelukast  |
| Type   | Exclusion  | Exclusion  | Exclusion  | Exclusion  | Exclusion  | Exclusion  |
| Evaluation Window  | 0,0  | 0,0  | 0,0  | 0,0  | 0,0  | 0,0  |
| Care Setting/PDX   | Any  | Any  | Any  | Any  | Any  | Any  |

**Appendix L. Specifications for Parameters for this Request, Part 2**

| Criteria                             | Primary outcomes:<br>Inpatient Primary<br>Depressive Disorder,<br>Outpatient Depressive<br>Disorder, Self-harm<br>hospitalizations (Patrick<br>et al.), E-codes for Self-<br>Harm   | Primary outcomes:<br>Inpatient Primary<br>Depressive Disorder,<br>Outpatient Depressive<br>Disorder, Self-harm<br>hospitalizations (Patrick<br>et al.), E-codes for Self-<br>Harm   | Primary outcomes:<br>Inpatient Primary<br>Depressive Disorder,<br>Outpatient Depressive<br>Disorder, Self-harm<br>hospitalizations (Patrick<br>et al.), E-codes for Self-<br>Harm   | Primary outcomes:<br>Inpatient Primary<br>Depressive Disorder,<br>Outpatient Depressive<br>Disorder, Self-harm<br>hospitalizations (Patrick<br>et al.), E-codes for Self-<br>Harm   | Primary outcomes:<br>Inpatient Primary<br>Depressive Disorder,<br>Outpatient Depressive<br>Disorder, Self-harm<br>hospitalizations (Patrick<br>et al.), E-codes for Self-<br>Harm   | Primary outcomes:<br>Inpatient Primary<br>Depressive Disorder,<br>Outpatient Depressive<br>Disorder, Self-harm<br>hospitalizations (Patrick<br>et al.), E-codes for Self-<br>Harm   |
|--------------------------------------|---|---|---|---|---|---|
| Type                                 | Exclusion   | Exclusion   | Exclusion   | Exclusion   | Exclusion   | Exclusion   |
| Evaluation Window                    | 0,0   | 0,0   | 0,0   | 0,0   | 0,0   | 0,0   |
| At Risk Time                         |   |   |   |   |   |   |
| Minimum exposure episode<br>duration | ----  | ----  | ----  | ----  | ----  | ----  |
| Maximum exposure episode<br>duration | ----  | ----  | ----  | ----  | ----  | ----  |
| Truncation Criteria                  | (1) Dispensing of ICS<br>monotherapy, LABAs, ICS<br>combination therapies,<br>or LTRAs<br>(2) Dispensing of oral<br>corticosteroid<br>(3) Asthma-related<br>hospitalization in the<br>primary position<br>(4) Death<br>(5) DP End Date<br>(6) Query End Date<br>(7) Disenrollment<br>(8) Outcome<br>(9) End of treatment<br>episode | (1) Dispensing of<br>montelukast, LABAs, ICS<br>combination therapies,<br>or LTRAs<br>(2) Dispensing of oral<br>corticosteroid<br>(3) Asthma-related<br>hospitalization in the<br>primary position<br>(4) Death<br>(5) DP End Date<br>(6) Query End Date<br>(7) Disenrollment<br>(8) Outcome<br>(9) End of treatment<br>episode | (1) Dispensing of ICS<br>monotherapy, LABAs, ICS<br>combination therapies,<br>or LTRAs<br>(2) Dispensing of oral<br>corticosteroid<br>(3) Asthma-related<br>hospitalization in the<br>primary position<br>(4) Death<br>(5) DP End Date<br>(6) Query End Date<br>(7) Disenrollment<br>(8) Outcome<br>(9) End of treatment<br>episode | (1) Dispensing of<br>montelukast, LABAs, ICS<br>combination therapies,<br>or LTRAs<br>(2) Dispensing of oral<br>corticosteroid<br>(3) Asthma-related<br>hospitalization in the<br>primary position<br>(4) Death<br>(5) DP End Date<br>(6) Query End Date<br>(7) Disenrollment<br>(8) Outcome<br>(9) End of treatment<br>episode | (1) Dispensing of ICS<br>monotherapy, LABAs, ICS<br>combination therapies,<br>or LTRAs<br>(2) Dispensing of oral<br>corticosteroid<br>(3) Asthma-related<br>hospitalization in the<br>primary position<br>(4) Death<br>(5) DP End Date<br>(6) Query End Date<br>(7) Disenrollment<br>(8) Outcome<br>(9) End of treatment<br>episode | (1) Dispensing of<br>montelukast, LABAs, ICS<br>combination therapies,<br>or LTRAs<br>(2) Dispensing of oral<br>corticosteroid<br>(3) Asthma-related<br>hospitalization in the<br>primary position<br>(4) Death<br>(5) DP End Date<br>(6) Query End Date<br>(7) Disenrollment<br>(8) Outcome<br>(9) End of treatment<br>episode |
| Blackout Period                      | 1 (no same day exposure<br>outcome, minimum 2<br>day episode)   | 1 (no same day exposure<br>outcome, minimum 2<br>day episode)   | 1 (no same day exposure<br>outcome, minimum 2<br>day episode)   | 1 (no same day exposure<br>outcome, minimum 2<br>day episode)   | 1 (no same day exposure<br>outcome, minimum 2<br>day episode)   | 1 (no same day exposure<br>outcome, minimum 2<br>day episode)   |
| Event/Outcome                        |   |   |   |   |   |   |

| Appendix L. Specifications for Parameters for this Request, Part 2   |  |  |  |  |  |  |
|--|--|--|--|--|--|--|
| Event/Outcome<br><i>See Appendices D and E</i>   | Outpatient Depressive Disorder   | Outpatient Depressive Disorder   | Self-harm hospitalizations (Patrick et al.)  | Self-harm hospitalizations (Patrick et al.)  | Self-harm hospitalizations (Patrick et al.)<br>OR an E-code for Self-harm  | Self-harm hospitalizations (Patrick et al.)<br>OR an E-code for Self-harm  |
| Propensity Score Matching  |  |  |  |  |  |  |
| Covariates   | See Appendices I and J   | See Appendices I and J   | See Appendices I and J   | See Appendices I and J   | See Appendices I and J   | See Appendices I and J   |
| Matching Ratio   | 1:1  | 1:1  | 1:1  | 1:1  | 1:1  | 1:1  |
| Matching Caliper Settings  | 0.050  | 0.050  | 0.050  | 0.050  | 0.050  | 0.050  |
| Analysis Type  | Unconditional, Conditional   | Unconditional, Conditional   | Unconditional, Conditional   | Unconditional, Conditional   | Unconditional, Conditional   | Unconditional, Conditional   |
| Additional Covariates to Adjust for  | -----  | -----  | -----  | -----  | -----  | -----  |
| Subgroup Analysis  | (1) Label change via dichotomous periods (2000-2007, 2008-2015)<br><br>(2) Sex (Male and Female)<br><br>(3) Age (6-11, 12-17, 18+)<br><br>(4) History of psych | (1) Label change via dichotomous periods (2000-2007, 2008-2015)<br><br>(2) Sex (Male and Female)<br><br>(3) Age (6-11, 12-17, 18+)<br><br>(4) History of psych | (1) Label change via dichotomous periods (2000-2007, 2008-2015)<br><br>(2) Sex (Male and Female)<br><br>(3) Age (6-11, 12-17, 18+)<br><br>(4) History of psych | (1) Label change via dichotomous periods (2000-2007, 2008-2015)<br><br>(2) Sex (Male and Female)<br><br>(3) Age (6-11, 12-17, 18+)<br><br>(4) History of psych | (1) Label change via dichotomous periods (2000-2007, 2008-2015)<br><br>(2) Sex (Male and Female)<br><br>(3) Age (6-11, 12-17, 18+)<br><br>(4) History of psych | (1) Label change via dichotomous periods (2000-2007, 2008-2015)<br><br>(2) Sex (Male and Female)<br><br>(3) Age (6-11, 12-17, 18+)<br><br>(4) History of psych |
| Re-matching within subgroup  | From Matched   | From Matched   | From Matched   | From Matched   | From Matched   | From Matched   |
| Effect Estimation  | Risk set level   | Risk set level   | Risk set level   | Risk set level   | Risk set level   | Risk set level   |
| Kaplan Meier Plot  | Yes  | Yes  | Yes  | Yes  | Yes  | Yes  |
| International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) codes are provided by Optum360. National Drug Codes (NDCs) are checked against First Data Bank's "National Drug Data File (NDDF®) Plus." |  |  |  |  |  |  |

# Appendix M. Specifications Defining Outcomes in this Request

| Outcome  | Operational Definition                                | Care Setting                 | Principal Diagnosis Position | Combo, Time Between | Combo, Date          | Washout |
|--|---|------------------------------|------------------------------|---------------------|----------------------|---------|
| Inpatient Primary Depressive Disorder                                | Depression  | Inpatient                    | Primary                      | N/A                 | N/A                  | 0       |
| Inpatient Primary Depressive Disorder - Episode Extension of 0 Days  | Depression  | Inpatient                    | Primary                      | N/A                 | N/A                  | 0       |
| Outpatient Depressive Disorder                                       | Depression  | Ambulatory, Other Ambulatory | Any                          | ---                 | ---                  | 0       |
|  | Antidepressant  | N/A                          | N/A                          | (0,30)              | 1st component date   | 0       |
|  | Psychotherapy   | Ambulatory, Other Ambulatory | Any                          |                     |                      | 0       |
| Self-harm hospitalizations (algorithm by Patrick et al)              | Depression  | Inpatient                    | Any                          | ---                 | ---                  | 0       |
|  | Personality disorder                                  | Inpatient                    | Any                          | ---                 | ---                  | 0       |
|  | Mania   | Inpatient                    | Any                          | ---                 | ---                  | 0       |
|  | Adjustment reaction                                   | Inpatient                    | Any                          | ---                 | ---                  | 0       |
|  | Unspecified non-psychotic mental disorder             | Inpatient                    | Any                          | ---                 | ---                  | 0       |
|  | Poisoning   | Inpatient                    | Any                          | Same Day            | Inpatient Admin Date | 0       |
|  | Toxicity of a substance chiefly non-medical in nature | Inpatient                    | Any                          |                     |                      | 0       |
|  | Asphyxiation  | Inpatient                    | Any                          |                     |                      | 0       |
|  | Open wound to elbow/wrist/forearm                     | Inpatient                    | Any                          |                     |                      | 0       |
| Self-harm hospitalizations (algorithm by Patrick et al) with E-codes | Depression  | Inpatient                    | Any                          | ---                 | ---                  | 0       |
|  | Personality disorder                                  | Inpatient                    | Any                          | ---                 | ---                  | 0       |
|  | Mania   | Inpatient                    | Any                          | ---                 | ---                  | 0       |
|  | Adjustment reaction                                   | Inpatient                    | Any                          | ---                 | ---                  | 0       |
|  | Unspecified non-psychotic mental disorder             | Inpatient                    | Any                          | ---                 | ---                  | 0       |
|  | Poisoning   | Inpatient                    | Any                          | Same Day            | Inpatient Admin Date | 0       |
|  | Toxicity of a substance chiefly non-medical in nature | Inpatient                    | Any                          |                     |                      | 0       |
|  | Asphyxiation  | Inpatient                    | Any                          |                     |                      | 0       |
|  | Open wound to elbow/wrist/forearm                     | Inpatient                    | Any                          |                     |                      | 0       |
|  | Suicide and self-inflicted injury E-code              | Any                          | Any                          | ---                 | ---                  | 0       |

## Appendix N. Specifications Defining Covariates in this Request

| Covariate  | Table 1 | Propensity Score | Subgroup                   | Care Setting | Principal Diagnosis Position | Evaluation Period Start | Evaluation Period End | Dispensing Evaluation      | Number of Instances the Covariate Should be Found in Evaluation Period |
|--|---------|------------------|----------------------------|--------------|------------------------------|-------------------------|-----------------------|----------------------------|--|
| Comorbidity Score  | Yes     | Yes              | --                         | Any          | Any                          | -183                    | 0                     | N/A                        | 1  |
| Age  | Yes     | Yes (continuous) | Yes (6-11, 12-17, 18+)     | N/A          | N/A                          | N/A                     | N/A                   | N/A                        | N/A  |
| Sex  | Yes     | Yes              | Yes                        | N/A          | N/A                          | N/A                     | N/A                   | N/A                        | N/A  |
| Year   | Yes     | Yes              | Yes (2000-2007, 2008-2015) | N/A          | N/A                          | N/A                     | N/A                   | N/A                        | N/A  |
| History of psychiatric disorder: Psychiatric and psychotropic drugs, self harm, or any other psychiatric event | Yes     | Yes              | Yes                        | Any          | Any                          | -183                    | 0                     | Dispensing and days supply | 1  |
| Psychiatric and psychotropic drugs   | Yes     | --               | --                         | Any          | Any                          | -183                    | 0                     | Dispensing and days supply | 1  |
| Self harm  | Yes     | --               | --                         | Inpatient    | Any                          | -183                    | 0 <sup>1</sup>        | N/A                        | 1  |
| Depression   | Yes     | --               | --                         | Inpatient    | Any                          | -183                    | 0                     | N/A                        | 1  |
| Personality disorder   | Yes     | --               | --                         | Inpatient    | Any                          | -183                    | 0                     | N/A                        | 1  |
| Mania  | Yes     | --               | --                         | Inpatient    | Any                          | -183                    | 0                     | N/A                        | 1  |
| Adjustment reaction  | Yes     | --               | --                         | Inpatient    | Any                          | -183                    | 0                     | N/A                        | 1  |
| Unspecified non-psychotic mental disorder  | Yes     | --               | --                         | Inpatient    | Any                          | -183                    | 0                     | N/A                        | 1  |
| Poisoning  | Yes     | --               | --                         | Inpatient    | Any                          | -183                    | 0                     | N/A                        | 1  |
| Toxicity of a substance chiefly non-medical in nature  | Yes     | --               | --                         | Inpatient    | Any                          | -183                    | 0                     | N/A                        | 1  |
| Asphyxiation   | Yes     | --               | --                         | Inpatient    | Any                          | -183                    | 0                     | N/A                        | 1  |
| Open wound to elbow/wrist/forearm  | Yes     | --               | --                         | Inpatient    | Any                          | -183                    | 0                     | N/A                        | 1  |
| Any other psychiatric event  | Yes     | --               | --                         | Any          | Any                          | -183                    | 0                     | N/A                        | 1  |
| Substance Abuse  | Yes     | Yes              | --                         | Any          | Any                          | -183                    | 0                     | N/A                        | 1  |
| Allergic Rhinitis  | Yes     | Yes              | --                         | Any          | Any                          | -183                    | 0                     | N/A                        | 1  |
| Respiratory Disorder (other than chronic obstructive pulmonary disease or asthma), at least 2                  | Yes     | Yes              | --                         | Any          | Any                          | -183                    | 0                     | N/A                        | 2  |
| Asthma, Emergency  | Yes     | Yes              | --                         | Emergency    | N/A                          | -183                    | 0                     | N/A                        | 1  |
| Asthma, Inpatient Primary  | Yes     | Yes              | --                         | Inpatient    | Primary                      | -183                    | 0 <sup>1</sup>        | N/A                        | 1  |
| Asthma, Inpatient Secondary or Unknown   | Yes     | Yes              | --                         | Inpatient    | Secondary, Unknown           | -183                    | 0                     | N/A                        | 1  |

## Appendix N. Specifications Defining Covariates in this Request

| Covariate   | Table 1 | Propensity Score | Subgroup | Care Setting                 | Principal Diagnosis Position | Evaluation Period Start | Evaluation Period End | Dispensing Evaluation      | Number of Instances the Covariate Should be Found in Evaluation Period |
|---|---------|------------------|----------|------------------------------|------------------------------|-------------------------|-----------------------|----------------------------|--|
| Asthma, Outpatient                                      | Yes     | Yes              | --       | Ambulatory, Other Ambulatory | N/A                          | -183                    | 0                     | N/A                        | 2  |
| Asthma Exacerbations/Status Asthmaticus                 | Yes     | Yes              | --       | Any                          | Any                          | -183                    | 0                     | N/A                        | 1  |
| Oral Corticosteroid                                     | Yes     | Yes              | --       | N/A                          | N/A                          | -183                    | 0                     | Dispensing and days supply | 1  |
| Other asthma medications : Short acting beta-agonists   | Yes     | Yes              | --       | N/A                          | N/A                          | -183                    | 0                     | Dispensing and days supply | 1  |
| Other asthma medications : Anticholinergic agents       | Yes     | Yes              | --       | N/A                          | N/A                          | -183                    | 0                     | Dispensing and days supply | 1  |
| Other asthma medications : Phosphodiesterase inhibitors | Yes     | Yes              | --       | N/A                          | N/A                          | -183                    | 0                     | Dispensing and days supply | 1  |

<sup>1</sup> Evaluation on day 0 is limited to those members entering the cohort

For Inpatient Primary Asthma, which is additionally an exclusion criteria, members are dropped for evidence of the censoring criteria on the

For Self-harm, which is additionall an outcome, members are dropped for evidence of the outcome on the index date due to the blackout.

# Appendix O. Design Diagram for this Request

## Inpatient Primary Depressive Disorder

