

## 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 Query Builder analysis.

If you are using a web page screen reader and are unable to access this document, please contact the Sentinel Operations Center for assistance at [info@sentinelssystem.org](mailto:info@sentinelssystem.org).

## Overview

**Query Builder Report:** This report details the results of an analysis generated by the Sentinel Query Builder application. Query Builder enables FDA to visualize, draft, and create standardized medical product utilization queries examining dispensing patterns and cohort characteristics using a set of pre-defined parameters. This is a Type 5 (Medical Product Utilization) analysis as described in the Query Request Package (QRP) documentation.

**Sentinel Routine Querying Module:** Cohort Identification and Descriptive Analysis (CIDA) module, version 9.1.0.

**Data Source:** We executed this request on IBM® MarketScan® Commercial Claims and Encounters Database and Medicare Supplemental Database, which included 140 million members, on June 30, 2020. The study period included data from September 1, 2015 to December 31, 2018. Please see Appendix A for data availability dates.

**Limitations:** Algorithms used to define exposures and inclusion and exclusion criteria are imperfect; thus it is possible that there may be misclassification. Therefore, data should be interpreted with these limitations in mind.

**Notes:** Please contact the Sentinel Operations Center ([info@sentinelssystem.org](mailto:info@sentinelssystem.org)) for questions.

## Table of Contents

**Table 1a** Baseline table (Clozapine, 0 day gap, 30 day washout) from September 1, 2015 to December 31, 2018

**Table 1b** Baseline table (Clozapine, 0 day gap, 0 day washout) from September 1, 2015 to December 31, 2018

**Table 1c** Baseline table (Clozapine, 14 day gap, 14 day washout) from September 1, 2015 to December 31, 2018

**Table 1d** Baseline table (Clozapine, 14 day gap, 30 day washout) from September 1, 2015 to December 31, 2018

**Table 1e** Baseline table (Clozapine, 30 day gap, 30 day washout) from September 1, 2015 to December 31, 2018

**Table 1f** Baseline table (Clozapine, 7 day gap, 7 day washout) from September 1, 2015 to December 31, 2018

**Table 1g** Baseline table (Clozapine, 7 day gap, 30 day washout) from September 1, 2015 to December 31, 2018

**Table 2a** Descriptive statistics of cumulative clozapine exposure duration, all episodes, in days, from September 1, 2015 to December 31, 2018

**Table 2b** Descriptive statistics of cumulative clozapine exposure duration, all episodes, in days, by sex, from September 1, 2015 to December 31, 2018

**Table 2c** Descriptive statistics of cumulative clozapine exposure duration, all episodes, in days, by age group (years), from September 1, 2015 to December 31, 2018

**Table 3a** Descriptive statistics of first clozapine exposure episode duration, in days, from September 1, 2015 to December 31, 2018

**Table 3b** Descriptive statistics of first clozapine exposure episode duration, in days, by sex, from September 1, 2015 to December 31, 2018

**Table 3c** Descriptive statistics of first clozapine exposure episode duration, in days, by age group (years), from September 1, 2015 to December 31, 2018

**Table 4a** Descriptive statistics of all clozapine episode durations, in days, from September 1, 2015 to December 31, 2018

**Table 4b** Descriptive statistics of all clozapine episode durations, in days, by sex, from September 1, 2015 to December 31, 2018

**Table 4c** Descriptive statistics of all clozapine episode durations, in days, by age group (years), from September 1, 2015 to December 31, 2018

**Table 5a** Descriptive statistics of days supplied per clozapine dispensing from September 1, 2015 to December 31, 2018

**Table 5b** Descriptive statistics of days supplied per clozapine dispensing, by sex from September 1, 2015 to December 31, 2018

**Table 5c** Descriptive statistics of days supplied per clozapine dispensing, by age group (years) from September 1, 2015 to December 31, 2018

**Table 6** Counts of reason for censoring, all clozapine episodes and first clozapine episode from September 1, 2015 to December 31, 2018

**Table 7** Cohort Attrition table

**Appendix A** Dates of Available Data for Each Data Partner (DP) up to Request End Date (12/31/2018) as of Query Distribution Date

**Appendix B** Specifications Used to Define Parameters in this Query

**Appendix C** List of Generic and Brand Name Medical Products Used to Define Index Exposures in this Request

Table 1a: Baseline table (Clozapine, 0 day gap, 30 day washout) from September 1, 2015 to December 31, 2018

Characteristic <sup>1</sup>	N/Mean	%/Std Dev <sup>2</sup>
Number of unique patients	1,369	
<b>Demographics</b>		
Mean Age (Years)	37.7	18.4
Age: 00-01 (Years)	-	-
Age: 02-04 (Years)	-	-
Age: 05-09 (Years)	1	0.1%
Age: 10-14 (Years)	27	2.0%
Age: 15-18 (Years)	104	7.6%
Age: 19-21 (Years)	154	11.2%
Age: 22-44 (Years)	614	44.9%
Age: 45-64 (Years)	340	24.8%
Age: 65-74 (Years)	80	5.8%
Age: 75+ (Years)	49	3.6%
Sex (Female)	533	38.9%
Sex (Male)	836	61.1%
Year (2015)	190	13.9%
Year (2016)	474	34.6%
Year (2017)	365	26.7%
Year (2018)	340	24.8%
<b>Recorded history of:</b>		
Prior combined comorbidity score <sup>3</sup>	1.8	1.7
Acquired Hypothyroidism	194	14.2%
Acute Myocardial Infarction	3	0.2%
Alzheimer's Disease	23	1.7%
Alzheimer's Disease, Related Disorders, or Senile Dementia	143	10.4%
Anemia	138	10.1%
Asthma	93	6.8%
Atrial Fibrillation	21	1.5%
Benign Prostatic Hyperplasia	29	2.1%
Breast Cancer	8	0.6%
Cataracts	55	4.0%
Chronic Kidney Disease	140	10.2%
Chronic Obstructive Pulmonary Disease	67	4.9%
Colorectal Cancer	4	0.3%
Depression	651	47.6%
Diabetes	172	12.6%
Endometrial Cancer	0	0.0%
Glaucoma	33	2.4%
Heart Failure	28	2.0%
Hip / Pelvic Fracture	8	0.6%
Hyperlipidemia	309	22.6%
Hypertension	339	24.8%
Ischemic Heart Disease	50	3.7%
Lung Cancer	1	0.1%
Osteoporosis	16	1.2%
Prostate Cancer	6	0.4%
Rheumatoid Arthritis / Osteoarthritis	111	8.1%
Stroke / Transient Ischemic Attack	35	2.6%
<b>Health Service Utilization Intensity:</b>		
Mean number of ambulatory encounters (AV)	13.9	14.5
Mean number of emergency room encounters (ED)	1.1	2.4

Table 1a: Baseline table (Clozapine, 0 day gap, 30 day washout) from September 1, 2015 to December 31, 2018

Characteristic <sup>1</sup>	N/Mean	%/Std Dev <sup>2</sup>
Mean number of inpatient hospital encounters (IP)	0.9	1.2
Mean number of non-acute institutional encounters (IS)	0.2	0.7
Mean number of other ambulatory encounters (OA)	6.4	12.7
Mean number of filled prescriptions	20.9	17.6
Mean number of generics	7.6	5.4
Mean number of unique drug classes	7.1	4.9
<sup>1</sup> All metrics based on total number of unique patients <sup>2</sup> Value represents standard deviation where no % follows the value <sup>3</sup> The Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (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; Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and Validation of the Combined Comorbidity Score for ICD-10-CM. Med Care. 2017;55(12):1046-1051).		

Table 1b: Baseline table (Clozapine, 0 day gap, 0 day washout) from September 1, 2015 to December 31, 2018

Characteristic <sup>1</sup>	N/Mean	%/Std Dev <sup>2</sup>
Number of unique patients	2,141	
<b>Demographics</b>		
Mean Age (Years)	39.5	17.6
Age: 00-01 (Years)	-	-
Age: 02-04 (Years)	-	-
Age: 05-09 (Years)	1	0.0%
Age: 10-14 (Years)	32	1.5%
Age: 15-18 (Years)	125	5.8%
Age: 19-21 (Years)	187	8.7%
Age: 22-44 (Years)	974	45.5%
Age: 45-64 (Years)	649	30.3%
Age: 65-74 (Years)	105	4.9%
Age: 75+ (Years)	68	3.2%
Sex (Female)	845	39.5%
Sex (Male)	1,296	60.5%
Year (2015)	659	30.8%
Year (2016)	604	28.2%
Year (2017)	431	20.1%
Year (2018)	447	20.9%
<b>Recorded history of:</b>		
Prior combined comorbidity score <sup>3</sup>	1.6	1.5
Acquired Hypothyroidism	311	14.5%
Acute Myocardial Infarction	3	0.1%
Alzheimer's Disease	25	1.2%
Alzheimer's Disease, Related Disorders, or Senile Dementia	160	7.5%
Anemia	189	8.8%
Asthma	142	6.6%
Atrial Fibrillation	28	1.3%
Benign Prostatic Hyperplasia	52	2.4%
Breast Cancer	12	0.6%
Cataracts	80	3.7%
Chronic Kidney Disease	170	7.9%
Chronic Obstructive Pulmonary Disease	98	4.6%
Colorectal Cancer	8	0.4%
Depression	850	39.7%
Diabetes	302	14.1%
Endometrial Cancer	1	0.0%
Glaucoma	58	2.7%
Heart Failure	30	1.4%
Hip / Pelvic Fracture	4	0.2%
Hyperlipidemia	515	24.1%
Hypertension	474	22.1%
Ischemic Heart Disease	63	2.9%
Lung Cancer	2	0.1%
Osteoporosis	24	1.1%
Prostate Cancer	11	0.5%
Rheumatoid Arthritis / Osteoarthritis	169	7.9%
Stroke / Transient Ischemic Attack	39	1.8%
<b>Health Service Utilization Intensity:</b>		
Mean number of ambulatory encounters (AV)	12.9	13.3
Mean number of emergency room encounters (ED)	0.8	2.2

Table1b: Baseline table (Clozapine, 0 day gap, 0 day washout) from September 1, 2015 to December 31, 2018

Characteristic <sup>1</sup>	N/Mean	%/Std Dev <sup>2</sup>
Mean number of inpatient hospital encounters (IP)	0.6	1.1
Mean number of non-acute institutional encounters (IS)	0.1	0.6
Mean number of other ambulatory encounters (OA)	5.8	11.1
Mean number of filled prescriptions	22.7	17.2
Mean number of generics	7.4	5.1
Mean number of unique drug classes	6.9	4.6

<sup>1</sup>All metrics based on total number of unique patients

<sup>2</sup>Value represents standard deviation where no % follows the value

<sup>3</sup>The Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (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; Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and Validation of the Combined Comorbidity Score for ICD-10-CM. Med Care. 2017;55(12):1046-1051).

Table 1c: Baseline table (Clozapine, 14 day gap, 14 day washout) from September 1, 2015 to December 31, 2018

Characteristic <sup>1</sup>	N/Mean	%/Std Dev <sup>2</sup>
Number of unique patients	1,574	
<b>Demographics</b>		
Mean Age (Years)	38.5	18.3
Age: 00-01 (Years)	-	-
Age: 02-04 (Years)	-	-
Age: 05-09 (Years)	1	0.1%
Age: 10-14 (Years)	28	1.8%
Age: 15-18 (Years)	106	6.7%
Age: 19-21 (Years)	166	10.5%
Age: 22-44 (Years)	708	45.0%
Age: 45-64 (Years)	419	26.6%
Age: 65-74 (Years)	90	5.7%
Age: 75+ (Years)	56	3.6%
Sex (Female)	617	39.2%
Sex (Male)	957	60.8%
Year (2015)	294	18.7%
Year (2016)	524	33.3%
Year (2017)	384	24.4%
Year (2018)	372	23.6%
<b>Recorded history of:</b>		
Prior combined comorbidity score <sup>3</sup>	1.7	1.6
Acquired Hypothyroidism	232	14.7%
Acute Myocardial Infarction	4	0.3%
Alzheimer's Disease	22	1.4%
Alzheimer's Disease, Related Disorders, or Senile Dementia	145	9.2%
Anemia	159	10.1%
Asthma	111	7.1%
Atrial Fibrillation	23	1.5%
Benign Prostatic Hyperplasia	33	2.1%
Breast Cancer	9	0.6%
Cataracts	59	3.7%
Chronic Kidney Disease	157	10.0%
Chronic Obstructive Pulmonary Disease	71	4.5%
Colorectal Cancer	5	0.3%
Depression	718	45.6%
Diabetes	205	13.0%
Endometrial Cancer	0	0.0%
Glaucoma	38	2.4%
Heart Failure	28	1.8%
Hip / Pelvic Fracture	7	0.4%
Hyperlipidemia	365	23.2%
Hypertension	381	24.2%
Ischemic Heart Disease	53	3.4%
Lung Cancer	1	0.1%
Osteoporosis	22	1.4%
Prostate Cancer	8	0.5%
Rheumatoid Arthritis / Osteoarthritis	128	8.1%
Stroke / Transient Ischemic Attack	34	2.2%
<b>Health Service Utilization Intensity:</b>		
Mean number of ambulatory encounters (AV)	13.3	13.9
Mean number of emergency room encounters (ED)	1.0	2.4



**Table 1c: Baseline table (Clozapine, 14 day gap, 14 day washout) from September 1, 2015 to December 31, 2018**

Characteristic <sup>1</sup>	N/Mean	%/Std Dev <sup>2</sup>
Mean number of inpatient hospital encounters (IP)	0.8	1.2
Mean number of non-acute institutional encounters (IS)	0.2	0.6
Mean number of other ambulatory encounters (OA)	6.2	12.1
Mean number of filled prescriptions	21.5	17.4
Mean number of generics	7.6	5.3
Mean number of unique drug classes	7.1	4.8

<sup>1</sup>All metrics based on total number of unique patients

<sup>2</sup>Value represents standard deviation where no % follows the value

<sup>3</sup>The Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (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; Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and Validation of the Combined Comorbidity Score for ICD-10-CM. Med Care. 2017;55(12):1046-1051).

Table 1d: Baseline table (Clozapine, 14 day gap, 30 day washout) from September 1, 2015 to December 31, 2018

Characteristic <sup>1</sup>	N/Mean	%/Std Dev <sup>2</sup>
Number of unique patients	1,369	
<b>Demographics</b>		
Mean Age (Years)	37.7	18.4
Age: 00-01 (Years)	-	-
Age: 02-04 (Years)	-	-
Age: 05-09 (Years)	1	0.1%
Age: 10-14 (Years)	27	2.0%
Age: 15-18 (Years)	104	7.6%
Age: 19-21 (Years)	154	11.2%
Age: 22-44 (Years)	614	44.9%
Age: 45-64 (Years)	340	24.8%
Age: 65-74 (Years)	80	5.8%
Age: 75+ (Years)	49	3.6%
Sex (Female)	533	38.9%
Sex (Male)	836	61.1%
Year (2015)	190	13.9%
Year (2016)	474	34.6%
Year (2017)	365	26.7%
Year (2018)	340	24.8%
<b>Recorded history of:</b>		
Prior combined comorbidity score <sup>3</sup>	1.8	1.7
Acquired Hypothyroidism	194	14.2%
Acute Myocardial Infarction	3	0.2%
Alzheimer's Disease	23	1.7%
Alzheimer's Disease, Related Disorders, or Senile Dementia	143	10.4%
Anemia	138	10.1%
Asthma	93	6.8%
Atrial Fibrillation	21	1.5%
Benign Prostatic Hyperplasia	29	2.1%
Breast Cancer	8	0.6%
Cataracts	55	4.0%
Chronic Kidney Disease	140	10.2%
Chronic Obstructive Pulmonary Disease	67	4.9%
Colorectal Cancer	4	0.3%
Depression	651	47.6%
Diabetes	172	12.6%
Endometrial Cancer	0	0.0%
Glaucoma	33	2.4%
Heart Failure	28	2.0%
Hip / Pelvic Fracture	8	0.6%
Hyperlipidemia	309	22.6%
Hypertension	339	24.8%
Ischemic Heart Disease	50	3.7%
Lung Cancer	1	0.1%
Osteoporosis	16	1.2%
Prostate Cancer	6	0.4%
Rheumatoid Arthritis / Osteoarthritis	111	8.1%
Stroke / Transient Ischemic Attack	35	2.6%
<b>Health Service Utilization Intensity:</b>		
Mean number of ambulatory encounters (AV)	13.9	14.5
Mean number of emergency room encounters (ED)	1.1	2.4

Table 1d: Baseline table (Clozapine, 14 day gap, 30 day washout) from September 1, 2015 to December 31, 2018

Characteristic <sup>1</sup>	N/Mean	%/Std Dev <sup>2</sup>
Mean number of inpatient hospital encounters (IP)	0.9	1.2
Mean number of non-acute institutional encounters (IS)	0.2	0.7
Mean number of other ambulatory encounters (OA)	6.4	12.7
Mean number of filled prescriptions	20.9	17.6
Mean number of generics	7.6	5.4
Mean number of unique drug classes	7.1	4.9

<sup>1</sup>All metrics based on total number of unique patients

<sup>2</sup>Value represents standard deviation where no % follows the value

<sup>3</sup>The Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (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; Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and Validation of the Combined Comorbidity Score for ICD-10-CM. Med Care. 2017;55(12):1046-1051).

Table 1e: Baseline table (Clozapine, 30 day gap, 30 day washout) from September 1, 2015 to December 31, 2018

Characteristic <sup>1</sup>	N/Mean	%/Std Dev <sup>2</sup>
Number of unique patients	1,357	
<b>Demographics</b>		
Mean Age (Years)	37.6	18.3
Age: 00-01 (Years)	-	-
Age: 02-04 (Years)	-	-
Age: 05-09 (Years)	1	0.1%
Age: 10-14 (Years)	26	1.9%
Age: 15-18 (Years)	104	7.7%
Age: 19-21 (Years)	153	11.3%
Age: 22-44 (Years)	612	45.1%
Age: 45-64 (Years)	335	24.7%
Age: 65-74 (Years)	79	5.8%
Age: 75+ (Years)	47	3.5%
Sex (Female)	526	38.8%
Sex (Male)	831	61.2%
Year (2015)	187	13.8%
Year (2016)	469	34.6%
Year (2017)	363	26.8%
Year (2018)	338	24.9%
<b>Recorded history of:</b>		
Prior combined comorbidity score <sup>3</sup>	1.8	1.7
Acquired Hypothyroidism	192	14.1%
Acute Myocardial Infarction	3	0.2%
Alzheimer's Disease	23	1.7%
Alzheimer's Disease, Related Disorders, or Senile Dementia	143	10.5%
Anemia	134	9.9%
Asthma	93	6.9%
Atrial Fibrillation	21	1.5%
Benign Prostatic Hyperplasia	29	2.1%
Breast Cancer	8	0.6%
Cataracts	54	4.0%
Chronic Kidney Disease	138	10.2%
Chronic Obstructive Pulmonary Disease	67	4.9%
Colorectal Cancer	4	0.3%
Depression	647	47.7%
Diabetes	166	12.2%
Endometrial Cancer	0	0.0%
Glaucoma	33	2.4%
Heart Failure	27	2.0%
Hip / Pelvic Fracture	8	0.6%
Hyperlipidemia	305	22.5%
Hypertension	333	24.5%
Ischemic Heart Disease	49	3.6%
Lung Cancer	1	0.1%
Osteoporosis	16	1.2%
Prostate Cancer	6	0.4%
Rheumatoid Arthritis / Osteoarthritis	111	8.2%
Stroke / Transient Ischemic Attack	35	2.6%
<b>Health Service Utilization Intensity:</b>		
Mean number of ambulatory encounters (AV)	13.9	14.5
Mean number of emergency room encounters (ED)	1.1	2.4

Table 1e: Baseline table (Clozapine, 30 day gap, 30 day washout) from September 1, 2015 to December 31, 2018

Characteristic <sup>1</sup>	N/Mean	%/Std Dev <sup>2</sup>
Mean number of inpatient hospital encounters (IP)	0.9	1.2
Mean number of non-acute institutional encounters (IS)	0.2	0.7
Mean number of other ambulatory encounters (OA)	6.4	12.7
Mean number of filled prescriptions	20.8	17.7
Mean number of generics	7.6	5.4
Mean number of unique drug classes	7.1	4.9
<sup>1</sup> All metrics based on total number of unique patients <sup>2</sup> Value represents standard deviation where no % follows the value <sup>3</sup> The Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (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; Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and Validation of the Combined Comorbidity Score for ICD-10-CM. Med Care. 2017;55(12):1046-1051).		

Table 1f: Baseline table (Clozapine, 7 day gap, 7 day washout) from September 1, 2015 to December 31, 2018

Characteristic <sup>1</sup>	N/Mean	%/Std Dev <sup>2</sup>
Number of unique patients	1,765	
<b>Demographics</b>		
Mean Age (Years)	38.8	18.1
Age: 00-01 (Years)	-	-
Age: 02-04 (Years)	-	-
Age: 05-09 (Years)	1	0.1%
Age: 10-14 (Years)	31	1.8%
Age: 15-18 (Years)	114	6.5%
Age: 19-21 (Years)	176	10.0%
Age: 22-44 (Years)	793	44.9%
Age: 45-64 (Years)	492	27.9%
Age: 65-74 (Years)	95	5.4%
Age: 75+ (Years)	63	3.6%
Sex (Female)	698	39.5%
Sex (Male)	1,067	60.5%
Year (2015)	399	22.6%
Year (2016)	556	31.5%
Year (2017)	411	23.3%
Year (2018)	399	22.6%
<b>Recorded history of:</b>		
Prior combined comorbidity score <sup>3</sup>	1.7	1.6
Acquired Hypothyroidism	253	14.3%
Acute Myocardial Infarction	4	0.2%
Alzheimer's Disease	22	1.2%
Alzheimer's Disease, Related Disorders, or Senile Dementia	151	8.6%
Anemia	170	9.6%
Asthma	126	7.1%
Atrial Fibrillation	25	1.4%
Benign Prostatic Hyperplasia	36	2.0%
Breast Cancer	10	0.6%
Cataracts	69	3.9%
Chronic Kidney Disease	165	9.3%
Chronic Obstructive Pulmonary Disease	81	4.6%
Colorectal Cancer	6	0.3%
Depression	762	43.2%
Diabetes	234	13.3%
Endometrial Cancer	0	0.0%
Glaucoma	44	2.5%
Heart Failure	30	1.7%
Hip / Pelvic Fracture	7	0.4%
Hyperlipidemia	411	23.3%
Hypertension	410	23.2%
Ischemic Heart Disease	56	3.2%
Lung Cancer	1	0.1%
Osteoporosis	20	1.1%
Prostate Cancer	9	0.5%
Rheumatoid Arthritis / Osteoarthritis	138	7.8%
Stroke / Transient Ischemic Attack	38	2.2%
<b>Health Service Utilization Intensity:</b>		
Mean number of ambulatory encounters (AV)	13.1	13.6
Mean number of emergency room encounters (ED)	0.9	2.3

Table 1f: Baseline table (Clozapine, 7 day gap, 7 day washout) from September 1, 2015 to December 31, 2018

Characteristic <sup>1</sup>	N/Mean	%/Std Dev <sup>2</sup>
Mean number of inpatient hospital encounters (IP)	0.7	1.2
Mean number of non-acute institutional encounters (IS)	0.2	0.6
Mean number of other ambulatory encounters (OA)	6.0	11.6
Mean number of filled prescriptions	21.8	17.2
Mean number of generics	7.5	5.2
Mean number of unique drug classes	7.0	4.7

<sup>1</sup>All metrics based on total number of unique patients

<sup>2</sup>Value represents standard deviation where no % follows the value

<sup>3</sup>The Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (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; Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and Validation of the Combined Comorbidity Score for ICD-10-CM. Med Care. 2017;55(12):1046-1051).

Table 1g: Baseline table (Clozapine, 7 day gap, 30 day washout) from September 1, 2015 to December 31, 2018

Characteristic <sup>1</sup>	N/Mean	%/Std Dev <sup>2</sup>
Number of unique patients	1,369	
<b>Demographics</b>		
Mean Age (Years)	37.7	18.4
Age: 00-01 (Years)	-	-
Age: 02-04 (Years)	-	-
Age: 05-09 (Years)	1	0.1%
Age: 10-14 (Years)	27	2.0%
Age: 15-18 (Years)	104	7.6%
Age: 19-21 (Years)	154	11.2%
Age: 22-44 (Years)	614	44.9%
Age: 45-64 (Years)	340	24.8%
Age: 65-74 (Years)	80	5.8%
Age: 75+ (Years)	49	3.6%
Sex (Female)	533	38.9%
Sex (Male)	836	61.1%
Year (2015)	190	13.9%
Year (2016)	474	34.6%
Year (2017)	365	26.7%
Year (2018)	340	24.8%
<b>Recorded history of:</b>		
Prior combined comorbidity score <sup>3</sup>	1.8	1.7
Acquired Hypothyroidism	194	14.2%
Acute Myocardial Infarction	3	0.2%
Alzheimer's Disease	23	1.7%
Alzheimer's Disease, Related Disorders, or Senile Dementia	143	10.4%
Anemia	138	10.1%
Asthma	93	6.8%
Atrial Fibrillation	21	1.5%
Benign Prostatic Hyperplasia	29	2.1%
Breast Cancer	8	0.6%
Cataracts	55	4.0%
Chronic Kidney Disease	140	10.2%
Chronic Obstructive Pulmonary Disease	67	4.9%
Colorectal Cancer	4	0.3%
Depression	651	47.6%
Diabetes	172	12.6%
Endometrial Cancer	0	0.0%
Glaucoma	33	2.4%
Heart Failure	28	2.0%
Hip / Pelvic Fracture	8	0.6%
Hyperlipidemia	309	22.6%
Hypertension	339	24.8%
Ischemic Heart Disease	50	3.7%
Lung Cancer	1	0.1%
Osteoporosis	16	1.2%
Prostate Cancer	6	0.4%
Rheumatoid Arthritis / Osteoarthritis	111	8.1%
Stroke / Transient Ischemic Attack	35	2.6%
<b>Health Service Utilization Intensity:</b>		
Mean number of ambulatory encounters (AV)	13.9	14.5
Mean number of emergency room encounters (ED)	1.1	2.4



**Table 1g: Baseline table (Clozapine, 7 day gap, 30 day washout) from September 1, 2015 to December 31, 2018**

Characteristic <sup>1</sup>	N/Mean	%/Std Dev <sup>2</sup>
Mean number of inpatient hospital encounters (IP)	0.9	1.2
Mean number of non-acute institutional encounters (IS)	0.2	0.7
Mean number of other ambulatory encounters (OA)	6.4	12.7
Mean number of filled prescriptions	20.9	17.6
Mean number of generics	7.6	5.4
Mean number of unique drug classes	7.1	4.9
<sup>1</sup> All metrics based on total number of unique patients <sup>2</sup> Value represents standard deviation where no % follows the value <sup>3</sup> The Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (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; Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and Validation of the Combined Comorbidity Score for ICD-10-CM. Med Care. 2017;55(12):1046-1051).		

**Table 2a: Descriptive statistics of cumulative clozapine exposure duration, all episodes, in days, from September 1, 2015 to December 31, 2018**

Exposures	Total Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Clozapine, 0 day gap, 30 day washout	1,369	285.29	292.93	1	53	174	438	1,198
Clozapine, 0 day gap, 0 day washout	2,141	375.01	346.48	1	84	260	600	1,209
Clozapine, 14 day gap, 14 day washout	1,574	339.69	320.92	1	76	225	519	1,206
Clozapine, 14 day gap, 30 day washout	1,369	310.98	303.38	1	70	193	464	1,198
Clozapine, 30 day gap, 30 day washout	1,357	326.10	307.91	1	81	207	490	1,207
Clozapine, 7 day gap, 7 day washout	1,765	351.05	328.74	1	76	237	546	1,209
Clozapine, 7 day gap, 30 day washout	1,369	301.68	300.13	1	62	186	456	1,198

**Table 2b: Descriptive statistics of cumulative clozapine exposure duration, all episodes, in days, by sex, from September 1, 2015 to December 31, 2018**

Exposures	Total Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
<b>Clozapine, 0 day gap, 30 day washout</b>	<b>1,369</b>	<b>285.29</b>	<b>292.93</b>	<b>1</b>	<b>53</b>	<b>174</b>	<b>438</b>	<b>1,198</b>
Female	533	267.70	273.37	4	56	168	398	1,177
Male	836	296.50	304.38	1	50	176	462	1,198
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 0 day gap, 0 day washout</b>	<b>2,141</b>	<b>375.01</b>	<b>346.48</b>	<b>1</b>	<b>84</b>	<b>260</b>	<b>600</b>	<b>1,209</b>
Female	845	367.86	343.93	4	84	244	573	1,209
Male	1,296	379.67	348.19	1	84	270	614	1,204
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 14 day gap, 14 day washout</b>	<b>1,574</b>	<b>339.69</b>	<b>320.92</b>	<b>1</b>	<b>76</b>	<b>225</b>	<b>519</b>	<b>1,206</b>
Female	617	325.00	307.41	4	80	214	470	1,178
Male	957	349.16	329.14	1	75	237	538	1,206
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 14 day gap, 30 day washout</b>	<b>1,369</b>	<b>310.98</b>	<b>303.38</b>	<b>1</b>	<b>70</b>	<b>193</b>	<b>464</b>	<b>1,198</b>
Female	533	295.26	286.22	4	72	188	426	1,178
Male	836	321.00	313.59	1	67	200	491	1,198
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 30 day gap, 30 day washout</b>	<b>1,357</b>	<b>326.10</b>	<b>307.91</b>	<b>1</b>	<b>81</b>	<b>207</b>	<b>490</b>	<b>1,207</b>
Female	526	310.91	291.93	4	85	194	454	1,190
Male	831	335.72	317.41	1	75	216	515	1,207
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 7 day gap, 7 day washout</b>	<b>1,765</b>	<b>351.05</b>	<b>328.74</b>	<b>1</b>	<b>76</b>	<b>237</b>	<b>546</b>	<b>1,209</b>
Female	698	337.36	316.27	4	83	222	514	1,209
Male	1,067	360.01	336.48	1	74	244	576	1,198
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 7 day gap, 30 day washout</b>	<b>1,369</b>	<b>301.68</b>	<b>300.13</b>	<b>1</b>	<b>62</b>	<b>186</b>	<b>456</b>	<b>1,198</b>
Female	533	285.35	281.86	4	65	180	419	1,178
Male	836	312.09	310.94	1	58	193	481	1,198
Other	0	-	-	-	-	-	-	-

**Table 2c: Descriptive statistics of cumulative clozapine exposure duration, all episodes, in days, by age group (years), from September 1, 2015 to December 31, 2018**

Exposures	Total Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
<b>Clozapine, 0 day gap, 30 day washout</b>	<b>1,369</b>	<b>285.29</b>	<b>292.93</b>	<b>1</b>	<b>53</b>	<b>174</b>	<b>438</b>	<b>1,198</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	1	215.00	-	215	215	215	215	215
10-14	27	393.52	334.78	13	123	291	513	1,154
15-18	104	368.58	334.62	1	80	239	582	1,190
19-21	154	295.23	318.36	7	62	137	441	1,129
22-44	614	272.73	282.28	1	49	160	419	1,158
45-64	340	272.05	284.77	4	40	176	382	1,198
65-74	80	331.09	278.18	4	81	264	527	1,003
75+	49	193.51	257.76	3	24	90	270	1,110
<b>Clozapine, 0 day gap, 0 day washout</b>	<b>2,141</b>	<b>375.01</b>	<b>346.48</b>	<b>1</b>	<b>84</b>	<b>260</b>	<b>600</b>	<b>1,209</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	1	215.00	-	215	215	215	215	215
10-14	32	399.16	328.81	13	145	263	613	1,154
15-18	125	407.66	362.38	1	98	293	627	1,209
19-21	187	333.11	333.93	7	70	155	540	1,154
22-44	974	353.11	334.31	1	80	232	536	1,201
45-64	649	408.90	367.92	5	93	291	687	1,204
65-74	105	412.99	321.81	7	105	372	630	1,195
75+	68	352.79	332.24	3	60	275	540	1,110
<b>Clozapine, 14 day gap, 14 day washout</b>	<b>1,574</b>	<b>339.69</b>	<b>320.92</b>	<b>1</b>	<b>76</b>	<b>225</b>	<b>519</b>	<b>1,206</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	1	234.00	-	234	234	234	234	234
10-14	28	430.93	342.82	13	174	331	658	1,154
15-18	106	386.76	339.72	1	89	283	595	1,196
19-21	166	325.60	328.73	16	78	171	503	1,164
22-44	708	322.04	312.95	1	70	206	492	1,200
45-64	419	347.70	324.64	4	76	238	505	1,206
65-74	90	417.40	310.38	21	125	393	646	1,183
75+	56	286.82	317.66	3	49	146	382	1,176
<b>Clozapine, 14 day gap, 30 day washout</b>	<b>1,369</b>	<b>310.98</b>	<b>303.38</b>	<b>1</b>	<b>70</b>	<b>193</b>	<b>464</b>	<b>1,198</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	1	234.00	-	234	234	234	234	234
10-14	27	415.30	339.02	13	154	305	604	1,154

**Table 2c: Descriptive statistics of cumulative clozapine exposure duration, all episodes, in days, by age group (years), from September 1, 2015 to December 31, 2018**

Exposures	Total Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
15-18	104	387.01	343.13	1	86	283	605	1,196
19-21	154	315.29	320.44	18	78	169	494	1,147
22-44	614	296.62	293.62	1	63	177	459	1,191
45-64	340	302.56	298.16	4	58	197	429	1,198
65-74	80	371.08	293.06	4	108	272	577	1,074
75+	49	220.45	272.67	3	38	104	314	1,176
<b>Clozapine, 30 day gap, 30 day washout</b>	<b>1,357</b>	<b>326.10</b>	<b>307.91</b>	<b>1</b>	<b>81</b>	<b>207</b>	<b>490</b>	<b>1,207</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	1	234.00	-	234	234	234	234	234
10-14	26	430.69	346.07	13	167	339	614	1,154
15-18	104	395.28	345.08	1	95	291	619	1,196
19-21	153	327.21	321.10	18	86	185	495	1,167
22-44	612	310.79	297.90	1	73	183	474	1,207
45-64	335	321.01	303.54	4	76	218	454	1,198
65-74	79	395.39	304.89	4	121	288	630	1,101
75+	47	232.87	281.86	3	44	117	342	1,190
<b>Clozapine, 7 day gap, 7 day washout</b>	<b>1,765</b>	<b>351.05</b>	<b>328.74</b>	<b>1</b>	<b>76</b>	<b>237</b>	<b>546</b>	<b>1,209</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	1	227.00	-	227	227	227	227	227
10-14	31	407.10	333.18	13	139	298	584	1,154
15-18	114	395.97	342.42	1	102	321	615	1,209
19-21	176	329.95	335.59	14	70	158	525	1,130
22-44	793	330.27	318.50	1	70	211	504	1,193
45-64	492	372.80	338.71	1	90	269	593	1,198
65-74	95	408.79	315.93	14	123	377	652	1,155
75+	63	307.78	332.62	3	63	148	450	1,149
<b>Clozapine, 7 day gap, 30 day washout</b>	<b>1,369</b>	<b>301.68</b>	<b>300.13</b>	<b>1</b>	<b>62</b>	<b>186</b>	<b>456</b>	<b>1,198</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	1	227.00	-	227	227	227	227	227
10-14	27	408.52	337.34	13	139	298	584	1,154
15-18	104	380.92	340.75	1	84	279	602	1,196
19-21	154	308.53	320.22	14	71	158	478	1,130
22-44	614	287.76	289.98	1	57	172	447	1,180
45-64	340	291.55	294.22	4	50	190	413	1,198

**Table 2c: Descriptive statistics of cumulative clozapine exposure duration, all episodes, in days, by age group (years), from September 1, 2015 to December 31, 2018**

Exposures	Total Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
65-74	80	356.31	286.80	4	104	269	563	1,050
75+	49	210.10	268.24	3	30	96	305	1,149

**Table 3a: Descriptive statistics of first clozapine exposure episode duration, in days, from September 1, 2015 to December 31, 2018**

Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Clozapine, 0 day gap, 30 day washout	1,369	112.84	196.25	1	14	30	112	1,198
Clozapine, 0 day gap, 0 day washout	2,141	111.51	189.36	1	28	30	105	1,209
Clozapine, 14 day gap, 14 day washout	1,574	228.50	267.31	1	44	112	308	1,198
Clozapine, 14 day gap, 30 day washout	1,369	222.97	264.26	1	44	107	299	1,198
Clozapine, 30 day gap, 30 day washout	1,357	263.58	276.80	1	60	146	368	1,198
Clozapine, 7 day gap, 7 day washout	1,765	196.17	249.73	1	37	90	256	1,209
Clozapine, 7 day gap, 30 day washout	1,369	188.86	243.34	1	36	83	244	1,198

**Table 3b: Descriptive statistics of first clozapine exposure episode duration, in days, by sex, from September 1, 2015 to December 31, 2018**

Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
<b>Clozapine, 0 day gap, 30 day washout</b>	<b>1,369</b>	<b>112.84</b>	<b>196.25</b>	<b>1</b>	<b>14</b>	<b>30</b>	<b>112</b>	<b>1,198</b>
Female	533	95.91	168.94	3	14	30	90	1,118
Male	836	123.63	211.23	1	14	30	121	1,198
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 0 day gap, 0 day washout</b>	<b>2,141</b>	<b>111.51</b>	<b>189.36</b>	<b>1</b>	<b>28</b>	<b>30</b>	<b>105</b>	<b>1,209</b>
Female	845	95.20	163.33	3	26	30	90	1,209
Male	1,296	122.15	203.91	1	28	30	117	1,204
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 14 day gap, 14 day washout</b>	<b>1,574</b>	<b>228.50</b>	<b>267.31</b>	<b>1</b>	<b>44</b>	<b>112</b>	<b>308</b>	<b>1,198</b>
Female	617	208.58	244.10	4	44	107	269	1,178
Male	957	241.34	280.63	1	44	117	336	1,198
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 14 day gap, 30 day washout</b>	<b>1,369</b>	<b>222.97</b>	<b>264.26</b>	<b>1</b>	<b>44</b>	<b>107</b>	<b>299</b>	<b>1,198</b>
Female	533	202.19	238.50	4	44	105	264	1,178
Male	836	236.22	278.78	1	44	108	327	1,198
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 30 day gap, 30 day washout</b>	<b>1,357</b>	<b>263.58</b>	<b>276.80</b>	<b>1</b>	<b>60</b>	<b>146</b>	<b>368</b>	<b>1,198</b>
Female	526	246.68	256.39	4	60	144	350	1,190
Male	831	274.27	288.61	1	60	152	389	1,198
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 7 day gap, 7 day washout</b>	<b>1,765</b>	<b>196.17</b>	<b>249.73</b>	<b>1</b>	<b>37</b>	<b>90</b>	<b>256</b>	<b>1,209</b>
Female	698	182.83	234.41	4	37	89	225	1,209
Male	1,067	204.90	258.99	1	37	91	267	1,198
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 7 day gap, 30 day washout</b>	<b>1,369</b>	<b>188.86</b>	<b>243.34</b>	<b>1</b>	<b>36</b>	<b>83</b>	<b>244</b>	<b>1,198</b>
Female	533	169.00	217.29	4	37	75	219	1,178
Male	836	201.52	257.92	1	35	87	267	1,198
Other	0	-	-	-	-	-	-	-



**Table 3c: Descriptive statistics of first clozapine exposure episode duration, in days, by age group (years), from September 1, 2015 to December 31, 2018**

Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
<b>Clozapine, 0 day gap, 30 day washout</b>	<b>1,369</b>	<b>112.84</b>	<b>196.25</b>	<b>1</b>	<b>14</b>	<b>30</b>	<b>112</b>	<b>1,198</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	1	126.00	-	126	126	126	126	126
10-14	27	180.11	321.81	6	14	30	194	1,154
15-18	104	141.41	232.68	1	14	31	135	1,146
19-21	154	145.73	249.98	5	14	39	112	1,128
22-44	614	113.94	185.34	1	15	30	120	1,110
45-64	340	91.91	175.37	1	14	30	88	1,198
65-74	80	99.99	158.84	3	14	30	116	928
75+	49	63.94	123.17	3	8	30	60	780
<b>Clozapine, 0 day gap, 0 day washout</b>	<b>2,141</b>	<b>111.51</b>	<b>189.36</b>	<b>1</b>	<b>28</b>	<b>30</b>	<b>105</b>	<b>1,209</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	1	126.00	-	126	126	126	126	126
10-14	32	154.66	300.62	6	14	29	109	1,154
15-18	125	155.90	259.38	1	14	49	153	1,209
19-21	187	133.47	231.79	5	14	35	111	1,128
22-44	974	108.78	176.13	1	28	30	105	1,155
45-64	649	102.26	178.80	1	28	30	90	1,204
65-74	105	105.31	158.47	4	28	30	117	928
75+	68	85.97	153.30	3	14	30	88	881
<b>Clozapine, 14 day gap, 14 day washout</b>	<b>1,574</b>	<b>228.50</b>	<b>267.31</b>	<b>1</b>	<b>44</b>	<b>112</b>	<b>308</b>	<b>1,198</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	1	234.00	-	234	234	234	234	234
10-14	28	328.96	337.01	13	87	216	408	1,154
15-18	106	302.49	313.99	1	70	172	468	1,196
19-21	166	236.90	286.28	16	52	110	303	1,130
22-44	708	222.42	258.87	1	44	105	314	1,175
45-64	419	214.95	257.16	3	44	107	282	1,198
65-74	90	240.08	259.63	19	42	125	355	973
75+	56	172.77	243.84	3	36	80	187	1,006
<b>Clozapine, 14 day gap, 30 day washout</b>	<b>1,369</b>	<b>222.97</b>	<b>264.26</b>	<b>1</b>	<b>44</b>	<b>107</b>	<b>299</b>	<b>1,198</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	1	234.00	-	234	234	234	234	234
10-14	27	330.41	343.35	13	83	209	414	1,154

**Table 3c: Descriptive statistics of first clozapine exposure episode duration, in days, by age group (years), from September 1, 2015 to December 31, 2018**

Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
15-18	104	304.65	316.56	1	70	172	469	1,196
19-21	154	250.08	298.05	18	54	118	325	1,130
22-44	614	215.63	250.99	1	44	105	299	1,143
45-64	340	198.54	248.61	3	44	86	267	1,198
65-74	80	228.99	250.86	4	43	122	281	973
75+	49	156.67	225.49	3	32	73	186	1,006
<b>Clozapine, 30 day gap, 30 day washout</b>	<b>1,357</b>	<b>263.58</b>	<b>276.80</b>	<b>1</b>	<b>60</b>	<b>146</b>	<b>368</b>	<b>1,198</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	1	234.00	-	234	234	234	234	234
10-14	26	400.42	339.11	13	125	292	582	1,154
15-18	104	336.92	323.21	1	85	197	497	1,196
19-21	153	286.42	305.29	18	68	146	410	1,167
22-44	612	249.13	261.22	1	60	139	342	1,143
45-64	335	247.34	266.92	3	60	145	332	1,198
65-74	79	296.85	270.25	4	60	245	445	973
75+	47	199.79	267.08	3	44	90	228	1,190
<b>Clozapine, 7 day gap, 7 day washout</b>	<b>1,765</b>	<b>196.17</b>	<b>249.73</b>	<b>1</b>	<b>37</b>	<b>90</b>	<b>256</b>	<b>1,209</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	1	208.00	-	208	208	208	208	208
10-14	31	305.32	327.86	13	69	223	394	1,154
15-18	114	284.84	317.14	1	53	155	445	1,209
19-21	176	220.97	290.10	14	37	92	253	1,130
22-44	793	193.84	242.24	1	37	94	259	1,170
45-64	492	171.01	225.71	1	37	71	223	1,198
65-74	95	203.85	233.25	12	37	111	268	1,057
75+	63	126.94	183.65	3	26	63	111	917
<b>Clozapine, 7 day gap, 30 day washout</b>	<b>1,369</b>	<b>188.86</b>	<b>243.34</b>	<b>1</b>	<b>36</b>	<b>83</b>	<b>244</b>	<b>1,198</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	1	208.00	-	208	208	208	208	208
10-14	27	313.89	347.99	13	69	209	394	1,154
15-18	104	279.22	311.69	1	47	150	445	1,196
19-21	154	228.75	296.80	14	37	93	271	1,130
22-44	614	183.73	229.87	1	35	86	246	1,143
45-64	340	154.33	208.12	3	35	66	205	1,198

**Table 3c: Descriptive statistics of first clozapine exposure episode duration, in days, by age group (years), from September 1, 2015 to December 31, 2018**

Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
65-74	80	188.18	225.00	4	35	85	267	973
75+	49	107.33	147.04	3	24	59	97	787

**Table 4a: Descriptive statistics of all clozapine episode durations, in days, from September 1, 2015 to December 31, 2018**

Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Clozapine, 0 day gap, 30 day washout	5,324	73.36	143.19	1	14	30	60	1,198
Clozapine, 0 day gap, 0 day washout	10,811	74.27	134.53	1	28	30	60	1,209
Clozapine, 14 day gap, 14 day washout	2,916	183.36	233.97	1	44	80	223	1,198
Clozapine, 14 day gap, 30 day washout	2,347	181.39	233.72	1	44	78	222	1,198
Clozapine, 30 day gap, 30 day washout	1,846	239.72	261.50	1	60	128	327	1,198
Clozapine, 7 day gap, 7 day washout	4,427	139.96	200.88	1	35	58	148	1,209
Clozapine, 7 day gap, 30 day washout	2,940	140.47	203.00	1	35	51	152	1,198

**Table 4b: Descriptive statistics of all clozapine episode durations, in days, by sex, from September 1, 2015 to December 31, 2018**

Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
<b>Clozapine, 0 day gap, 30 day washout</b>	<b>5,324</b>	<b>73.36</b>	<b>143.19</b>	<b>1</b>	<b>14</b>	<b>30</b>	<b>60</b>	<b>1,198</b>
Female	2,191	65.12	129.47	1	14	30	56	1,173
Male	3,133	79.12	151.80	1	14	30	60	1,198
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 0 day gap, 0 day washout</b>	<b>10,811</b>	<b>74.27</b>	<b>134.53</b>	<b>1</b>	<b>28</b>	<b>30</b>	<b>60</b>	<b>1,209</b>
Female	4,498	69.11	125.37	1	27	30	60	1,209
Male	6,313	77.94	140.59	1	28	30	60	1,204
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 14 day gap, 14 day washout</b>	<b>2,916</b>	<b>183.36</b>	<b>233.97</b>	<b>1</b>	<b>44</b>	<b>80</b>	<b>223</b>	<b>1,198</b>
Female	1,178	170.22	215.33	1	44	80	200	1,178
Male	1,738	192.26	245.46	1	44	81	238	1,198
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 14 day gap, 30 day washout</b>	<b>2,347</b>	<b>181.39</b>	<b>233.72</b>	<b>1</b>	<b>44</b>	<b>78</b>	<b>222</b>	<b>1,198</b>
Female	935	168.31	213.33	4	44	78	192	1,178
Male	1,412	190.06	245.99	1	44	78	238	1,198
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 30 day gap, 30 day washout</b>	<b>1,846</b>	<b>239.72</b>	<b>261.50</b>	<b>1</b>	<b>60</b>	<b>128</b>	<b>327</b>	<b>1,198</b>
Female	717	228.09	245.24	4	60	127	300	1,190
Male	1,129	247.11	271.16	1	60	128	339	1,198
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 7 day gap, 7 day washout</b>	<b>4,427</b>	<b>139.96</b>	<b>200.88</b>	<b>1</b>	<b>35</b>	<b>58</b>	<b>148</b>	<b>1,209</b>
Female	1,811	130.02	187.45	1	35	57	133	1,209
Male	2,616	146.84	209.43	1	35	60	162	1,198
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 7 day gap, 30 day washout</b>	<b>2,940</b>	<b>140.47</b>	<b>203.00</b>	<b>1</b>	<b>35</b>	<b>51</b>	<b>152</b>	<b>1,198</b>
Female	1,183	128.56	185.69	1	35	53	135	1,178
Male	1,757	148.50	213.54	1	35	51	164	1,198
Other	0	-	-	-	-	-	-	-

**Table 4c: Descriptive statistics of all clozapine episode durations, in days, by age group (years), from September 1, 2015 to December 31, 2018**

Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
<b>Clozapine, 0 day gap, 30 day washout</b>	<b>5,324</b>	<b>73.36</b>	<b>143.19</b>	<b>1</b>	<b>14</b>	<b>30</b>	<b>60</b>	<b>1,198</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	3	71.67	53.52	19	19	70	126	126
10-14	108	98.38	204.89	3	14	28	60	1,154
15-18	370	103.60	200.10	1	14	30	71	1,176
19-21	522	87.10	185.51	1	7	28	60	1,128
22-44	2,245	74.59	137.36	1	14	30	60	1,135
45-64	1,471	62.88	124.02	1	14	30	56	1,198
65-74	434	61.03	105.57	3	14	30	56	928
75+	171	55.45	89.79	3	14	30	60	780
<b>Clozapine, 0 day gap, 0 day washout</b>	<b>10,811</b>	<b>74.27</b>	<b>134.53</b>	<b>1</b>	<b>28</b>	<b>30</b>	<b>60</b>	<b>1,209</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	3	71.67	53.52	19	19	70	126	126
10-14	146	87.49	182.16	2	14	30	60	1,154
15-18	538	94.72	187.27	1	16	30	70	1,209
19-21	829	75.14	157.74	1	14	30	60	1,128
22-44	4,521	76.07	134.64	1	28	30	60	1,155
45-64	3,758	70.62	123.59	1	28	30	60	1,204
65-74	633	68.51	110.96	3	28	30	60	951
75+	383	62.64	101.13	3	28	30	60	917
<b>Clozapine, 14 day gap, 14 day washout</b>	<b>2,916</b>	<b>183.36</b>	<b>233.97</b>	<b>1</b>	<b>44</b>	<b>80</b>	<b>223</b>	<b>1,198</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	1	234.00	-	234	234	234	234	234
10-14	44	274.23	296.61	5	78	170	402	1,154
15-18	163	251.52	299.62	1	44	109	400	1,196
19-21	252	214.48	273.86	5	44	88	241	1,130
22-44	1,271	179.39	227.59	1	44	80	216	1,175
45-64	864	168.62	216.65	2	44	78	206	1,198
65-74	220	170.75	213.02	4	44	71	233	980
75+	101	159.03	212.70	3	44	74	186	1,006
<b>Clozapine, 14 day gap, 30 day washout</b>	<b>2,347</b>	<b>181.39</b>	<b>233.72</b>	<b>1</b>	<b>44</b>	<b>78</b>	<b>222</b>	<b>1,198</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	1	234.00	-	234	234	234	234	234
10-14	42	266.98	300.29	5	78	149	401	1,154

Table 4c: Descriptive statistics of all clozapine episode durations, in days, by age group (years), from September 1, 2015 to December 31, 2018

Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
15-18	154	261.36	304.90	1	44	114	426	1,196
19-21	218	222.73	283.39	6	44	93	264	1,130
22-44	1,029	176.99	222.22	1	43	79	216	1,143
45-64	640	160.73	213.72	3	44	72	192	1,198
65-74	186	159.60	202.83	4	44	68	204	973
75+	77	140.29	200.74	3	42	72	138	1,006
<b>Clozapine, 30 day gap, 30 day washout</b>	<b>1,846</b>	<b>239.72</b>	<b>261.50</b>	<b>1</b>	<b>60</b>	<b>128</b>	<b>327</b>	<b>1,198</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	1	234.00	-	234	234	234	234	234
10-14	29	386.14	325.45	13	157	262	565	1,154
15-18	127	323.69	322.85	1	74	173	494	1,196
19-21	185	270.61	298.60	6	60	132	407	1,167
22-44	827	229.99	247.58	1	60	124	313	1,143
45-64	486	221.27	245.59	3	60	120	293	1,198
65-74	133	234.86	249.23	4	60	118	293	973
75+	58	188.71	247.23	3	54	91	208	1,190
<b>Clozapine, 7 day gap, 7 day washout</b>	<b>4,427</b>	<b>139.96</b>	<b>200.88</b>	<b>1</b>	<b>35</b>	<b>58</b>	<b>148</b>	<b>1,209</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	2	113.50	133.64	19	19	114	208	208
10-14	59	213.90	272.44	5	37	97	291	1,154
15-18	223	202.43	275.99	1	35	69	245	1,209
19-21	368	157.80	237.97	4	35	58	143	1,130
22-44	1,892	138.43	199.33	1	35	52	141	1,170
45-64	1,414	129.72	181.24	1	35	63	141	1,198
65-74	296	131.20	178.39	4	35	47	157	1,057
75+	173	112.08	152.95	3	35	53	109	917
<b>Clozapine, 7 day gap, 30 day washout</b>	<b>2,940</b>	<b>140.47</b>	<b>203.00</b>	<b>1</b>	<b>35</b>	<b>51</b>	<b>152</b>	<b>1,198</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	2	113.50	133.64	19	19	114	208	208
10-14	53	208.11	280.27	5	37	91	239	1,154
15-18	186	212.99	282.32	1	34	71	263	1,196
19-21	270	175.97	257.05	4	35	64	166	1,130
22-44	1,280	138.03	194.80	1	35	51	152	1,143
45-64	810	122.38	175.65	1	35	44	135	1,198

**Table 4c: Descriptive statistics of all clozapine episode durations, in days, by age group (years), from September 1, 2015 to December 31, 2018**

Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
65-74	235	121.30	168.56	4	35	41	127	973
75+	104	98.99	147.47	3	28	37	91	840



**Table 5a: Descriptive statistics of days supplied per clozapine dispensing from September 1, 2015 to December 31, 2018**

Exposures	Total Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Clozapine, 0 day gap, 30 day washout	22,220	17.58	12.12	1	7	14	28	90
Clozapine, 0 day gap, 0 day washout	37,727	21.28	11.73	1	7	28	30	90
Clozapine, 14 day gap, 14 day washout	25,784	18.90	12.12	1	7	14	30	90
Clozapine, 14 day gap, 30 day washout	22,220	17.58	12.12	1	7	14	28	90
Clozapine, 30 day gap, 30 day washout	22,137	17.55	12.13	1	7	14	28	90
Clozapine, 7 day gap, 7 day washout	29,356	19.86	12.01	1	7	17	30	90
Clozapine, 7 day gap, 30 day washout	22,220	17.58	12.12	1	7	14	28	90

**Table 5b: Descriptive statistics of days supplied per clozapine dispensing, by sex from September 1, 2015 to December 31, 2018**

Exposures	Total Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
<b>Clozapine, 0 day gap, 30 day washout</b>	<b>22,220</b>	<b>17.58</b>	<b>12.12</b>	<b>1</b>	<b>7</b>	<b>14</b>	<b>28</b>	<b>90</b>
Female	8,500	16.79	12.00	1	7	14	28	90
Male	13,720	18.07	12.17	1	7	14	28	90
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 0 day gap, 0 day washout</b>	<b>37,727</b>	<b>21.28</b>	<b>11.73</b>	<b>1</b>	<b>7</b>	<b>28</b>	<b>30</b>	<b>90</b>
Female	15,009	20.71	11.73	1	7	28	30	90
Male	22,718	21.66	11.71	1	8	28	30	90
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 14 day gap, 14 day washout</b>	<b>25,784</b>	<b>18.90</b>	<b>12.12</b>	<b>1</b>	<b>7</b>	<b>14</b>	<b>30</b>	<b>90</b>
Female	9,920	18.22	12.07	1	7	14	30	90
Male	15,864	19.32	12.13	1	7	14	30	90
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 14 day gap, 30 day washout</b>	<b>22,220</b>	<b>17.58</b>	<b>12.12</b>	<b>1</b>	<b>7</b>	<b>14</b>	<b>28</b>	<b>90</b>
Female	8,500	16.79	12.00	1	7	14	28	90
Male	13,720	18.07	12.17	1	7	14	28	90
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 30 day gap, 30 day washout</b>	<b>22,137</b>	<b>17.55</b>	<b>12.13</b>	<b>1</b>	<b>7</b>	<b>14</b>	<b>28</b>	<b>90</b>
Female	8,445	16.73	12.01	1	7	14	28	90
Male	13,692	18.05	12.18	1	7	14	28	90
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 7 day gap, 7 day washout</b>	<b>29,356</b>	<b>19.86</b>	<b>12.01</b>	<b>1</b>	<b>7</b>	<b>17</b>	<b>30</b>	<b>90</b>
Female	11,455	19.23	11.91	1	7	14	30	90
Male	17,901	20.27	12.05	1	7	21	30	90
Other	0	-	-	-	-	-	-	-
<b>Clozapine, 7 day gap, 30 day washout</b>	<b>22,220</b>	<b>17.58</b>	<b>12.12</b>	<b>1</b>	<b>7</b>	<b>14</b>	<b>28</b>	<b>90</b>
Female	8,500	16.79	12.00	1	7	14	28	90
Male	13,720	18.07	12.17	1	7	14	28	90
Other	0	-	-	-	-	-	-	-

**Table 5c: Descriptive statistics of days supplied per clozapine dispensing, by age group (years) from September 1, 2015 to December 31, 2018**

Exposures	Total Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
<b>Clozapine, 0 day gap, 30 day washout</b>	<b>22,220</b>	<b>17.58</b>	<b>12.12</b>	<b>1</b>	<b>7</b>	<b>14</b>	<b>28</b>	<b>90</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	29	7.41	1.86	5	7	7	7	14
10-14	618	17.19	12.21	1	7	14	28	84
15-18	2,354	16.28	12.20	1	7	14	28	90
19-21	2,822	16.11	11.93	1	7	14	28	90
22-44	9,310	17.99	12.30	1	7	14	30	90
45-64	4,882	18.95	12.16	1	7	14	30	90
65-74	1,655	16.00	10.92	1	7	14	28	60
75+	550	17.24	10.97	1	7	14	28	90
<b>Clozapine, 0 day gap, 0 day washout</b>	<b>37,727</b>	<b>21.28</b>	<b>11.73</b>	<b>1</b>	<b>7</b>	<b>28</b>	<b>30</b>	<b>90</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	29	7.41	1.86	5	7	7	7	14
10-14	707	18.07	12.04	1	7	14	30	84
15-18	2,869	17.76	12.50	1	7	14	28	90
19-21	3,476	17.92	11.99	1	7	14	28	90
22-44	15,939	21.58	11.82	1	7	28	30	90
45-64	11,308	23.47	10.83	1	14	28	30	90
65-74	2,278	19.04	11.46	1	7	14	30	90
75+	1,121	21.40	10.84	1	7	28	30	90
<b>Clozapine, 14 day gap, 14 day washout</b>	<b>25,784</b>	<b>18.90</b>	<b>12.12</b>	<b>1</b>	<b>7</b>	<b>14</b>	<b>30</b>	<b>90</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	29	7.41	1.86	5	7	7	7	14
10-14	649	17.64	12.21	1	7	14	28	84
15-18	2,375	16.39	12.24	1	7	14	28	90
19-21	3,012	16.71	12.02	1	7	14	28	90
22-44	10,814	19.25	12.18	1	7	14	30	90
45-64	6,265	20.82	11.95	1	7	28	30	90
65-74	1,920	17.53	11.21	1	7	14	28	60
75+	720	19.61	11.61	1	7	27	30	90
<b>Clozapine, 14 day gap, 30 day washout</b>	<b>22,220</b>	<b>17.58</b>	<b>12.12</b>	<b>1</b>	<b>7</b>	<b>14</b>	<b>28</b>	<b>90</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	29	7.41	1.86	5	7	7	7	14
10-14	618	17.19	12.21	1	7	14	28	84

**Table 5c: Descriptive statistics of days supplied per clozapine dispensing, by age group (years) from September 1, 2015 to December 31, 2018**

Exposures	Total Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
15-18	2,354	16.28	12.20	1	7	14	28	90
19-21	2,822	16.11	11.93	1	7	14	28	90
22-44	9,310	17.99	12.30	1	7	14	30	90
45-64	4,882	18.95	12.16	1	7	14	30	90
65-74	1,655	16.00	10.92	1	7	14	28	60
75+	550	17.24	10.97	1	7	14	28	90
<b>Clozapine, 30 day gap, 30 day washout</b>	<b>22,137</b>	<b>17.55</b>	<b>12.13</b>	<b>1</b>	<b>7</b>	<b>14</b>	<b>28</b>	<b>90</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	29	7.41	1.86	5	7	7	7	14
10-14	610	17.07	12.24	1	7	14	28	84
15-18	2,354	16.28	12.20	1	7	14	28	90
19-21	2,817	16.09	11.93	1	7	14	28	90
22-44	9,302	17.98	12.31	1	7	14	30	90
45-64	4,843	18.91	12.18	1	7	14	30	90
65-74	1,647	15.94	10.91	1	7	14	28	60
75+	535	16.92	10.94	1	7	14	28	90
<b>Clozapine, 7 day gap, 7 day washout</b>	<b>29,356</b>	<b>19.86</b>	<b>12.01</b>	<b>1</b>	<b>7</b>	<b>17</b>	<b>30</b>	<b>90</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	29	7.41	1.86	5	7	7	7	14
10-14	683	17.79	12.09	1	7	14	30	84
15-18	2,555	17.03	12.37	1	7	14	28	90
19-21	3,203	17.21	12.01	1	7	14	28	90
22-44	12,291	20.10	12.04	1	7	20	30	90
45-64	7,756	22.02	11.56	1	9	28	30	90
65-74	1,983	18.29	11.45	1	7	14	28	90
75+	856	20.92	11.24	1	7	28	30	90
<b>Clozapine, 7 day gap, 30 day washout</b>	<b>22,220</b>	<b>17.58</b>	<b>12.12</b>	<b>1</b>	<b>7</b>	<b>14</b>	<b>28</b>	<b>90</b>
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	29	7.41	1.86	5	7	7	7	14
10-14	618	17.19	12.21	1	7	14	28	84
15-18	2,354	16.28	12.20	1	7	14	28	90
19-21	2,822	16.11	11.93	1	7	14	28	90
22-44	9,310	17.99	12.30	1	7	14	30	90
45-64	4,882	18.95	12.16	1	7	14	30	90

**Table 5c: Descriptive statistics of days supplied per clozapine dispensing, by age group (years) from September 1, 2015 to December 31, 2018**

Exposures	Total Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
65-74	1,655	16.00	10.92	1	7	14	28	60
75+	550	17.24	10.97	1	7	14	28	90

**Table 6: Counts of reason for censoring, all clozapine episodes and first clozapine episode from September 1, 2015 to December 31, 2018**

	Total		Disenrollment		Evidence of death		Episode end	
	N	%	N	%	N	%	N	%
<b>Exposures</b>								
Clozapine, 0 day gap, 30 day washout	5,324	100.0	775	14.6	0	0.0	5,324	100.0
Clozapine, 0 day gap, 0 day washout	10,811	100.0	1,408	13.0	0	0.0	10,811	100.0
Clozapine, 14 day gap, 14 day washout	2,916	100.0	1,023	35.1	0	0.0	1,895	65.0
Clozapine, 14 day gap, 30 day washout	2,347	100.0	851	36.3	0	0.0	1,497	63.8
Clozapine, 30 day gap, 30 day washout	1,846	100.0	890	48.2	0	0.0	957	51.8
Clozapine, 7 day gap, 7 day washout	4,427	100.0	1,145	25.9	0	0.0	3,287	74.2
Clozapine, 7 day gap, 30 day washout	2,940	100.0	823	28.0	0	0.0	2,121	72.1
<b>Patients' First Episode</b>								
Clozapine, 0 day gap, 30 day washout	1,369	100.0	312	22.8	0	0.0	1,369	100.0
Clozapine, 0 day gap, 0 day washout	2,141	100.0	425	19.9	0	0.0	2,141	100.0
Clozapine, 14 day gap, 14 day washout	1,574	100.0	675	42.9	0	0.0	899	57.1
Clozapine, 14 day gap, 30 day washout	1,369	100.0	594	43.4	0	0.0	775	56.6
Clozapine, 30 day gap, 30 day washout	1,357	100.0	707	52.1	0	0.0	651	48.0
Clozapine, 7 day gap, 7 day washout	1,765	100.0	639	36.2	0	0.0	1,128	63.9
Clozapine, 7 day gap, 30 day washout	1,369	100.0	510	37.3	0	0.0	860	62.8

**Table 7: Cohort Attrition Table**

Attrition Criteria	Members
<b>Clozapine, 0 day gap, 30 day washout</b>	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	49,338,922 (100.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y during the query period	46,227,507 (93.7%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	46,227,507 (93.7%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y during the query period	46,227,507 (93.7%)
Exclusion - Members must satisfy the age range condition within the query period	46,227,426 (93.7%)
Exclusion - Members must meet chart availability criterion within the query period	46,227,426 (93.7%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	46,227,426 (93.7%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	3,340 (0.0%)
Exclusion - Members must have at least one cohort episode beginning within the age range condition	3,340 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	2,246 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	2,246 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	1,369 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	1,369 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	1,369 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	1,369 (0.0%)
<b>Clozapine, 0 day gap, 0 day washout</b>	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	49,338,922 (100.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y during the query period	46,227,507 (93.7%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	46,227,507 (93.7%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y during the query period	46,227,507 (93.7%)
Exclusion - Members must satisfy the age range condition within the query period	46,227,426 (93.7%)
Exclusion - Members must meet chart availability criterion within the query period	46,227,426 (93.7%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	46,227,426 (93.7%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	3,340 (0.0%)
Exclusion - Members must have at least one cohort episode beginning within the age range condition	3,340 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	2,732 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	2,732 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	2,141 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	2,141 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	2,141 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	2,141 (0.0%)
<b>Clozapine, 14 day gap, 14 day washout</b>	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	49,338,922 (100.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y during the query period	46,227,507 (93.7%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	46,227,507 (93.7%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y during the query period	46,227,507 (93.7%)
Exclusion - Members must satisfy the age range condition within the query period	46,227,426 (93.7%)

**Table 7: Cohort Attrition Table**

Attrition Criteria	Members
Exclusion - Members must meet chart availability criterion within the query period	46,227,426 (93.7%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	46,227,426 (93.7%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	3,340 (0.0%)
Exclusion - Members must have at least one cohort episode beginning within the age range condition	3,340 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	2,388 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	2,388 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	1,574 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	1,574 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	1,574 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	1,574 (0.0%)
<b>Clozapine, 14 day gap, 30 day washout</b>	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	49,338,922 (100.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y during the query period	46,227,507 (93.7%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	46,227,507 (93.7%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y during the query period	46,227,507 (93.7%)
Exclusion - Members must satisfy the age range condition within the query period	46,227,426 (93.7%)
Exclusion - Members must meet chart availability criterion within the query period	46,227,426 (93.7%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	46,227,426 (93.7%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	3,340 (0.0%)
Exclusion - Members must have at least one cohort episode beginning within the age range condition	3,340 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	2,246 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	2,246 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	1,369 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	1,369 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	1,369 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	1,369 (0.0%)
<b>Clozapine, 30 day gap, 30 day washout</b>	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	49,338,922 (100.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y during the query period	46,227,507 (93.7%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	46,227,507 (93.7%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y during the query period	46,227,507 (93.7%)
Exclusion - Members must satisfy the age range condition within the query period	46,227,426 (93.7%)
Exclusion - Members must meet chart availability criterion within the query period	46,227,426 (93.7%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	46,227,426 (93.7%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	3,340 (0.0%)
Exclusion - Members must have at least one cohort episode beginning within the age range condition	3,340 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	2,239 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	2,239 (0.0%)



**Table 7: Cohort Attrition Table**

Attrition Criteria	Members
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	1,357 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	1,357 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	1,357 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	1,357 (0.0%)
<b>Clozapine, 7 day gap, 7 day washout</b>	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	49,338,922 (100.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y during the query period	46,227,507 (93.7%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	46,227,507 (93.7%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y during the query period	46,227,507 (93.7%)
Exclusion - Members must satisfy the age range condition within the query period	46,227,426 (93.7%)
Exclusion - Members must meet chart availability criterion within the query period	46,227,426 (93.7%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	46,227,426 (93.7%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	3,340 (0.0%)
Exclusion - Members must have at least one cohort episode beginning within the age range condition	3,340 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	2,518 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	2,518 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	1,765 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	1,765 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	1,765 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	1,765 (0.0%)
<b>Clozapine, 7 day gap, 30 day washout</b>	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	49,338,922 (100.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y during the query period	46,227,507 (93.7%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	46,227,507 (93.7%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y during the query period	46,227,507 (93.7%)
Exclusion - Members must satisfy the age range condition within the query period	46,227,426 (93.7%)
Exclusion - Members must meet chart availability criterion within the query period	46,227,426 (93.7%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	46,227,426 (93.7%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	3,340 (0.0%)
Exclusion - Members must have at least one cohort episode beginning within the age range condition	3,340 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	2,246 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	2,246 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	1,369 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	1,369 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	1,369 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	1,369 (0.0%)

**Appendix A. Dates of Available Data for Each Data Partner (DP) up to Request End Date (12/31/2018) as of Query Distribution Date**

Data Partner (Masked)	Start Date	End Date
DP01	01/01/2010	12/31/2018



Appendix B. Specifications Used to Define Parameters in this Query

Global Values

Enrollment Criteria:**Medical and Drug Coverage**

Enrollment Gap (Days):**45**

Age Groups (Years):**00-01, 02-04, 05-09, 10-14, 15-18, 19-21, 22-44, 45-64, 65-74, 75+**

Query Period: **09/01/2015-12/31/2018**

Baseline Characteristics Table:**Yes**

Baseline Evaluation Window (Day): **-183,-1**

#	Cohort Name	Index Exposure	Pre-Index Enrollment Period (Days)	Washout Period (Days)	Treatment Episode Gap (Days)	Treatment Episode Extension (Days)	Inclusion/Exclusion	Criteria	Criteria Definition	Evaluation Period Start (Day)	Evaluation Period End (Day)
1	Clozapine, 0 day gap, 30 day washout	Clozapine <sup>[1]</sup>	183	30	0	0	--	--	--	--	--
							--	--	--	--	--
2	Clozapine, 0 day gap, 0 day washout	Clozapine <sup>[2]</sup>	183	-	0	0	--	--	--	--	--
							--	--	--	--	--
3	Clozapine, 14 day gap, 14 day washout	Clozapine <sup>[3]</sup>	183	14	14	14	--	--	--	--	--
							--	--	--	--	--
4	Clozapine, 14 day gap, 30 day washout	Clozapine <sup>[4]</sup>	183	30	14	14	--	--	--	--	--
							--	--	--	--	--
5	Clozapine, 30 day gap, 30 day washout	Clozapine <sup>[5]</sup>	183	30	30	30	--	--	--	--	--
							--	--	--	--	--
6	Clozapine, 7 day gap, 7 day washout	Clozapine <sup>[6]</sup>	183	7	7	7	--	--	--	--	--
							--	--	--	--	--
7	Clozapine, 7 day gap, 30 day washout	Clozapine <sup>[7]</sup>	183	30	7	7	--	--	--	--	--
							--	--	--	--	--

ICD-9,ICD-10,HCPCS AND CPT are provided by Optum360  
NDCs are checked against First Data Bank's MedKnowledge.

Appendix of Generic Names and Chronic Conditions

- [1] See Appendix C
- [2] See Appendix C
- [3] See Appendix C
- [4] See Appendix C
- [5] See Appendix C
- [6] See Appendix C
- [7] See Appendix C

Baseline Characteristics Table

Acquired Hypothyroidism	Chronic Kidney Disease	Hypertension
Acute Myocardial Infarction	Chronic Obstructive Pulmonary Disease	Ischemic Heart Disease
Alzheimer's Disease	Colorectal Cancer	Lung Cancer
Alzheimer's Disease, Related Disorders, or Senile Dementia	Depression	Osteoporosis
Anemia	Diabetes	Prostate Cancer
Asthma	Endometrial Cancer	Rheumatoid Arthritis / Osteoarthritis
Atrial Fibrillation	Glaucoma	Stroke / Transient Ischemic Attack
Benign Prostatic Hyperplasia	Heart Failure	
Breast Cancer	Hip / Pelvic Fracture	
Cataracts	Hyperlipidemia	

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

- Age Groups** - Age groups of members included in the cohort. Strata also used for reporting purposes.
- Ambulatory Visit (AV)** - A care setting value including visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.
- Baseline Characteristics Table** - Optional table containing general characteristics of study population, including background rates of 27 chronic conditions from the CMS Chronic Condition Warehouse (see above if table requested). Users define an evaluation period for the presence of baseline characteristics.
- 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.
- 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).
- Cohort Definition** - Cohort includes all valid exposure episodes during the query period. Only the first valid episode's incidence is assessed using the washout period.
- Emergency Department (ED)** - A care setting value including ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.
- Enrollment Criteria** - Type of coverage required during enrollment period. By default, all patients must have medical and drug coverage.
- Enrollment Gap** - Allowed gap between coverage periods.
- Episodes** - Treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the episode gap.
- Inclusion/Exclusion** - Contains the comprehensive set of codes used to define additional cohort inclusion and/or exclusion criteria (e.g., restrict cohort to individuals with evidence of a pre-existing condition 183 days before the index date). Criteria could be defined with complex algorithms (e.g., diagnosis codes and drug codes) defined under Criteria Definition.
- Inpatient Hospital Stay (IP)** - A care setting value including 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)** - A care setting value including hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.
- Other Ambulatory Visit (OA)** - A care setting value including 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.
- 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** - The period of time which patients can contribute index-defining exposure/events. Data prior to the start date may be used to determine enrollment, washout, and other cohort inclusion criteria.
- Treatment Episode Extension** - The episode extension adds the selected number of days to the end of an episode to count as exposed time.
- Treatment Episode Gap** - The maximum number of days allowed between two dispensings to consider them part of the same episode.
- Washout Period** - The period before an exposure episode during which an individual cannot have evidence of incidence-defining criteria.



## Appendix C. List of Generic and Brand Name Medical Products Used to Define Index Exposures in this Request

---

Generic Name	Brand Name
clozapine	clozapine
clozapine	Clozaril
clozapine	FazaClo
clozapine	Versacloz