

## 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\_mpl1r\_wp181

Request ID: cder\_mpl1r\_wp181\_nsdp\_v02

<u>Request Description:</u> In this report we tabulated the duration of first use among new users of dry powder inhalers (DPI) and metered dose inhalers (MDI) containing corticosteroid and long acting beta agonists (LABA) with asthma or chronic obstructive pulmonary disease (COPD).

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 9.3.0

<u>Data Source:</u> We distributed this request to 16 Sentinel Data Partners on April 3, 2020. The study period included data from May 10, 2013 through September 30, 2019. Please see Appendix A for a list of dates of available data for each Data Partner.

**Exposures of Interest:** The exposures of interest were Advair Diskus, Breo Ellipta, Symbicort, Airduo Respiclick, Advair HFA, and Dulera. Advair HFA and Dulera were grouped into a single exposure. We defined the exposures using outpatient pharmacy dispensing records and National Drug Codes (NDCs). Please see Appendix B for a list of generic and brand names of medical products used to define exposures in this request.

<u>Cohort Eligibility Criteria:</u> We required members to be enrolled in health plans with both medical and drug coverage for at least 365 days prior to their index date, during which gaps in coverage of up to 45 days were allowed. We excluded patients aged less than 4 years old on the index date. For each exposure group, we created two mutually exclusive cohorts. The first cohort required that patients had a recorded asthma or asthma exacerbation diagnosis and no evidence of COPD or COPD exacerbation in the year prior to the start of exposure. The second cohort required a COPD or COPD exacerbation diagnosis and no evidence of asthma or asthma exacerbation in the year prior to the start of exposure.

See Appendix C for a list of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes used to define asthma and COPD.

<u>Duration of Incident Use:</u> We evaluated the duration of first use among new users of each exposure of interest. New use was defined as not having a prior dispensing for the exposure of interest in the preceding 365 days. We only considered the first valid index date for each patient. Duration of exposure was based on the number of days supplied in the outpatient pharmacy dispensing records. We bridged together episodes less than 30 days apart, and applied a 30-day episode extension to the final dispensing. Patients were censored upon discontinuation of the index exposure, disenrollment from the health plan, death, or the end of available data from that Data Partner.

Please see Appendix D for the specifications used to define parameters in this request.

<u>Limitations:</u> As with all observational studies, this evaluation was limited in its ability to control for all sources of potential bias. Algorithms used to define exposures, event outcomes, inclusion and exclusion criteria, and covariates are imperfect and may be misclassified. Therefore, data should be interpreted with this limitation in mind.

<u>Notes:</u> Please contact the Sentinel Operations Center (info@sentinelsystem.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel's routine querying modules, please refer to the documentation (https://dev.sentinelsystem.org/projects/SENTINEL/repos/sentinel-routine-querying-tool-documentation/browse).



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# Glossary of Terms for Analyses Using Cohort Identification and Descriptive Analysis (CIDA) Module\*

**Amount Supplied** - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing. **Blackout Period** - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.

Care Setting - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency Department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or Missing (U). The Care Setting, along with the Principal Diagnosis Indicator (PDX), forms the Care Setting/PDX parameter.

**Ambulatory Visit (AV)** - includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.

**Emergency Department (ED)** - includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.

**Inpatient Hospital Stay (IP)** - includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date.

**Non-Acute Institutional Stay (IS)** - includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.

**Other Ambulatory Visit (OA)** - includes other non overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone and email consultations.

**Charlson/Elixhauser Combined Comorbidity Score** - calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (e.g., in the 183 days prior to index).

**Code Days** - the minimum number of times the diagnosis must be found during the evaluation period in order to fulfill the algorithm to identify the corresponding patient characteristic.

**Cohort Definition (drug/exposure)** - indicates how the cohort will be defined: 01: Cohort includes only the first valid treatment episode during the query period; 02: Cohort includes all valid treatment episodes during the query period; 03: Cohort includes all valid treatment episodes during the query period until an event occurs.

**Computed Start Marketing Date -** represents the first observed dispensing date among all valid users within a GROUP (scenario) within each Data Partner site.

Days Supplied - number of days supplied for all dispensings in qualifying treatment episodes.

**Eligible Members** - number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

**Enrollment Gap** - number of days allowed between two consecutive enrollment periods without breaking a "continuously enrolled" sequence.

**Episodes** - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the episode gap.

**Episode Gap** - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment episode.

**Event Deduplication** - specifies how events are counted by the Modular Program (MP) algorithm: 0: Counts all occurrences of a health outcome of interest (HOI) during an exposure episode; 1: de-duplicates occurrences of the same HOI code and code type on the same day; 2: de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

**Exposure Episode Length** - number of days after exposure initiation that is considered "exposed time." **Exposure Extension Period** - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extensions are added after any episode gaps have been bridged.

**Lookback Period** - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).



**Maximum Episode Duration** - truncates exposure episodes after a requester-specified number of exposed days. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

**Member-Years** - sum of all days of enrollment with medical and drug coverage in the query period preceded by an exposure washout period all divided by 365.25.

**Minimum Days Supplied -** specifies a minimum number of days in length of the days supplied for the episode to be considered.

**Minimum Episode Duration -** specifies a minimum number of days in length of the episode for it to be considered. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

**Monitoring Period** - used to define time periods of interest for both sequential analysis and simple cohort characterization requests.

**Principal Diagnosis (PDX)** - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.

**Query Period** - period in which the modular program looks for exposures and outcomes of interest.

**Switch Evaluation Step Value** - value used to differentiate evaluation step. Each switch pattern can support up to 2 evaluation steps (0 = switch pattern evaluation start; 1 = first evaluation; 2 = second evaluation).

**Switch Gap Inclusion Indicator - i**ndicator for whether gaps in treatment episodes that are included in a switch episode will be counted as part of the switch episode duration.

**Switch Pattern Cohort Inclusion Date** - indicates which date to use for inclusion into the switch pattern cohort of interest as well as optionally as the index date of the treatment episode initiating the switch pattern. Valid options are the product approval date, product marketing date, other requester defined date, or computed start marketing date.

**Switch Pattern Cohort Inclusion Strategy** - indicates how the switch pattern cohort inclusion date will be used: 01: used only as a switch cohort entry date. First treatment episode dispensing date is used as index for computing time to first switch; 02: used as switch cohort entry date and as initial switch step index date for computing time to first switch.

**Treatment Episode Truncation Indicator** - indicates whether the exposure episode will be truncated at the occurrence of a requester-specified code.

**Washout Period (drug/exposure)** - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.

**Washout Period (event/outcome)** - number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

Years at Risk - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

<sup>\*</sup>all terms may not be used in this report



Table 1: Summary of Incident Inhaled Corticosteroid/Long-acting Beta-Agonist (ICS/LABA) Inhaler Use among Members with a History of Asthma or Chronic Obstructive Pulmonary Disease (COPD) in the Sentinel Distributed Database (SDD) between May 10, 2013 to September 30, 2019, Overall

	New Users	Days At Risk	Years at Risk
May 10, 2013 - September 30, 2019			
New Users of Advair Diskus with Asthma	314,478	37,788,487	103,459.2
New Users of Breo Ellipta with Asthma	185,603	30,382,464	83,182.7
New Users of Symbicort with Asthma	304,889	35,760,310	97,906.4
New Users of Airduo Respiclick with Asthma	228	19,925	54.6
New Users of Advair HFA or Dulera with Asthma	169,825	19,231,480	52,652.9
New Users of Advair Diskus with Chronic Obstructive Pulmonary Disease (COPD)	643,097	92,505,330	253,265.8
New Users of Breo Ellipta with COPD	369,649	67,417,292	184,578.5
New Users of Symbicort with COPD	751,622	113,857,724	311,725.5
New Users of Airduo Respiclick with COPD	153	11,147	30.5
New Users of Advair HFA or Dulera with COPD	219,658	30,632,348	83,866.8



Table 2. Summary of Duration of Incident Inhaled Corticosteroid/Long-acting Beta-Agonist (ICS/LABA) Use in the Sentinel Distributed Database (SDD) between May 10, 2013 and September 30, 2019<sup>1</sup>

Number of Episodes by Duration of Incident Use

0-30 days 31-90 days 91-270 days 271-360 days 361+ days

			-	1	-	1	-	1	•	1	1
	Total Number	Number of	% Total								
	of Episodes	Episodes	Episodes	Episodes	Episodes	Episodes	Episodes	Episodes	Episodes	Episodes	Episodes
New Users of Advair Diskus with Asthma	314,478	7,887	2.5%	190,510	60.6%	91,165	29.0%	8,358	2.7%	16,558	5.3%
New Users of Breo Ellipta with Asthma	185,603	6,729	3.6%	90,103	48.5%	58,792	31.7%	9,090	4.9%	20,889	11.3%
New Users of Symbicort with Asthma	304,889	10,730	3.5%	187,915	61.6%	83,278	27.3%	8,083	2.7%	14,883	4.9%
New Users of Airduo Respiclick with Asthma	228	11	4.8%	160	70.2%	****	****	****	****	****	****
New Users of Advair HFA or Dulera with Asthma	169,825	4,354	2.6%	107,682	63.4%	46,368	27.3%	4,233	2.5%	7,188	4.2%
New Users of Advair Diskus with Chronic Obstructive Pulmonary Disease (COPD)	643,097	14,553	2.3%	368,092	57.2%	190,159	29.6%	20,895	3.2%	49,398	7.7%
New Users of Breo Ellipta with COPD	369,649	11,714	3.2%	174,573	47.2%	116,091	31.4%	18,438	5.0%	48,833	13.2%
New Users of Symbicort with COPD	751,622	20,197	2.7%	423,198	56.3%	217,474	28.9%	26,150	3.5%	64,603	8.6%
New Users of Airduo Respiclick with COPD	153	****	****	116	75.8%	****	****	****	****	0	0.0%
New Users of Advair HFA or Dulera with COPD	219,658	4,999	2.3%	129,109	58.8%	62,478	28.4%	7,174	3.3%	15,898	7.2%

<sup>&</sup>lt;sup>1</sup>A 30-day exposure extension was applied to each dispensing and included in duration of use calculations

<sup>\*\*\*\*\*</sup>Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.



Table 2. Summary of Duration of Incident Inhaled Corticosteroid/Long-acting Beta-Agonist (ICS/LABA) Use in the Sentinel Distributed Database (SDD) between May 10, 2013 and September 30, 2019<sup>1</sup>

	Minimum	01	Median	03	Maximum	Mean	Standard
New Users of Advair	1	<b>Q1</b> 60	60	<b>Q3</b> 120		120	Deviation 143
Diskus with Asthma	1	60	60	120	2,239	120	145
New Users of Breo Ellipta with Asthma	1	60	90	180	1,936	164	190
New Users of Symbicort with Asthma	1	60	60	120	2,237	117	141
New Users of Airduo Respiclick with Asthma	1	60	60	91	488	87	70
New Users of Advair HFA or Dulera with Asthma	1	60	60	120	2,245	113	134
New Users of Advair Diskus with Chronic Obstructive Pulmonary Disease (COPD)	1	60	60	123	2,329	144	201
New Users of Breo Ellipta with COPD	1	60	90	203	2,059	182	228
New Users of Symbicort with COPD	1	60	60	140	2,279	151	215
New Users of Airduo Respiclick with COPD	10	60	60	70	339	73	42
New Users of Advair HFA or Dulera with COPD	1	60	60	123	2,304	139	189

<sup>&</sup>lt;sup>1</sup>A 30-day exposure extension was applied to each dispensing and included in duration of use calculations



Table 3a. Summary of Reasons for Censoring in the Sentinel Distributed Database (SDD) between May 10, 2013 and September 30, 2019<sup>1</sup>

Treatment Disenrollment Discontinuation Death **Data Partner End Date Total Number** Number of % Total Number of % Total Number of % Total Number of % Total of Episodes **Episodes Episodes Episodes Episodes Episodes Episodes Episodes Episodes** New Users of Advair Diskus with 314,478 277,924 88.4% 32,795 10.4% 1,322 0.4% 19,897 6.3% Asthma New Users of Breo Ellipta with Asthma 185,603 140.119 75.5% 44,219 23.8% 1,132 0.6% 32,170 17.3% 9.7% New Users of Symbicort with Asthma 304,889 257,602 84.5% 15.2% 1,299 0.4% 46,330 29,438 New Users of Airduo Respiclick with 228 200 87.7% 26 11.4% 0 0.0% 17 7.5% **Asthma** New Users of Advair HFA or Dulera with 169,825 151,676 89.3% 17,373 10.2% 467 0.3% 9,149 5.4% Asthma New Users of Advair Diskus with 643,097 572,320 89.0% 42,251 6.6% 28,329 4.4% 20,679 3.2% Chronic Obstructive Pulmonary Disease (COPD) New Users of Breo Ellipta with COPD 369,649 289,617 78.3% 62,152 16.8% 18,913 5.1% 45,393 12.3% New Users of Symbicort with COPD 751,622 86.0% 76,467 10.2% 31,010 4.1% 46,211 6.1% 646,167 \*\*\*\* \*\*\*\* \*\*\*\* \*\*\*\* New Users of Airduo Respiclick with 153 134 87.6% 12 7.8% COPD New Users of Advair HFA or Dulera with 219,658 196,727 89.6% 6.8% 8,276 3.3% 15,014 3.8% 7,166 COPD

<sup>&</sup>lt;sup>1</sup>An episode may be censored due to more than one reason if they occur on the same date. Therefore, the sum of the reasons for censoring may be greater than the total number of episodes.

<sup>\*\*\*\*\*</sup>Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.



Table 3b. Summary of Duration of Incident Inhaled Corticosteroid/Long-acting Beta-Agonist (ICS/LABA) Use among Users Censored due to Treatment Discontinuation in the Sentinel Distributed Database (SDD) between May 10, 2013 and September 30, 2019<sup>1</sup>

Number of Episodes by Duration of Incident Use 0-30 days 31-90 days 91-270 days 271-360 days 361+ days **Total Number of Episodes Censored due** to Treatment Number of % Total **Episodes Episodes** Discontinuation **Episodes Episodes Episodes Episodes Episodes Episodes Episodes Episodes** New Users of Advair 277,924 0.0% 178,862 64.4% 82,994 29.9% 6,536 2.4% 9,532 3.4% Diskus with Asthma New Users of Breo Ellipta 0 0.0% 79.090 56.4% 46.234 33.0% 5.817 4.2% 8.978 6.4% 140.119 with Asthma New Users of Symbicort 257,602 0 0.0% 171,757 66.7% 71,604 27.8% 5,935 2.3% 8,306 3.2% with Asthma \*\*\*\* \*\*\*\* \*\*\*\* \*\*\*\* \*\*\*\* \*\*\*\* New Users of Airduo 200 0 0.0% 146 73.0% Respiclick with Asthma New Users of Advair HFA 151,676 0 0.0% 101,233 66.7% 42,039 27.7% 2.3% 4,986 3.3% 3,418 or Dulera with Asthma New Users of Advair 0 572,320 0.0% 346,722 60.6% 174,191 30.4% 17,290 3.0% 34,117 6.0% Diskus with Chronic **Obstructive Pulmonary** Disease (COPD) New Users of Breo Ellipta 289.617 0 0.0% 155.283 53.6% 95.843 33.1% 13.132 4.5% 25.359 8.8% with COPD 192,170 New Users of Symbicort 646,167 0 0.0% 392,429 60.7% 29.7% 20,523 3.2% 41,045 6.4% with COPD \*\*\*\* \*\*\*\* \*\*\*\* \*\*\*\* 0 New Users of Airduo 134 0 0.0% 106 79.1% 0.0% Respiclick with COPD

196,727

0.0%

121,712

61.9%

57,065

29.0%

6,021

3.1%

11,929

6.1%

0

New Users of Advair HFA

or Dulera with COPD

<sup>&</sup>lt;sup>1</sup>A 30-day exposure extension was applied to each dispensing and included in duration of use calculations

<sup>\*\*\*\*\*</sup>Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.



Table 3b. Summary of Duration of Incident Inhaled Corticosteroid/Long-acting Beta-Agonist (ICS/LABA) Use among Users Censored due to Treatment Discontinuation in the Sentinel Distributed Database (SDD) between May 10, 2013 and September 30, 2019<sup>1</sup>

	Minimum	Q1	Median	Q3	Maximum	Mean	Standard Deviation
New Users of Advair Diskus with Asthma	31	60	60	120	2,158	110	112
New Users of Breo Ellipta with Asthma	31	60	90	148	1,642	133	132
New Users of Symbicort with Asthma	31	60	60	120	2,018	107	106
New Users of Airduo Respiclick with Asthma	31	60	60	102	488	92	70
New Users of Advair HFA or Dulera with Asthma	31	60	60	120	1,997	107	111
New Users of Advair Diskus with Chronic Obstructive Pulmonary Disease (COPD)	31	60	60	120	2,250	131	166
New Users of Breo Ellipta with COPD	31	60	90	159	1,909	151	171
New Users of Symbicort with COPD	31	60	60	120	2,178	133	160
New Users of Airduo Respiclick with COPD	31	60	60	90	339	77	42
New Users of Advair HFA or Dulera with COPD	31	60	60	120	2,163	130	159

<sup>&</sup>lt;sup>1</sup>A 30-day exposure extension was applied to each dispensing and included in duration of use calculations

<sup>\*\*\*\*\*</sup>Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.



Table 3c. Summary of Duration of Incident Inhaled Corticosteroid/Long-acting Beta-Agonist (ICS/LABA) Use among Users Censored due to Disenrollment in the Sentinel Distributed Database (SDD) between May 10, 2013 and September 30, 2019<sup>1</sup>

Number of Episodes by Duration of Incident Use
0-30 days 31-90 days 91-270 days 271-360 days 361+ days

		1	1	· •		11		11		11	1
	Total Number of	Number of	% Total	Number of	% Total	Number of	0/ Total	Number of	% Total	Number of	% Total
	Episodes Censored due		% Total	Number of	% Total		% Total	Number of	% Total	Number of	
	to Disenrollment	Episodes	Episodes	Episodes	Episodes	Episodes	Episodes	Episodes	Episodes	Episodes	Episodes
New Users of Advair	32,795	7,232	22.1%	10,876	33.2%	7,269	22.2%	1,438	4.4%	5,980	18.2%
Diskus with Asthma											
New Users of Breo Ellipta	44,219	6,504	14.7%	10,720	24.2%	12,217	27.6%	3,163	7.2%	11,615	26.3%
with Asthma											
New Users of Symbicort	46,330	10,463	22.6%	15,974	34.5%	11,408	24.6%	2,083	4.5%	6,402	13.8%
with Asthma											
New Users of Airduo	26	****	****	14	53.8%	****	****	****	****	0	0.0%
Respiclick with Asthma											
New Users of Advair HFA	17,373	4,164	24.0%	6,243	35.9%	4,135	23.8%	772	4.4%	2,059	11.9%
or Dulera with Asthma	,	,		•		,				•	
New Users of Advair	42,251	7,909	18.7%	11,914	28.2%	9,455	22.4%	2,064	4.9%	10,909	25.8%
Diskus with Chronic	, -	,		,-		-,		,		-,	
Obstructive Pulmonary											
Disease (COPD)											
New Users of Breo Ellipta	62,152	8,232	13.2%	13,955	22.5%	15,497	24.9%	4,202	6.8%	20,266	32.6%
with COPD	02,132	0,232	13.270	10,555	22.570	13, 137	21.370	1,202	0.070	20,200	32.070
New Users of Symbicort	76,467	13,611	17.8%	21,432	28.0%	18,667	24.4%	4,107	5.4%	18,650	24.4%
with COPD	70,407	13,011	17.070	21,432	20.070	18,007	24.470	4,107	J. <del>4</del> 70	10,030	24.470
	12	****	****	****	****	0	0.00/	0	0.00/	0	0.00/
New Users of Airduo	12	4- 4- 4- 4- 4-	7, 4, 4, 4, 4,	45 45 45 45 45	4-4-4-4-4-	0	0.0%	0	0.0%	0	0.0%
Respiclick with COPD											
New Users of Advair HFA	15,014	2,999	20.0%	4,637	30.9%	3,677	24.5%	790	5.3%	2,911	19.4%
or Dulera with COPD											

<sup>&</sup>lt;sup>1</sup>A 30-day exposure extension was applied to each dispensing and included in duration of use calculations

<sup>\*\*\*\*\*</sup>Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.



Table 3c. Summary of Duration of Incident Inhaled Corticosteroid/Long-acting Beta-Agonist (ICS/LABA) Use among Users Censored due to Disenrollment in the Sentinel Distributed Database (SDD) between May 10, 2013 and September 30, 2019<sup>1</sup>

	Minimum	Q1	Median	Q3	Maximum	Mean	Standard Deviation
New Users of Advair	1	34	76	235	2,239	195	272
Diskus with Asthma							
New Users of Breo Ellipta	1	52	139	381	1,936	259	286
with Asthma							
New Users of Symbicort	1	33	71	187	2,237	171	253
with Asthma							
New Users of Airduo	1	21	48	67	312	59	63
Respiclick with Asthma							
New Users of Advair HFA	1	32	63	168	2,202	160	249
or Dulera with Asthma							
New Users of Advair	1	41	103	382	2,329	293	416
Diskus with Chronic							
Obstructive Pulmonary							
Disease (COPD)							
New Users of Breo Ellipta	1	55	169	479	2,059	322	362
with COPD							
New Users of Symbicort	1	42	107	349	2,279	293	424
with COPD							
New Users of Airduo	10	16	39	48	67	35	19
Respiclick with COPD							
New Users of Advair HFA	1	38	88	265	2,256	245	377
or Dulera with COPD							

<sup>&</sup>lt;sup>1</sup>A 30-day exposure extension was applied to each dispensing and included in duration of use calculations

<sup>\*\*\*\*\*</sup>Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.



Table 3d. Summary of Duration of Incident Inhaled Corticosteroid/Long-acting Beta-Agonist (ICS/LABA) Use among Users Censored due to Death in the Sentinel Distributed Database (SDD) between May 10, 2013 and September 30, 2019<sup>1</sup>

Number of Episodes by Duration of Incident Use
0-30 days 31-90 days 91-270 days 271-360 days 361+ days

		1	l			11				11	
	Total Number of Episodes Censored due to Death	Number of Episodes	% Total	Number of Episodes	% Total Episodes	Number of Episodes	% Total	Number of Episodes	% Total	Number of Episodes	% Total Episodes
New Users of Advair Diskus with Asthma	1,322	302	22.8%	432	32.7%	300	22.7%	80	6.1%	208	15.7%
New Users of Breo Ellipta with Asthma	1,132	180	15.9%	338	29.9%	314	27.7%	88	7.8%	212	18.7%
New Users of Symbicort with Asthma	1,299	269	20.7%	454	34.9%	329	25.3%	66	5.1%	181	13.9%
New Users of Airduo Respiclick with Asthma	0	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
New Users of Advair HFA or Dulera with Asthma	467	107	22.9%	178	38.1%	104	22.3%	18	3.9%	60	12.8%
New Users of Advair Diskus with Chronic Obstructive Pulmonary Disease (COPD)	28,329	6,791	24.0%	9,931	35.1%	6,432	22.7%	1,342	4.7%	3,833	13.5%
New Users of Breo Ellipta with COPD	18,913	3,610	19.1%	5,765	30.5%	5,044	26.7%	1,159	6.1%	3,335	17.6%
New Users of Symbicort with COPD	31,010	6,864	22.1%	10,221	33.0%	7,153	23.1%	1,614	5.2%	5,158	16.6%
New Users of Airduo Respiclick with COPD	****	****	****	****	****	****	****	0	0.0%	0	0.0%
New Users of Advair HFA or Dulera with COPD	8,276	2,058	24.9%	2,976	36.0%	1,803	21.8%	380	4.6%	1,059	12.8%

<sup>&</sup>lt;sup>1</sup>A 30-day exposure extension was applied to each dispensing and included in duration of use calculations

<sup>\*\*\*\*\*</sup>Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.



Table 3d. Summary of Duration of Incident Inhaled Corticosteroid/Long-acting Beta-Agonist (ICS/LABA) Use among Users Censored due to Death in the Sentinel Distributed Database (SDD) between May 10, 2013 and September 30, 2019<sup>1</sup>

							Standard
	Minimum	Q1	Median	Q3	Maximum	Mean	Deviation
New Users of Advair Diskus with Asthma	1	34	77	224	1,955	182	255
New Users of Breo Ellipta vith Asthma	1	45	109	287	1,423	196	217
New Users of Symbicort with Asthma	1	35	73	200	1,917	174	244
New Users of Airduo Respiclick with Asthma							
New Users of Advair HFA or Dulera with Asthma	2	34	70	162	1,445	160	239
New Users of Advair Diskus with Chronic Dbstructive Pulmonary Disease (COPD)	1	32	63	186	2,065	171	261
New Users of Breo Ellipta with COPD	1	39	92	258	1,934	198	250
New Users of Symbicort with COPD	1	34	74	228	2,194	198	293
New Users of Airduo Respiclick with COPD	23	24	40	59	134	50	39
New Users of Advair HFA or Dulera with COPD	1	31	59	177	2,031	160	241

<sup>&</sup>lt;sup>1</sup>A 30-day exposure extension was applied to each dispensing and included in duration of use calculations

<sup>\*\*\*\*\*</sup>Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.



Table 3e. Summary of Duration of Incident Inhaled Corticosteroid/Long-acting Beta-Agonist (ICS/LABA) Use among Users Censored due to Data Partner End Date in the Sentinel Distributed Database (SDD) between May 10, 2013 and September 30, 2019<sup>1</sup>

					Number of	Episodes by D	Ouration of	Incident Use			
		0-30	days	31-90		91-270		271-36	0 days	361+	days
	Total Number of Episodes Censored due to Data Partner End Date	Number of Episodes	% Total	Number of Episodes	% Total	Number of Episodes	% Total Episodes	Number of Episodes	% Total	Number of Episodes	% Total Episodes
New Users of Advair Diskus	19,897	3,260	16.4%	5,542	27.9%	4,422	22.2%	1,029	5.2%	5,644	28.4%
with Asthma	13,037	3,200	10.470	3,342	27.570	7,722	22.270	1,023	3.270	3,044	20.470
New Users of Breo Ellipta	32,170	4,149	12.9%	7,321	22.8%	8,515	26.5%	2,220	6.9%	9,965	31.0%
with Asthma											
New Users of Symbicort with Asthma	29,438	5,837	19.8%	9,749	33.1%	7,362	25.0%	1,356	4.6%	5,134	17.4%
New Users of Airduo	17	****	****	****	****	****	****	0	0.0%	0	0.0%
Respiclick with Asthma											
New Users of Advair HFA or Dulera with Asthma	9,149	1,709	18.7%	3,076	33.6%	2,339	25.6%	444	4.9%	1,581	17.3%
New Users of Advair Diskus with Chronic Obstructive Pulmonary Disease (COPD)	20,679	2,822	13.6%	4,650	22.5%	4,057	19.6%	1,013	4.9%	8,137	39.3%
New Users of Breo Ellipta with COPD	45,393	5,370	11.8%	9,547	21.0%	10,612	23.4%	2,894	6.4%	16,970	37.4%
New Users of Symbicort with COPD	46,211	7,266	15.7%	12,149	26.3%	10,772	23.3%	2,303	5.0%	13,721	29.7%
New Users of Airduo Respiclick with COPD	****	****	****	****	****	0	0.0%	0	0.0%	0	0.0%
New Users of Advair HFA or Dulera with COPD	7,166	1,220	17.0%	2,056	28.7%	1,656	23.1%	359	5.0%	1,875	26.2%

<sup>&</sup>lt;sup>1</sup>A 30-day exposure extension was applied to each dispensing and included in duration of use calculations

<sup>\*\*\*\*\*</sup>Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.



Table 3e. Summary of Duration of Incident Inhaled Corticosteroid/Long-acting Beta-Agonist (ICS/LABA) Use among Users Censored due to Data Partner End Date in the Sentinel Distributed Database (SDD) between May 10, 2013 and September 30, 2019<sup>1</sup>

	Minimum	Q1	Median	Q3	Maximum	Mean	Standard Deviation
New Users of Advair Diskus with Asthma	1	45	114	442	2,239	262	311
New Users of Breo Ellipta with Asthma	1	56	160	445	1,936	291	307
New Users of Symbicort with Asthma	1	38	83	229	2,237	199	284
New Users of Airduo Respiclick with Asthma	10	21	33	56	173	44	38
New Users of Advair HFA or Dulera with Asthma	1	40	84	228	2,245	208	305
New Users of Advair Diskus with Chronic Obstructive Pulmonary Disease (COPD)	1	54	186	585	2,329	417	500
New Users of Breo Ellipta with COPD	1	61	202	542	2,059	360	386
New Users of Symbicort with COPD	1	47	124	457	2,279	355	486
New Users of Airduo Respiclick with COPD	10	12	31	41	67	31	19
New Users of Advair HFA or Dulera with COPD	1	42	108	396	2,304	330	476

<sup>&</sup>lt;sup>1</sup>A 30-day exposure extension was applied to each dispensing and included in duration of use calculations

<sup>\*\*\*\*\*</sup>Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.



Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (April 3, 2020)

Masked ID	DP Start Date <sup>1</sup>	DP End Date <sup>1</sup>
DP01	06/01/2007	07/31/2019
DP02	01/01/2000	02/28/2019
DP03	01/01/2000	04/30/2019
DP04	01/01/2008	09/30/2019
DP05	01/01/2006	06/30/2019
DP06	01/01/2000	12/31/2017
DP07	01/01/2010	06/30/2019
DP08	01/01/2005	07/31/2018
DP09	01/01/2000	04/30/2018
DP10	01/01/2000	03/31/2019
DP11	01/01/2000	01/31/2019
DP12	01/01/2000	07/31/2019
DP13	01/01/2004	08/31/2019
DP14	01/01/2008	03/31/2019
DP15	01/01/2000	06/30/2019
DP16	01/01/2012	06/30/2018

<sup>&</sup>lt;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 Names of Medical Products Used to Define Index Exposure in this Request

Generic Name	Brand Name
fluticasone propionate/salmeterol xinafoate	Advair Diskus
budesonide/formoterol fumarate	Symbicort
mometasone furoate/formoterol fumarate	Dulera
fluticasone propionate/salmeterol xinafoate	Advair HFA
fluticasone furoate/vilanterol trifenatate	Breo Ellipta
fluticasone propionate/salmeterol xinafoate	Airduo RespiClick



Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Category	Code Type
	Asthma		
493	Extrinsic asthma, unspecified	Diagnosis	ICD-9-CM
493.1	Intrinsic asthma, unspecified	Diagnosis	ICD-9-CM
493.02	Extrinsic asthma, with (acute) exacerbation	Diagnosis	ICD-9-CM
493.12	Intrinsic asthma, with (acute) exacerbation	Diagnosis	ICD-9-CM
493.01	Extrinsic asthma with status asthmaticus	Diagnosis	ICD-9-CM
493.11	Intrinsic asthma with status asthmaticus	Diagnosis	ICD-9-CM
493.92	Asthma, unspecified, with (acute) exacerbation	Diagnosis	ICD-9-CM
493.91	Asthma, unspecified with status asthmaticus	Diagnosis	ICD-9-CM
493.9	Asthma, unspecified, unspecified status	Diagnosis	ICD-9-CM
493.82	Cough variant asthma	Diagnosis	ICD-9-CM
493.2	Chronic obstructive asthma, unspecified	Diagnosis	ICD-9-CM
493.21	Chronic obstructive asthma with status asthmaticus	Diagnosis	ICD-9-CM
493.22	Chronic obstructive asthma, with (acute) exacerbation	Diagnosis	ICD-9-CM
J45	Asthma	Diagnosis	ICD-10-CM
J45.2	Mild intermittent asthma	Diagnosis	ICD-10-CM
J45.20	Mild intermittent asthma, uncomplicated	Diagnosis	ICD-10-CM
J45.21	Mild intermittent asthma with (acute) exacerbation	Diagnosis	ICD-10-CM
J45.22	Mild intermittent asthma with status asthmaticus	Diagnosis	ICD-10-CM
J45.3	Mild persistent asthma	Diagnosis	ICD-10-CM
J45.30	Mild persistent asthma, uncomplicated	Diagnosis	ICD-10-CM
J45.31	Mild persistent asthma with (acute) exacerbation	Diagnosis	ICD-10-CM
J45.32	Mild persistent asthma with status asthmaticus	Diagnosis	ICD-10-CM
J45.4	Moderate persistent asthma	Diagnosis	ICD-10-CM
J45.40	Moderate persistent asthma, uncomplicated	Diagnosis	ICD-10-CM
J45.41	Moderate persistent asthma with (acute) exacerbation	Diagnosis	ICD-10-CM
J45.42	Moderate persistent asthma with status asthmaticus	Diagnosis	ICD-10-CM
J45.5	Severe persistent asthma	Diagnosis	ICD-10-CM
J45.50	Severe persistent asthma, uncomplicated	Diagnosis	ICD-10-CM
J45.51	Severe persistent asthma with (acute) exacerbation	Diagnosis	ICD-10-CM
J45.52	Severe persistent asthma with status asthmaticus	Diagnosis	ICD-10-CM
J45.9	Other and unspecified asthma	Diagnosis	ICD-10-CM
J45.90	Unspecified asthma	Diagnosis	ICD-10-CM
J45.901	Unspecified asthma with (acute) exacerbation	Diagnosis	ICD-10-CM
J45.902	Unspecified asthma with status asthmaticus	Diagnosis	ICD-10-CM
J45.909	Unspecified asthma, uncomplicated	Diagnosis	ICD-10-CM
J45.99	Other asthma	Diagnosis	ICD-10-CM
J45.991	Cough variant asthma	Diagnosis	ICD-10-CM
J45.998	Other asthma	Diagnosis	ICD-10-CM
493.91	Asthma, unspecified with status asthmaticus	Diagnosis	ICD-9-CM
493.92	Asthma, unspecified, with (acute) exacerbation	Diagnosis	ICD-9-CM
493.01	Extrinsic asthma with status asthmaticus	Diagnosis	ICD-9-CM
493.02	Extrinsic asthma, with (acute) exacerbation	Diagnosis	ICD-9-CM
493.11	Intrinsic asthma with status asthmaticus	Diagnosis	ICD-9-CM
493.12	Intrinsic asthma, with (acute) exacerbation	Diagnosis	ICD-9-CM
J45.21	Mild intermittent asthma with (acute) exacerbation	Diagnosis	ICD-10-CM
J45.22	Mild intermittent asthma with status asthmaticus	Diagnosis	ICD-10-CM
J45.31	Mild persistent asthma with (acute) exacerbation	Diagnosis	ICD-10-CM
J45.32	Mild persistent asthma with status asthmaticus	Diagnosis	ICD-10-CM
J45.41	Moderate persistent asthma with (acute) exacerbation	Diagnosis	ICD-10-CM
J45.42	Moderate persistent asthma with status asthmaticus	Diagnosis	ICD-10-CM



Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Inclusion and Exclusion Criteria in this Request

Jesus   Severe persistent asthma with (acute) exacerbation   Diagnosis   ICD-10-CM   Jesus   Jesus   Ids-10-CM   Ids	Code	Description	Code Category	Code Type
Unspecified asthma with (acute) exacerbation   Diagnosis   ICD-10-CM   I45.902   Unspecified asthma with status asthmaticus   CD-10-CM   I45.902   Unspecified asthma with status asthmaticus   CD-10-CM   CD-1	J45.51	Severe persistent asthma with (acute) exacerbation	Diagnosis	ICD-10-CM
Unspecified asthma with status asthmaticus   Diagnosis   ICD-10-CM	J45.52	Severe persistent asthma with status asthmaticus	Diagnosis	ICD-10-CM
## Chronic Obstructive Pulmonary Disease (COPD)  ## Bronchitis, not specified as acute or chronic  ## Simple chronic bronchitis  ## Mucopurulent chronic bronchitis  ## Diagnosis  ## ICD-9-CM  ## 1.1 Mucopurulent chronic bronchitis  ## Diagnosis  ## ICD-9-CM  ## 1.2 Obstructive chronic bronchitis, without exacerbation  ## Diagnosis  ## ICD-9-CM  ## 1.2 Obstructive chronic bronchitis, with (acute) exacerbation  ## Diagnosis  ## ICD-9-CM  ## 1.2 Obstructive chronic bronchitis with acute bronchitis  ## Diagnosis  ## ICD-9-CM  ## 1.2 Obstructive chronic bronchitis with acute bronchitis  ## Diagnosis  ## ICD-9-CM  ## 1.2 Obstructive chronic bronchitis  ## Diagnosis  ## ICD-9-CM  ## 1.9 Unspecified chronic bronchitis  ## Diagnosis  ## ICD-9-CM  ## 1.9 Unspecified chronic bronchitis  ## Diagnosis  ## ICD-9-CM  ## 1.2 Obstructive chronic bronchitis  ## Diagnosis  ## ICD-9-CM  ## 1.2 Obstructive chronic bronchitis  ## Diagnosis  ## ICD-9-CM  ## 1.1 Simple and mucopurulent chronic bronchitis  ## Diagnosis  ## ICD-10-CM  ## 1.1 Mucopurulent chronic bronchitis  ## Diagnosis  ## ICD-10-CM  ## 1.1 Mucopurulent chronic bronchitis  ## Diagnosis  ## ICD-10-CM  ## 1.1 Mucopurulent chronic bronchitis  ## Diagnosis  ## ICD-10-CM  ## 1.1 Mucopurulent chronic bronchitis  ## Diagnosis  ## ICD-10-CM  ## 1.1 Mucopurulent chronic bronchitis  ## Diagnosis  ## ICD-10-CM  ## 1.2 Unspecified chronic bronchitis  ## Diagnosis  ## ICD-10-CM  ## 1.3 Panlobular emphysema  ## Diagnosis  ## ICD-10-CM  ## 2.2 Centrilobular emphysema  ## Diagnosis  ## ICD-10-CM  ## 2.3 Emphysema  ## Diagnosis  ## ICD-10-CM  ## 2.4 Other emphysema  ## Diagnosis  ## ICD-10-CM  ## 2.5 Other emphysema  ## Diagnosis  ## ICD-10-CM  ## 2.5 Other emphysema  ## Diagnosis  ## ICD-10-CM  ## 2.5 Other emphysema  ## Diagnosis  ## ICD-10-CM  ## 3.3 Emphysema, unspecified  ## Diagnosis  ## ICD-10-CM  ## 2.5 Other emphysema  ## Diagnosis  ## ICD-10-CM  ## Other chronic obstructive pulmonary disease with acute lower respiratory infection  ## Diagnosis  ## ICD-10-CM  ## 2.5 Obstructiv	J45.901	Unspecified asthma with (acute) exacerbation	Diagnosis	ICD-10-CM
490Bronchitis, not specified as acute or chronicDiagnosisICD-9-CM491Simple chronic bronchitisDiagnosisICD-9-CM491.1Mucopurulent chronic bronchitisDiagnosisICD-9-CM491.2Obstructive chronic bronchitis, without exacerbationDiagnosisICD-9-CM491.21Obstructive chronic bronchitis, with (acute) exacerbationDiagnosisICD-9-CM491.22Obstructive chronic bronchitis with acute bronchitisDiagnosisICD-9-CM491.8Other chronic bronchitisDiagnosisICD-9-CM491.9Unspecified chronic bronchitisDiagnosisICD-9-CM492.8Other emphysemaDiagnosisICD-9-CM492.8Other emphysemaDiagnosisICD-9-CM496Chronic airway obstruction, not elsewhere classifiedDiagnosisICD-9-CMJ40Bronchitis, not specified as acute or chronicDiagnosisICD-9-CMJ41Simple and mucopurulent chronic bronchitisDiagnosisICD-10-CMJ41.0Simple chronic bronchitisDiagnosisICD-10-CMJ41.1Mucopurulent chronic bronchitisDiagnosisICD-10-CMJ41.8Mixed simple and mucopurulent chronic bronchitisDiagnosisICD-10-CMJ42Unspecified chronic bronchitisDiagnosisICD-10-CMJ43EmphysemaDiagnosisICD-10-CMJ43.1Panlobular emphysemaDiagnosisICD-10-CMJ43.2Centrilobular emphysemaDiagnosisICD-10-CMJ43.3Other emp	J45.902	Unspecified asthma with status asthmaticus	Diagnosis	ICD-10-CM
491Simple chronic bronchitisDiagnosisICD-9-CM491.1Mucopurulent chronic bronchitisDiagnosisICD-9-CM491.2Obstructive chronic bronchitis, without exacerbationDiagnosisICD-9-CM491.21Obstructive chronic bronchitis, with (acute) exacerbationDiagnosisICD-9-CM491.22Obstructive chronic bronchitis with acute bronchitisDiagnosisICD-9-CM491.8Other chronic bronchitisDiagnosisICD-9-CM491.9Unspecified chronic bronchitisDiagnosisICD-9-CM492.8Other emphysemaDiagnosisICD-9-CM492.8Other emphysemaDiagnosisICD-9-CM496Chronic airway obstruction, not elsewhere classifiedDiagnosisICD-9-CMJ40Bronchitis, not specified as acute or chronicDiagnosisICD-10-CMJ41.0Simple and mucopurulent chronic bronchitisDiagnosisICD-10-CMJ41.1Mucopurulent chronic bronchitisDiagnosisICD-10-CMJ41.1Mucopurulent chronic bronchitisDiagnosisICD-10-CMJ41.2Unspecified chronic bronchitisDiagnosisICD-10-CMJ43.1Panlobular emphysemaDiagnosisICD-10-CMJ43.2Centrilobular emphysemaDiagnosisICD-10-CMJ43.3EmphysemaDiagnosisICD-10-CMJ43.4Other emphysemaDiagnosisICD-10-CMJ44.0Chronic obstructive pulmonary disease with acute lower respiratory infectionDiagnosisICD-10-CMJ44.1 <th></th> <th></th> <th></th> <th></th>				
491.1Mucopurulent chronic bronchitisDiagnosisICD-9-CM491.2Obstructive chronic bronchitis, without exacerbationDiagnosisICD-9-CM491.21Obstructive chronic bronchitis, with (acute) exacerbationDiagnosisICD-9-CM491.22Obstructive chronic bronchitis with acute bronchitisDiagnosisICD-9-CM491.8Other chronic bronchitisDiagnosisICD-9-CM491.9Unspecified chronic bronchitisDiagnosisICD-9-CM492Emphysematous blebDiagnosisICD-9-CM492.8Other emphysemaDiagnosisICD-9-CM496Chronic airway obstruction, not elsewhere classifiedDiagnosisICD-9-CMJ40Bronchitis, not specified as acute or chronicDiagnosisICD-10-CMJ41Simple and mucopurulent chronic bronchitisDiagnosisICD-10-CMJ41.1Mucopurulent chronic bronchitisDiagnosisICD-10-CMJ41.2Mixed simple and mucopurulent chronic bronchitisDiagnosisICD-10-CMJ42Unspecified chronic bronchitisDiagnosisICD-10-CMJ43EmphysemaDiagnosisICD-10-CMJ43.1Panlobular emphysemaDiagnosisICD-10-CMJ43.2Centrilobular emphysemaDiagnosisICD-10-CMJ43.3Other emphysemaDiagnosisICD-10-CMJ44.0Chronic obstructive pulmonary diseaseDiagnosisICD-10-CMJ44.0Chronic obstructive pulmonary disease with acute lower respiratory infectionDiagnosisICD-10-CM			_	
491.2Obstructive chronic bronchitis, without exacerbationDiagnosisICD-9-CM491.21Obstructive chronic bronchitis, with (acute) exacerbationDiagnosisICD-9-CM491.22Obstructive chronic bronchitis with acute bronchitisDiagnosisICD-9-CM491.8Other chronic bronchitisDiagnosisICD-9-CM491.9Unspecified chronic bronchitisDiagnosisICD-9-CM492Emphysematous blebDiagnosisICD-9-CM492.8Other emphysemaDiagnosisICD-9-CM496Chronic airway obstruction, not elsewhere classifiedDiagnosisICD-9-CMJ40Bronchitis, not specified as acute or chronicDiagnosisICD-10-CMJ41Simple and mucopurulent chronic bronchitisDiagnosisICD-10-CMJ41.0Simple chronic bronchitisDiagnosisICD-10-CMJ41.1Mucopurulent chronic bronchitisDiagnosisICD-10-CMJ41.8Mixed simple and mucopurulent chronic bronchitisDiagnosisICD-10-CMJ42Unspecified chronic bronchitisDiagnosisICD-10-CMJ43EmphysemaDiagnosisICD-10-CMJ43.1Panlobular emphysemaDiagnosisICD-10-CMJ43.2Centrilobular emphysemaDiagnosisICD-10-CMJ43.3Other emphysemaDiagnosisICD-10-CMJ44.0Chronic obstructive pulmonary diseaseDiagnosisICD-10-CMJ44.0Chronic obstructive pulmonary disease with (acute) exacerbationDiagnosisICD-10-CM		·	Diagnosis	ICD-9-CM
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J41.1 Mucopurulent chronic bronchitis  J41.8 Mixed simple and mucopurulent chronic bronchitis  J42 Unspecified chronic bronchitis  J43 Emphysema  J43.1 Panlobular emphysema  J43.2 Centrilobular emphysema  J43.8 Other emphysema  J43.9 Emphysema, unspecified  J44 Other chronic obstructive pulmonary disease  J44 Other obstructive pulmonary disease with acute lower respiratory infection  J44.1 Chronic obstructive pulmonary disease, unspecified  J44.2 Obstructive chronic bronchitis with acute bronchitis  J44.9 Obstructive chronic bronchitis with acute bronchitis  Diagnosis  ICD-10-CM			Diagnosis	
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J44.9 Chronic obstructive pulmonary disease, unspecified Diagnosis ICD-10-CM 491.22 Obstructive chronic bronchitis with acute bronchitis Diagnosis ICD-9-CM	J44.0	Chronic obstructive pulmonary disease with acute lower respiratory infection	Diagnosis	ICD-10-CM
491.22 Obstructive chronic bronchitis with acute bronchitis Diagnosis ICD-9-CM	J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation	Diagnosis	ICD-10-CM
491.22 Obstructive chronic bronchitis with acute bronchitis Diagnosis ICD-9-CM	J44.9	Chronic obstructive pulmonary disease, unspecified	Diagnosis	ICD-10-CM
491.21 Obstructive chronic bronchitis, with (acute) exacerbation Diagnosis ICD-9-CM	491.22	Obstructive chronic bronchitis with acute bronchitis	_	ICD-9-CM
	491.21	Obstructive chronic bronchitis, with (acute) exacerbation	Diagnosis	ICD-9-CM



This report executed the Cohort Identification and Descriptive Analysis (CIDA) tool version 9.3.0 to evaluate duration of first use among new users of dry powder inhalers (DPI) and metered dose inhalers (MDI) containing corticosteroid and long acting β2 agonists (LABA) with asthma or chronic obstructive pulmonary disease (COPD) in the Sentinel Distributed Database (SDD).

**Query period:** May 10, 2013 - September 30, 2019

Coverage requirement: Medical and Drug Coverage

Pre-index enrollment requirement: 365 days
Post-index enrollment requirement: 0 days
Enrollment gap: 45 days

Age groups: 4-11, 12-18, 19-39, 40-64, 65+

Censor output categorization: 0-30, 31-90, 91-270, 271-360, 361+

Stratifications: None

Switching Groups Inclusion Criteria

	Exposure group	Cohort definition	Treatment episode gap and type	Exposure episode extension	Censoring criteria	Criteria	Inclusion group	Care setting	Principal diagnosis position	Evaluation period start (days)		Exclusion reference date for dispensings	Number of instances the criteria should be found in evaluation period	Forced days supply to attached to dispensings
	9 p					Inclusion	Asthma	Any	Any	-365	0	N/A	1	N/A
		Include the			Disenrollment,	Exclusion	COPD	Any	Any	-365	0	N/A	1	N/A
	Advair Diskus 1 (with prior asthma)	first valid exposure per patient	30 days	30 days	Death, Query End Date, DP End Date	Exclusion	Advair Diskus	N/A	N/A	-365	-1	Evaluation period should search for only evidence of a dispensing date	1	N/A
ľ						Inclusion	Asthma	Any	Any	-365	0	N/A	1	N/A
		Include the		s 30 days	Disenrollment, Death, Query End Date, DP End Date	Exclusion	COPD	Any	Any	-365	0	N/A	1	N/A
	Breo Ellipta 2 (with prior asthma)	first valid exposure per patient	30 days			Exclusion	Breo Ellipta	N/A	N/A	-365	-1	Evaluation period should search for only evidence of a dispensing date	1	N/A



		S	witching Gro	oups		Inclusion Criteria								
	Exposure Group	Cohort definition	Treatment episode gap and type	Exposure episode extension	Censoring Criteria	Criteria	Inclusion group	Care setting	Principal Diagnosis Position	Evaluation period start		Exclusion reference date for dispensings	Number of instances the criteria should be found in evaluation period	Forced Days supply to attached to dispensings
						Inclusion	Asthma	Any	Any	-365	0	N/A	1	N/A
		Include the			Disenrollment,	Exclusion	COPD	Any	Any	-365	0	N/A	1	N/A
3	Symbicort (with prior asthma)	first valid exposure per patient	30 days	30 days	Death, Query End Date, DP End Date	Exclusion	Symbicort	N/A	N/A	-365	-1	Evaluation period should search for only evidence of a dispensing date	1	N/A
						Inclusion	Asthma	Any	Any	-365	0	N/A	1	N/A
	Airduo	Include the			Disenrollment, Death, Query End Date, DP End Date	Exclusion	COPD	Any	Any	-365	0	N/A	1	N/A
4	Respiclick	first valid exposure per patient	30 days	30 days		Exclusion	Airduo Respiclick	N/A	N/A	-365	-1	Evaluation period should search for only evidence of a dispensing date	1	N/A
	Other					Inclusion	Asthma	Any	Any	-365	0	N/A	1	N/A
	Other ICS/LABA	Include the			Disenrollment, Death, Query End Date, DP End Date	Exclusion	COPD	Any	Any	-365	0	N/A	1	N/A
5	(Advair HFA or Dulera - with prior asthma)	first valid exposure per patient	30 days	30 days		Exclusion	Other ICS/LABA (Advair HFA or Dulera)	N/A	N/A	-365	-1	Evaluation period should search for only evidence of a dispensing date	1	N/A



		S	witching Gro	oups		Inclusion Criteria								
6	Exposure Group Advair Diskus (with prior	Cohort definition Include the first valid exposure	Treatment episode gap and type	Exposure episode extension	Censoring Criteria Disenrollment, Death, Query End Date, DP	<b>Criteria</b> Inclusion Exclusion	Inclusion group COPD Asthma	Care setting Any Any	Principal Diagnosis Position Any Any	Evaluation period start -365 -365		Exclusion reference date for dispensings N/A N/A Evaluation period	Number of instances the criteria should be found in evaluation period	Forced Days supply to attached to dispensings N/A N/A
	COPD)	per patient			End Date	Exclusion	Advair Diskus	N/A	N/A	-365	-1	should search for only evidence of a dispensing date	1	N/A
						Inclusion	COPD	Any	Any	-365	0	N/A	1	N/A
		Include the			Disenrollment,	Exclusion	Asthma	Any	Any	-365	0	N/A	1	N/A
7	Breo Ellipta (with prior COPD)	first valid exposure per patient	30 days	30 days	Death, Query End Date, DP End Date	Exclusion	Breo Ellipta	N/A	N/A	-365	-1	Evaluation period should search for only evidence of a dispensing date	1	N/A
						Inclusion	COPD	Any	Any	-365	0	N/A	1	N/A
		Include the			Disenrollment,	Exclusion	Asthma	Any	Any	-365	0	N/A	1	N/A
8	Symbicort (with prior COPD)	first valid	30 days	30 days	Death, Query End Date, DP End Date	Exclusion	Symbicort	N/A	N/A	-365	-1	Evaluation period should search for only evidence of a dispensing date	1	N/A



		S	witching Gro	oups		Г	Inclusion Criteria								
	Exposure Group	Cohort definition	Treatment episode gap and type	Exposure episode extension	Censoring Criteria	Criteria	Inclusion group	Care setting	Principal Diagnosis Position	Evaluation period start		Exclusion reference date for dispensings	Number of instances the criteria should be found in evaluation period	Forced Days supply to attached to dispensings	
	Airduo Respiclick (with prior COPD)					Inclusion	COPD	Any	Any	-365	0	N/A	1	N/A	
		Include the	30 days		Disenrollment, Death, Query End Date, DP End Date	Exclusion	Asthma	Any	Any	-365	0	N/A	1	N/A	
9		first valid exposure per patient		30 days		Exclusion	Airduo Respiclick	N/A	N/A	-365	-1	Evaluation period should search for only evidence of a dispensing date	1	N/A	
	Other					Inclusion	COPD	Any	Any	-365	0	N/A	1	N/A	
	Other ICS/LABA	Include the			Disenrollment,	Exclusion	Asthma	Any	Any	-365	0	N/A	1	N/A	
10	(Advair HFA first valid or Dulera - exposure with prior per patient COPD)	rst valid xposure 30 days	30 days 30 days	Death, Query End Date, DP End Date	Exclusion	Other ICS/LABA (Advair HFA or Dulera)	N/A	N/A	-365	-1	Evaluation period should search for only evidence of a dispensing date	1	N/A		

International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9), International Classification of Diseases, Tenth Edition, Clinical Modification (ICD-10), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology (CPT) codes are provided by Optum360. NDC codes are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."