

## Disclaimer

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

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

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

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

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## Overview for Request: cder\_mpl2r\_wp010

**Request ID:** cder\_mpl2r\_wp010\_ndsp\_v02

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

\*all terms may not be used in this report

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Characteristic	Medical Product				Covariate Balance	
	Montelukast		Inhaled Corticosteroids		Absolute Difference	Standardized Difference
Recorded History within 183 Days Prior to Index:	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Self-harm: Unspecified nonpsychotic mental disorder	398	0.1%	986	0.1%	0.003	0.001
Self-harm: Poisoning	523	0.1%	1,086	0.1%	0.02	0.007
Self-harm: Toxicity	80	0.0%	192	0.0%	0.001	0.001
Self-harm: Asphyxiation	****	****	****	****	0.001	0.002
Self-harm: Open wound	0	0.00%	0	0.0%	0	-
Substance Abuse	3,607	0.7%	15,219	1.1%	-0.441	-0.046
Allergic Rhinitis	249,167	48.5%	366,582	27.5%	20.99	0.443
Other Respiratory Disorder - At Least Two Claims	260,336	50.7%	465,422	35.0%	15.742	0.322
Asthma - Emergency Care Setting	42,514	8.3%	89,890	6.8%	1.528	0.058
Asthma - Inpatient Care Setting, Primary Diagnosis	2,189	0.4%	4,439	0.3%	0.093	0.015
Asthma - Inpatient Care Setting, Secondary/Unknown Diagnosis	18,995	3.7%	40,182	3.0%	0.681	0.038
Asthma - Outpatient Care Setting	149,895	29.2%	308,237	23.2%	6.04	0.138
Asthma Exacerbation	55,780	10.9%	147,751	11.1%	-0.234	-0.007
Recorded History of Use within 183 Days Prior to Index:	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Oral Corticosteroids	109,786	21.4%	192,882	14.5%	6.893	0.18
Other Asthma Medication: Short Acting Beta-Agonist	296,335	57.7%	1,040,457	78.1%	-20.436	-0.449
Other Asthma Medication: Anticholinergic Agents	5,578	1.1%	7,894	0.6%	0.493	0.054
Other Asthma Medication: Phosphodiesterase Inhibitors	3,039	0.6%	6,072	0.5%	0.136	0.019

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

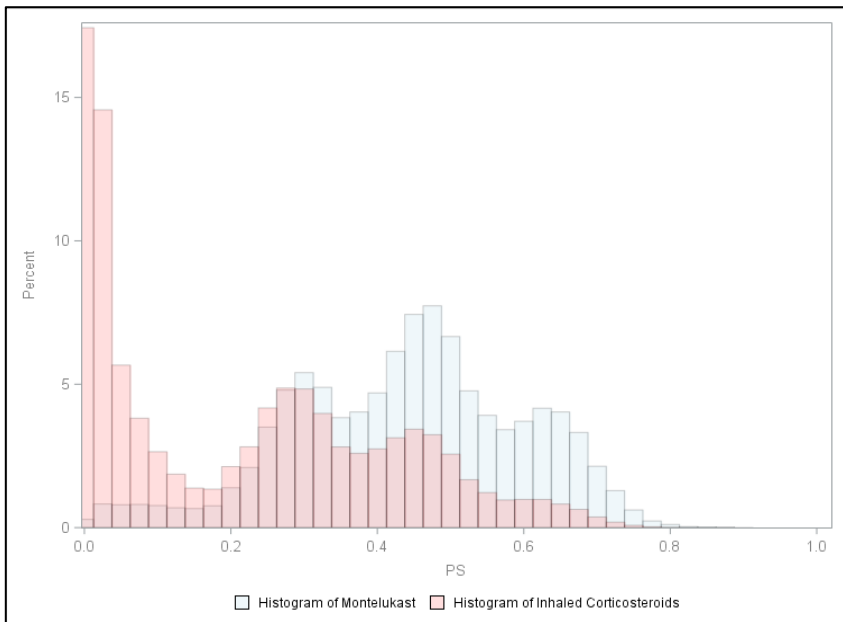
**Table 31b. Summary of Self-Harm with E-Code Through 365 Days after Exposure to Montelukast or Inhaled Corticosteroids in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015 by Analysis Type and Year**

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

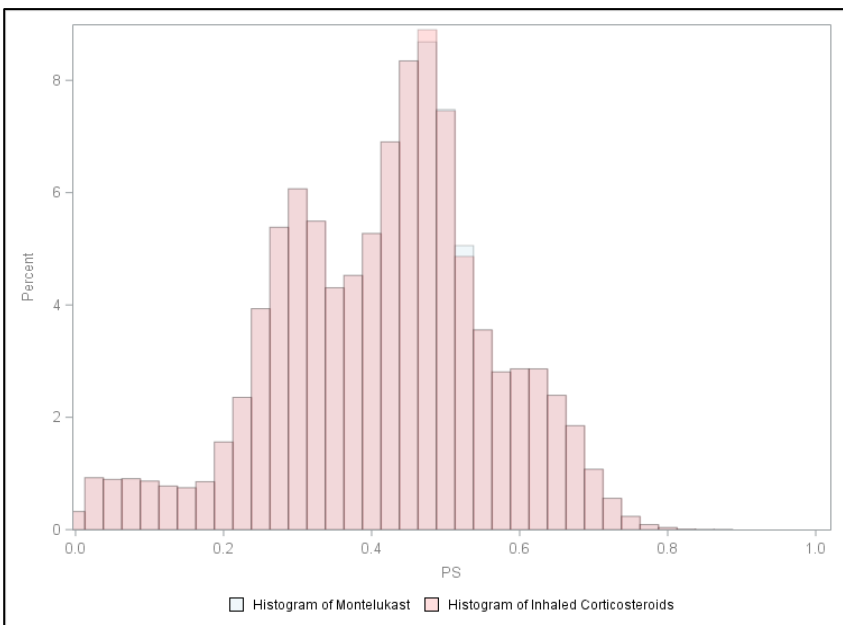


**Figure 1a. Propensity Score Distribution of Inpatient Depressive Disorder Before and After Matching among Montelukast and Inhaled Corticosteroid Users**

**Propensity Score Distribution Before Matching**

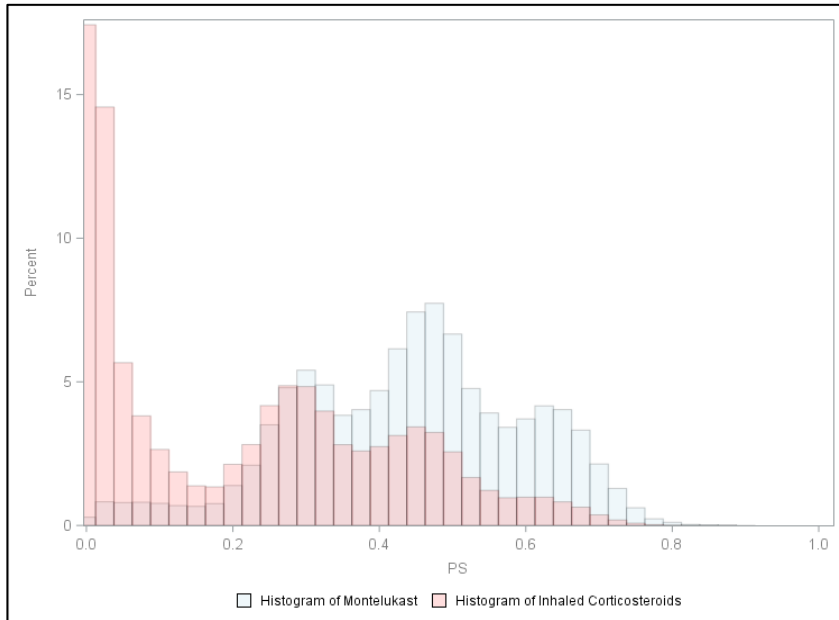


**Propensity Score 1:1 Aggregated Matched Cohort, Matched Caliper = 0.05**

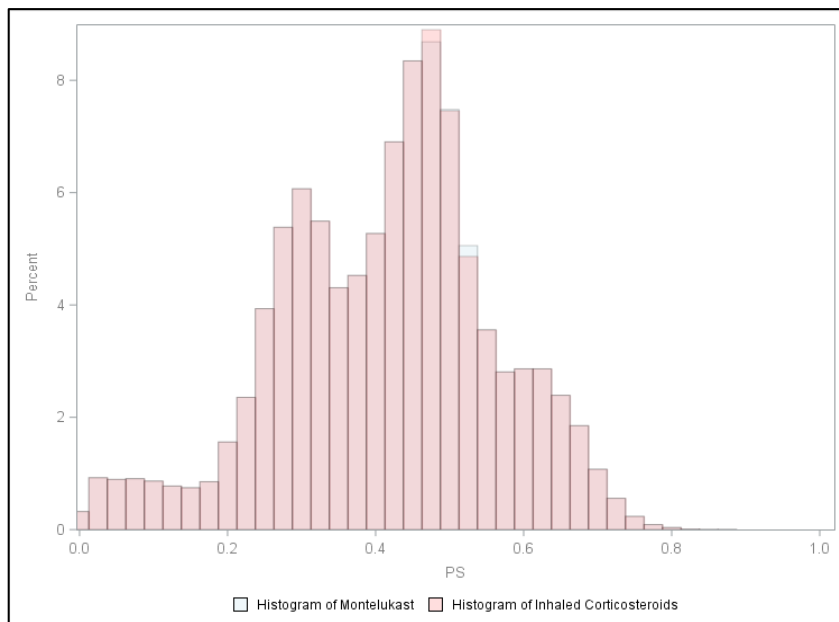


**Figure 1b. Propensity Score Distribution of Inpatient Depressive Disorder, Inhaled Corticosteroid 30-Day Extension and Gap Before and After Matching among Montelukast and Inhaled Corticosteroid Users**

**Propensity Score Distribution Before Matching**

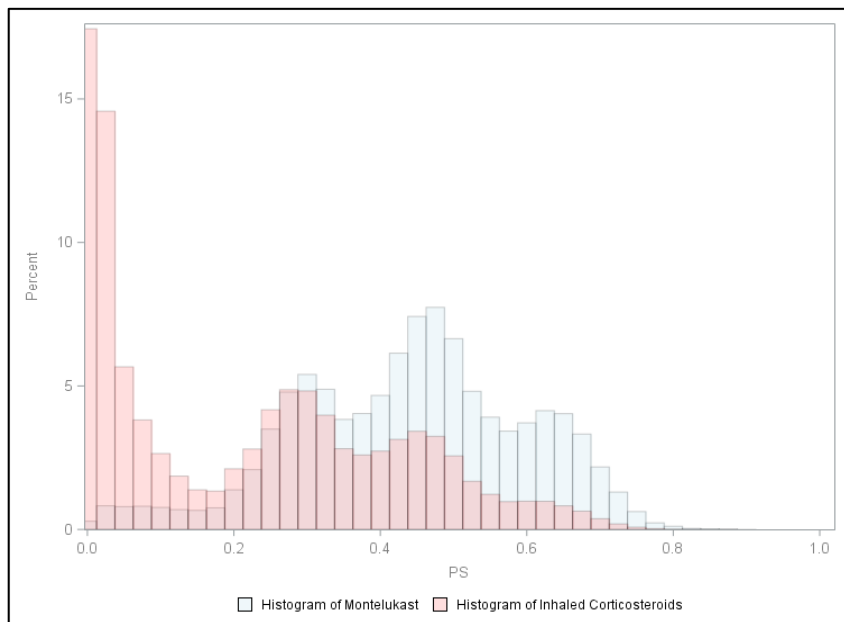


**Propensity Score 1:1 Aggregated Matched Cohort, Matched Caliper = 0.05**

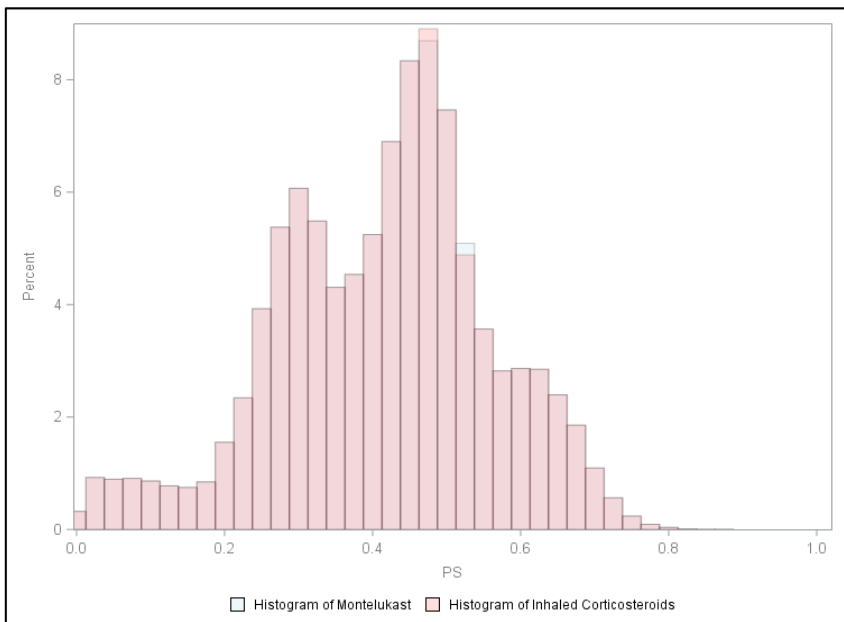


**Figure 1c. Propensity Score Distribution of Inpatient Depressive Disorder, No Episode Extension and Gap Before and After Matching among Montelukast and Inhaled Corticosteroid Users**

**Propensity Score Distribution Before Matching**

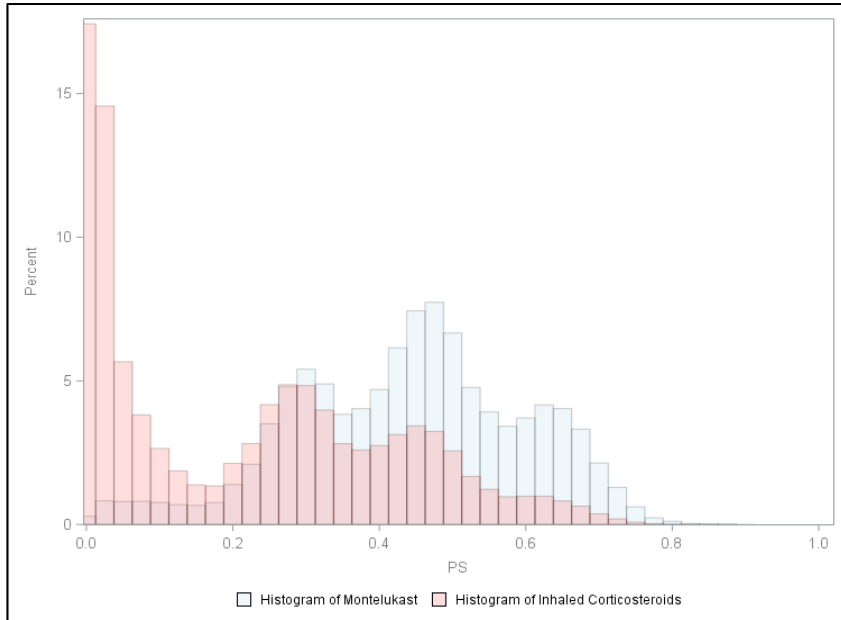


**Propensity Score 1:1 Aggregated Matched Cohort, Matched Caliper = 0.05**

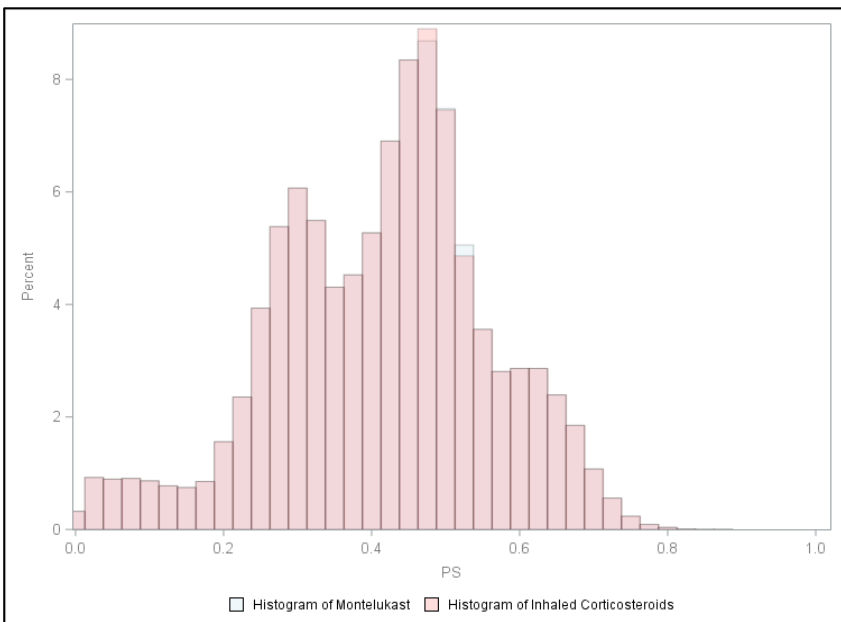


**Figure 1d. Propensity Score Distribution of Outpatient Depressive Disorder Before and After Matching among Montelukast and Inhaled Corticosteroid Users**

**Propensity Score Distribution Before Matching**

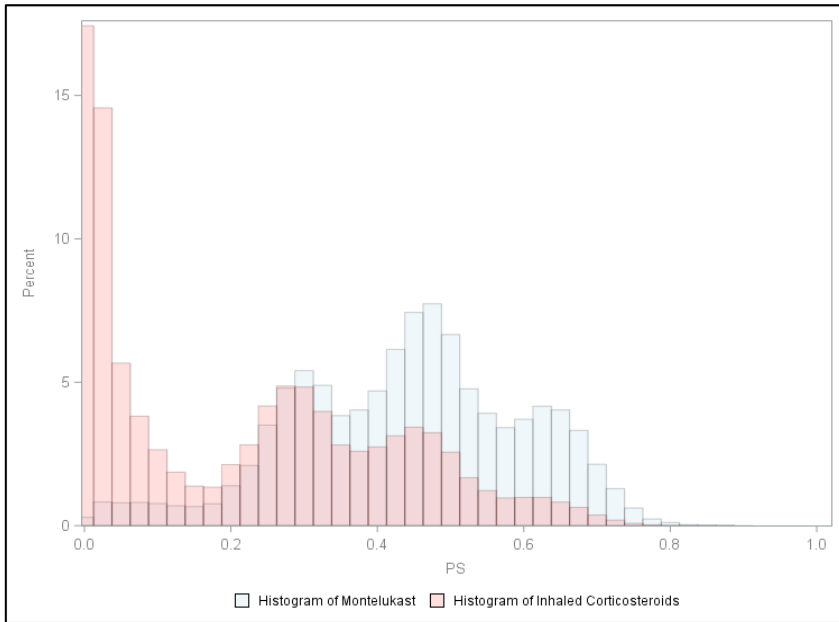


**Propensity Score 1:1 Aggregated Matched Cohort, Matched Caliper = 0.05**

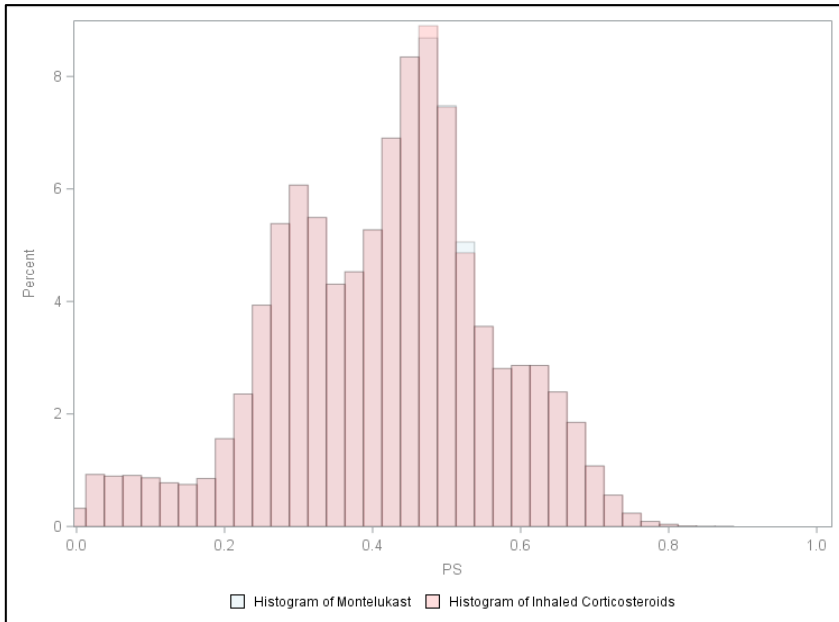


**Figure 1e. Propensity Score Distribution of Self-Harm Before and After Matching among Montelukast and Inhaled Corticosteroid Users**

**Propensity Score Distribution Before Matching**

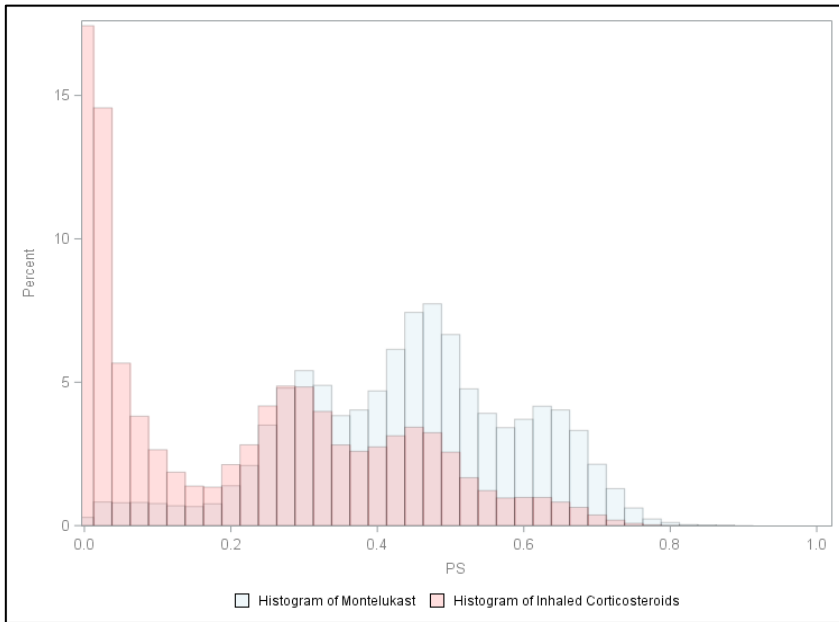


**Propensity Score 1:1 Aggregated Matched Cohort, Matched Caliper = 0.05**

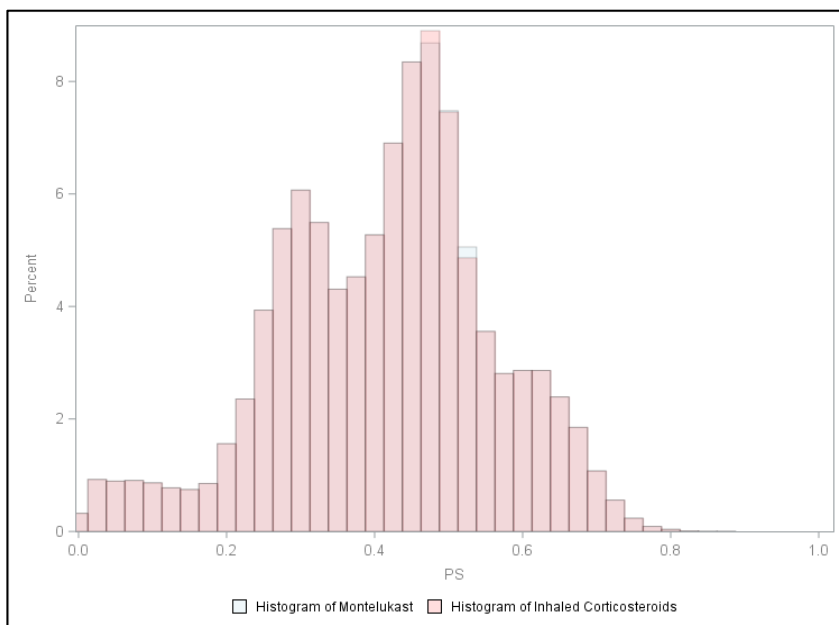


**Figure 1f. Propensity Score Distribution of Self-Harm with E-Code Before and After Matching among Montelukast and Inhaled Corticosteroid Users**

**Propensity Score Distribution Before Matching**

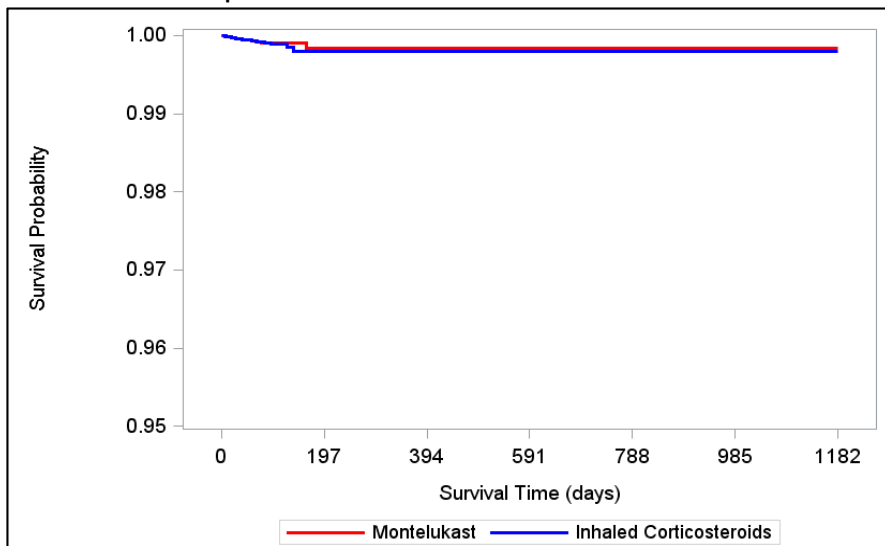


**Propensity Score 1:1 Aggregated Matched Cohort, Matched Caliper = 0.05**



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

**All Available Follow-Up**



**Follow-Up Truncated at 365 Days**

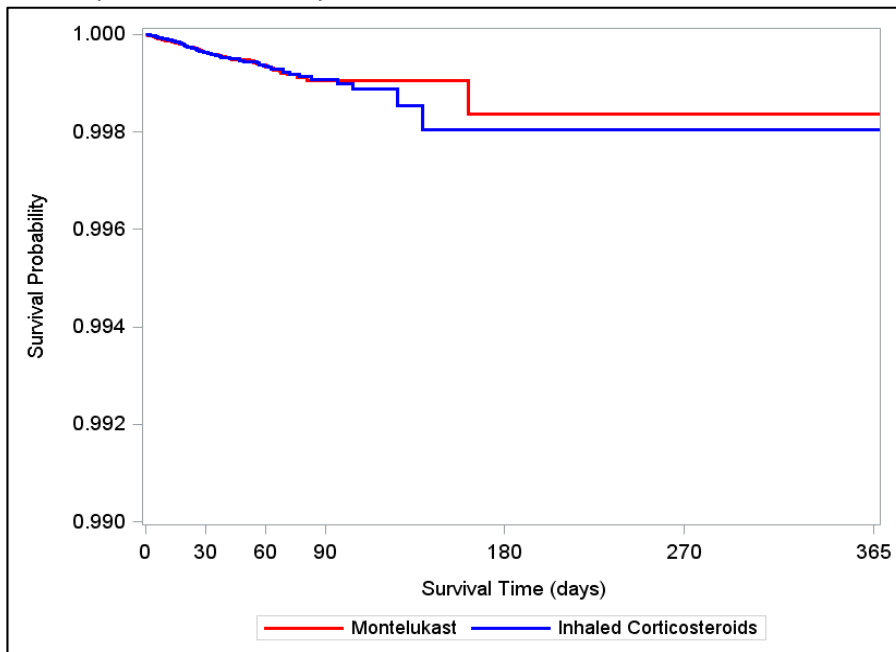
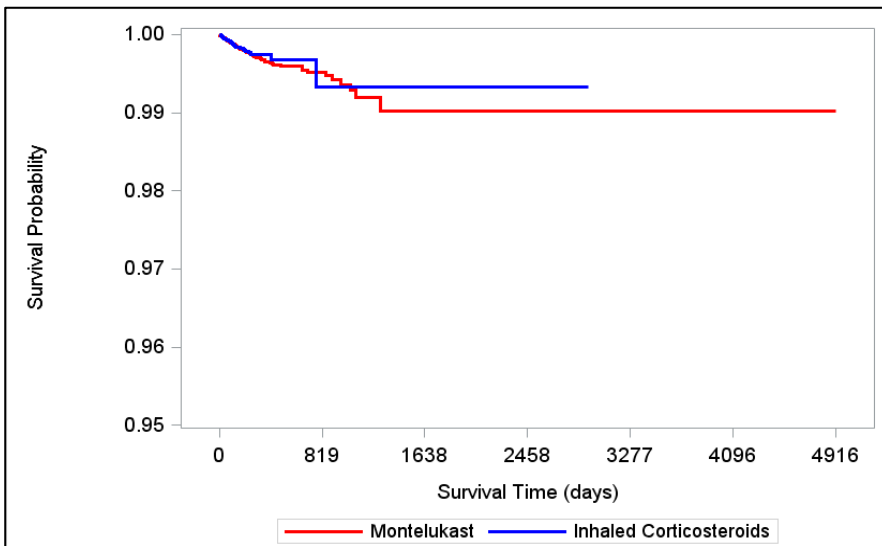


Figure 2b. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, Unconditional Matched Cohort

All Available Follow-Up



Follow-Up Truncated at 365 Days

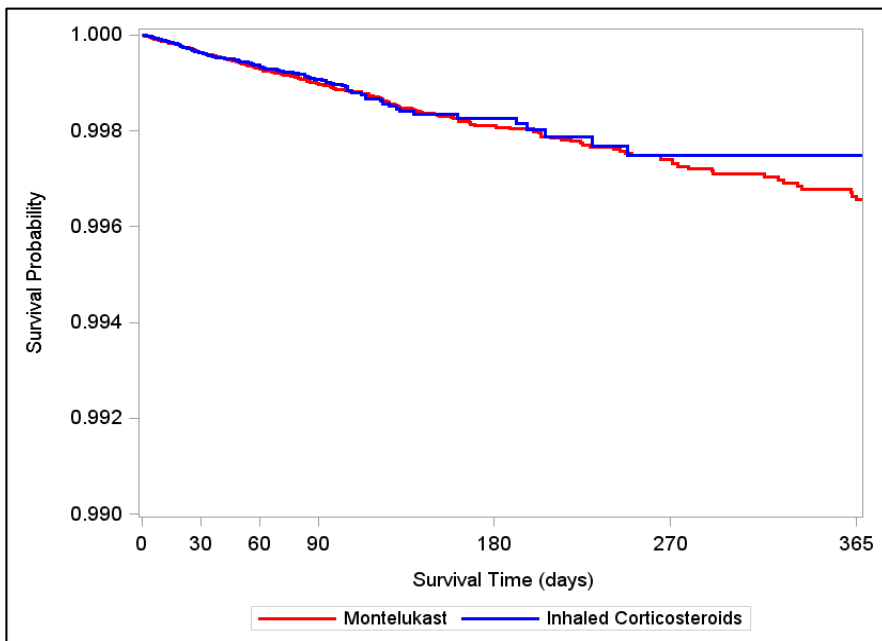
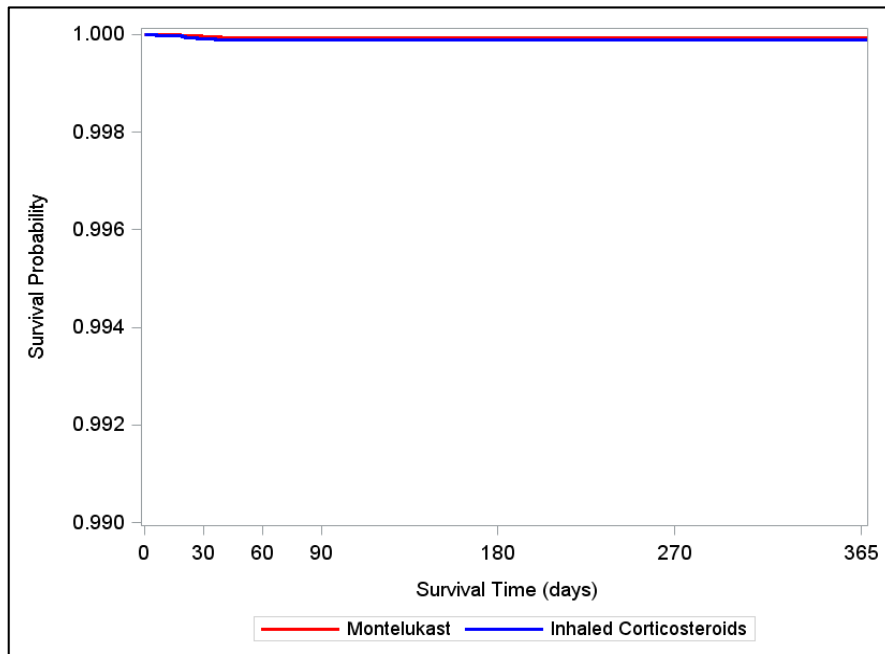




Figure 2c. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by History of Psychiatric Disorder, Conditional Matched Cohort, Follow-Up Truncated to 365 Days

No History of Psychiatric Disorder



History of Psychiatric Disorder

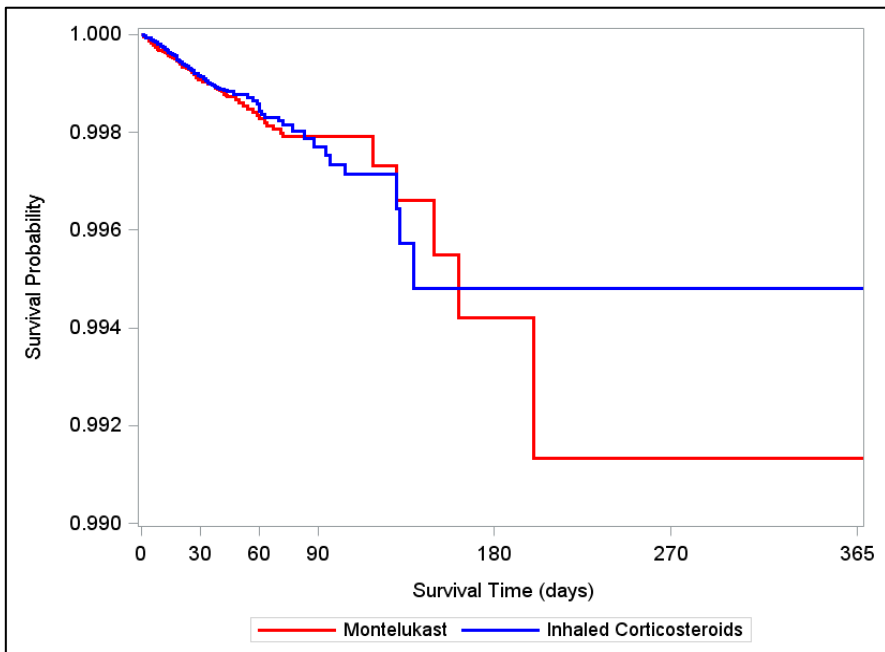
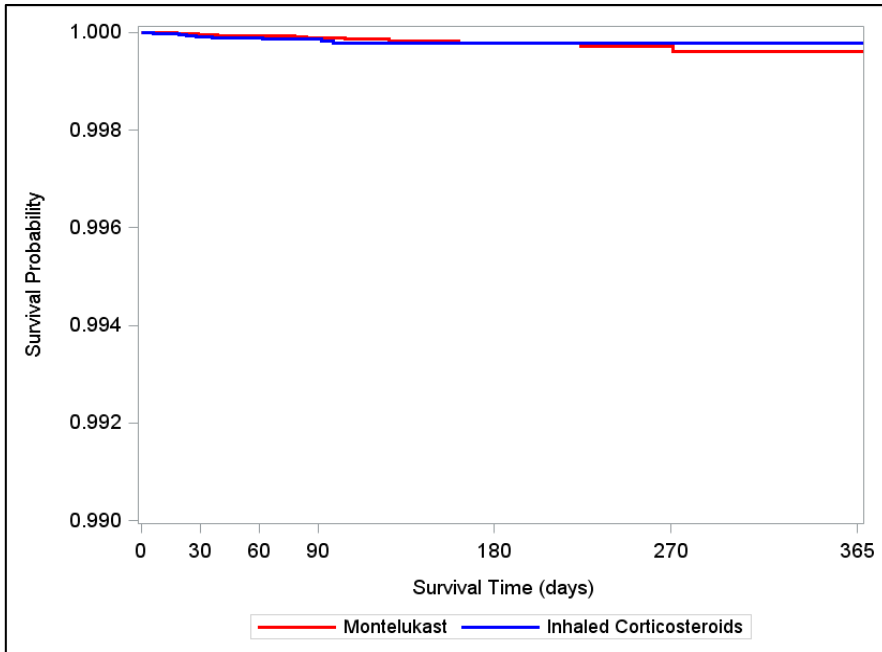
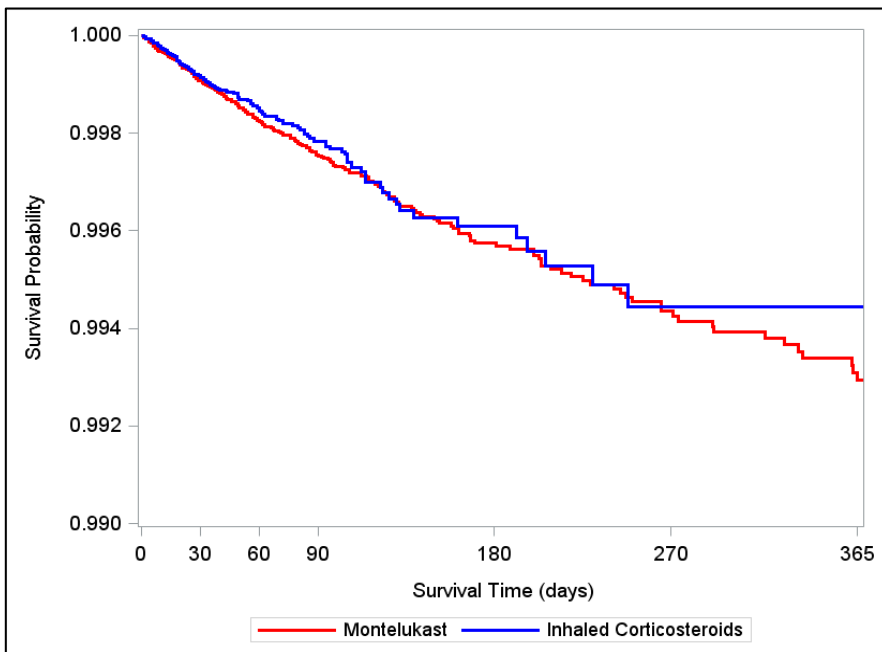


Figure 2d. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by History of Psychiatric Disorder, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days

No History of Psychiatric Disorder

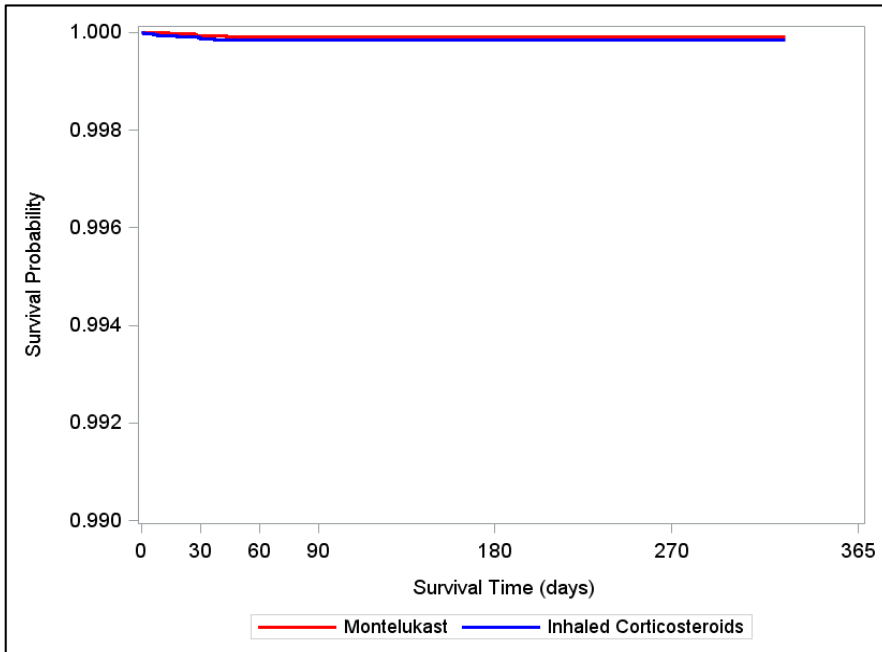


History of Psychiatric Disorder



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

**Ages 6-11 years**



**Ages 12-17 years**

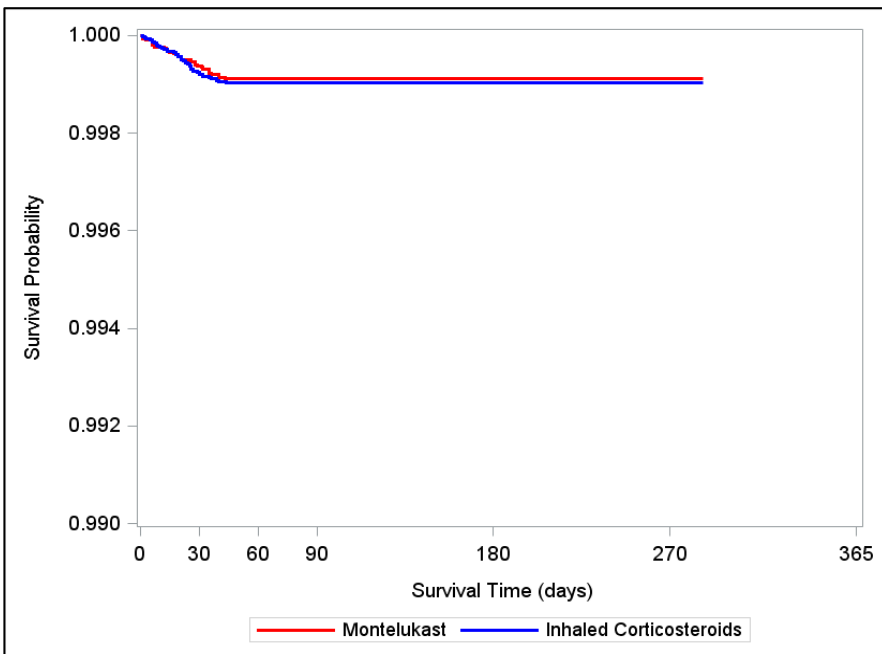
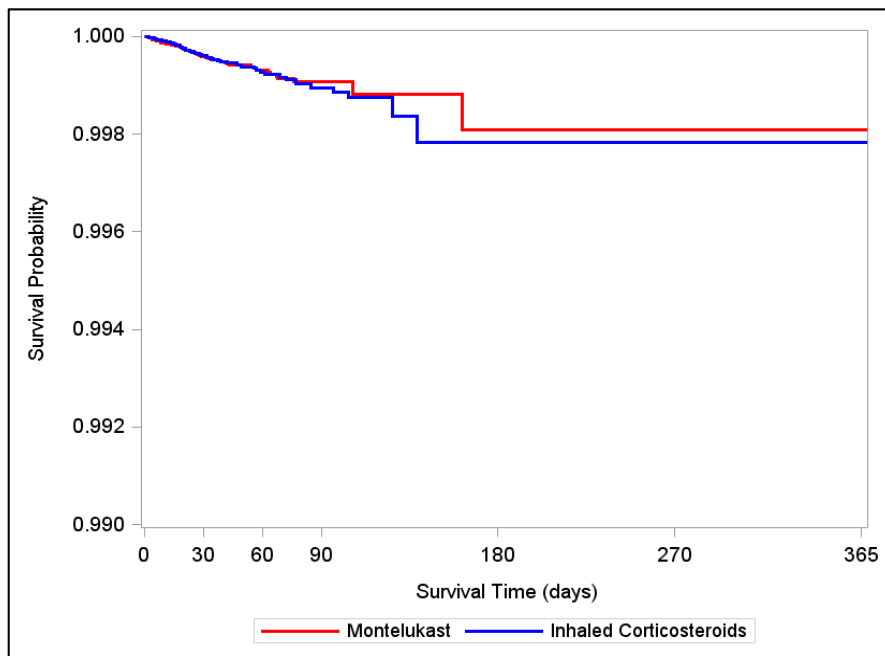


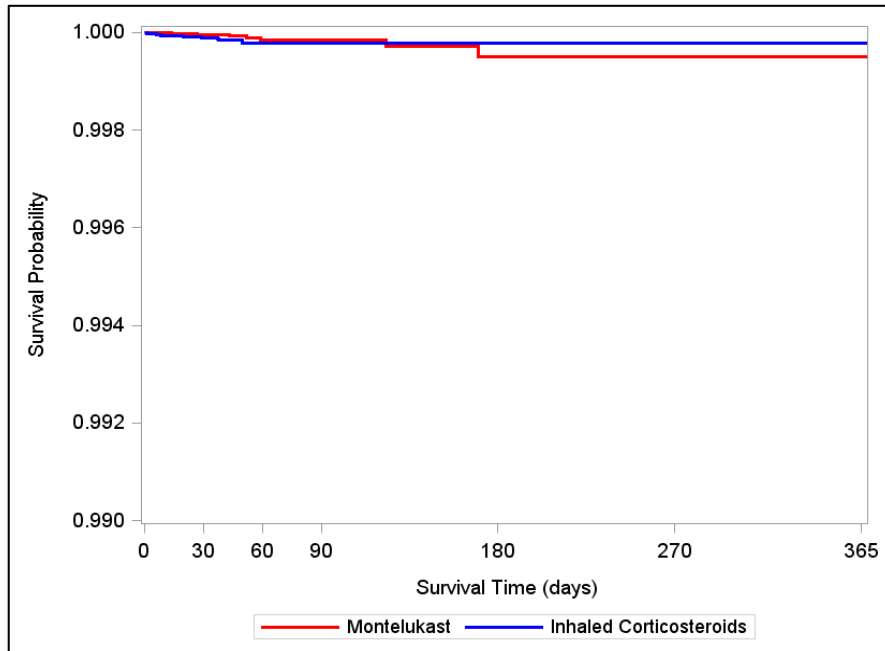
Figure 2e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, Conditional Matched Cohort, Follow-Up Truncated to 365 Days

Ages 18+ years



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

**Ages 6-11 years**



**Ages 12-17 years**

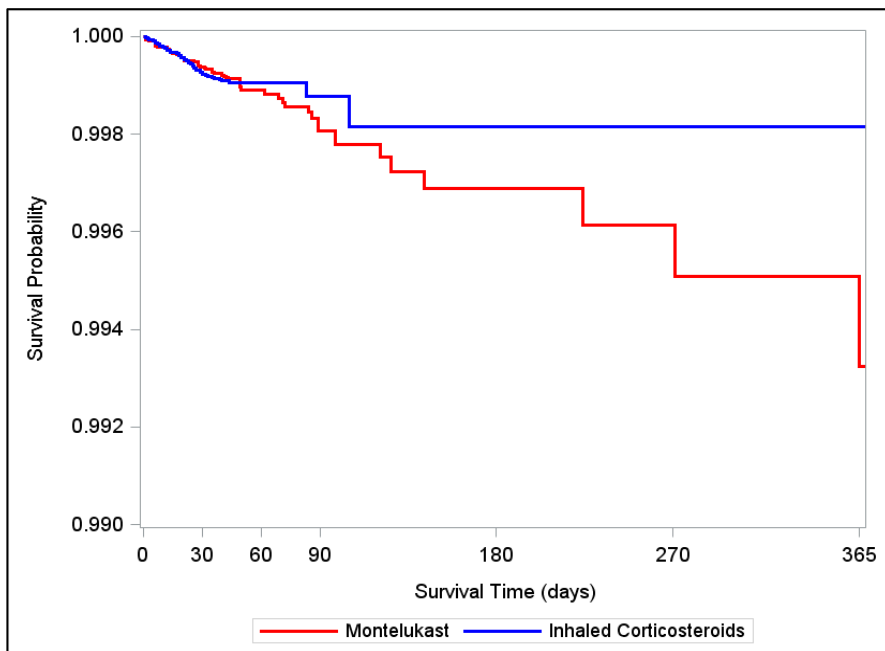
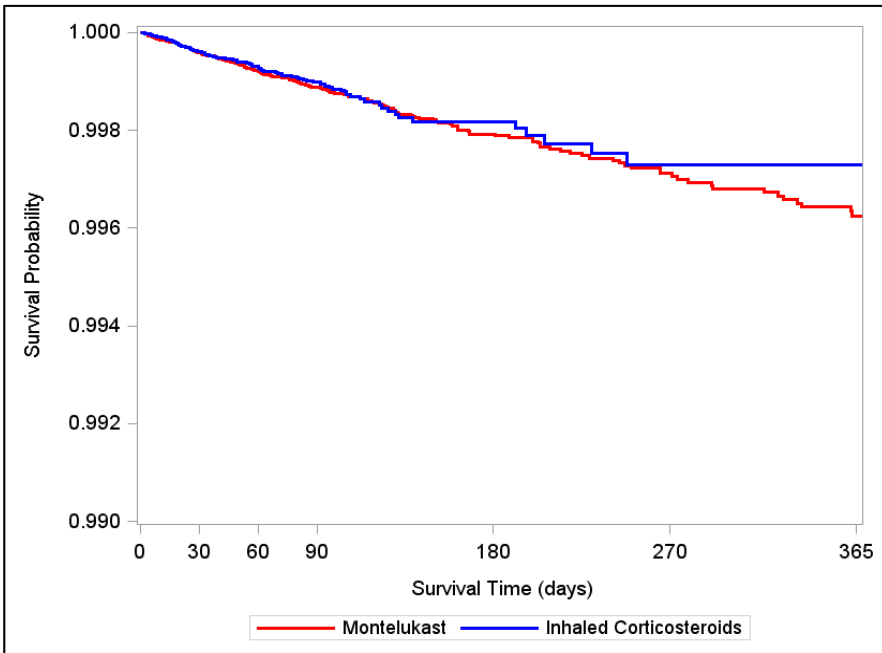


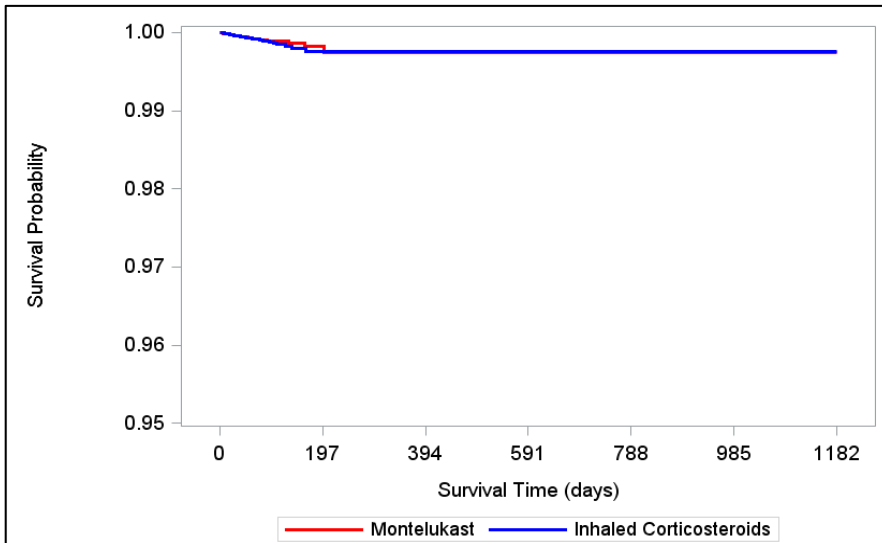
Figure 2f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days

Ages 18+ years

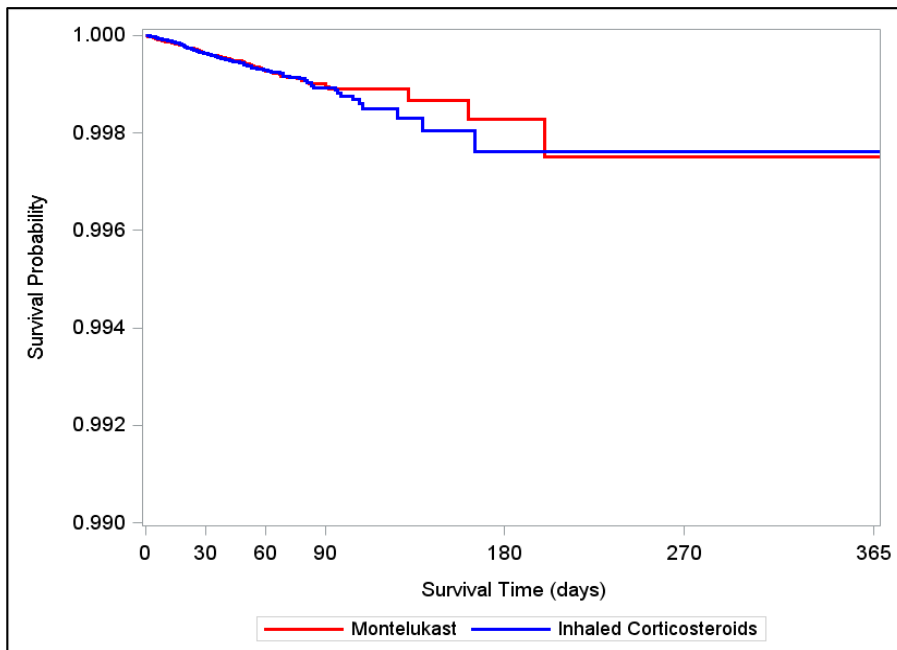


**Figure 3a. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, Inhaled Corticosteroids 30-day Extension and Gap, Conditional Matched Cohort**

**All Available Follow-Up**

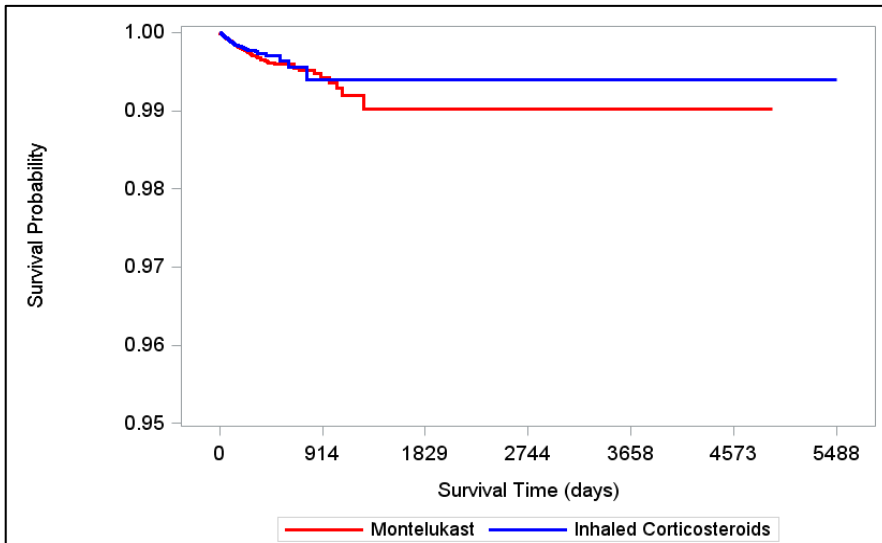


**Follow-Up Truncated at 365 Days**

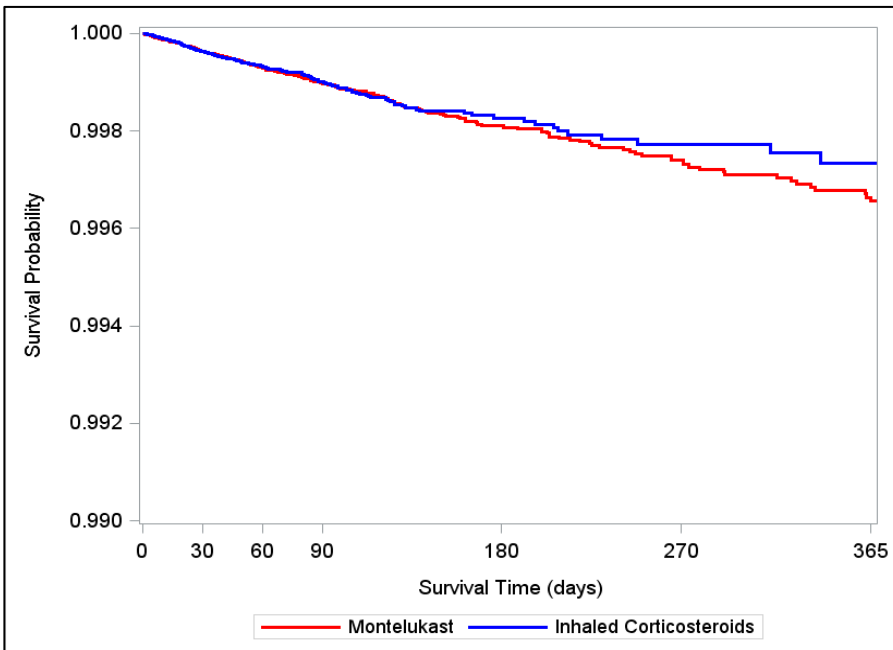


**Figure 3b. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, Inhaled Corticosteroids 30-day Extension and Gap, Unconditional Matched Cohort**

**All Available Follow-Up**



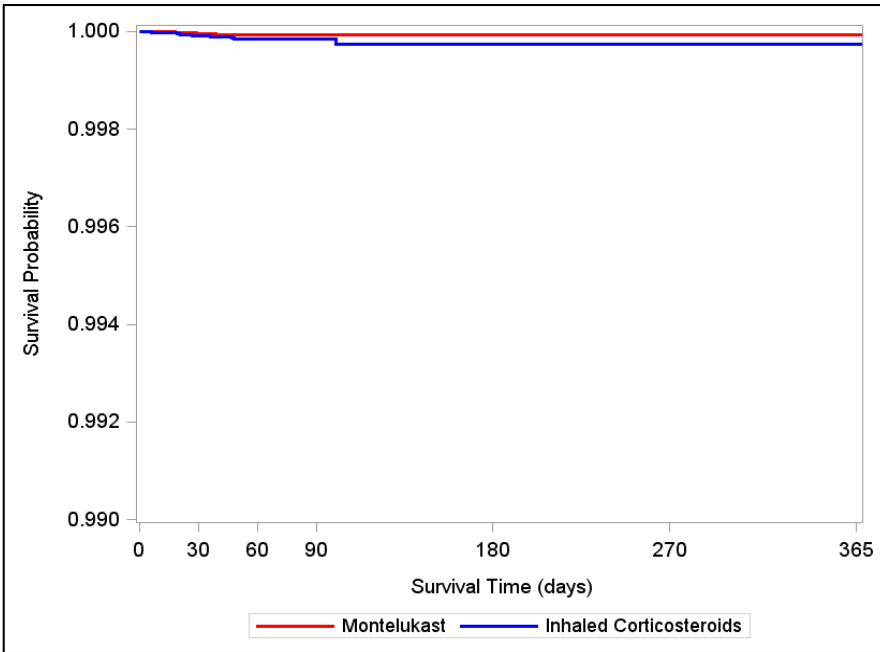
**Follow-Up Truncated at 365 Days**



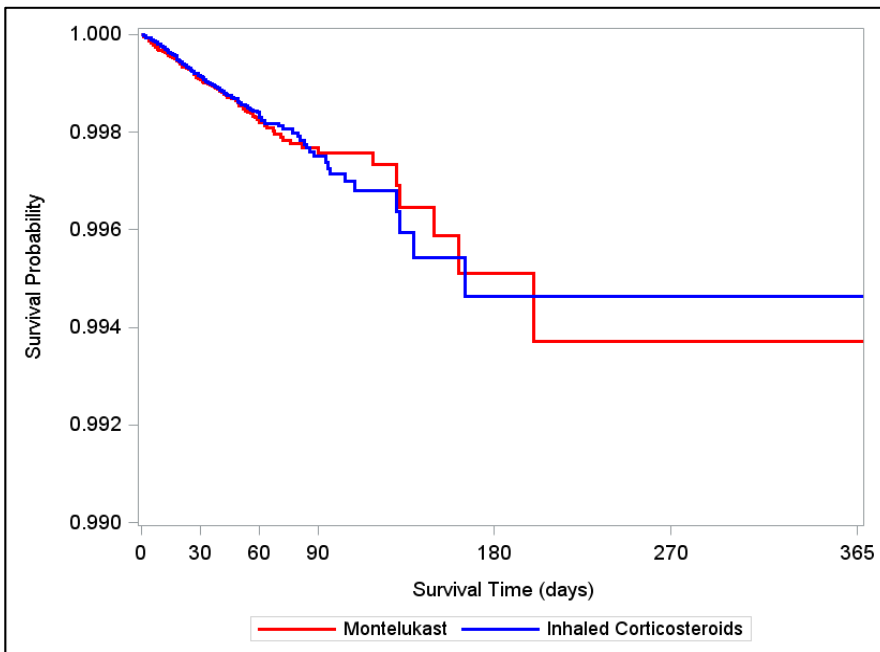


**Figure 3c. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by History of Psychiatric Disorder, ICS 30 day Extension and Gap, Conditional Matched Cohort, Follow-Up Truncated to 365 Days**

**No History of Psychiatric Disorder**

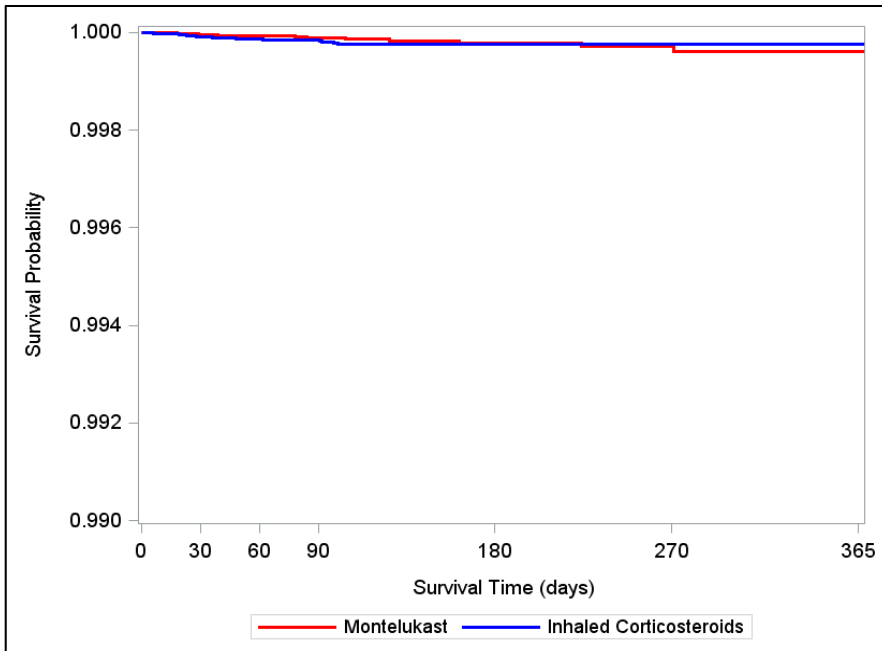


**History of Psychiatric Disorder**



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

**No History of Psychiatric Disorder**



**History of Psychiatric Disorder**

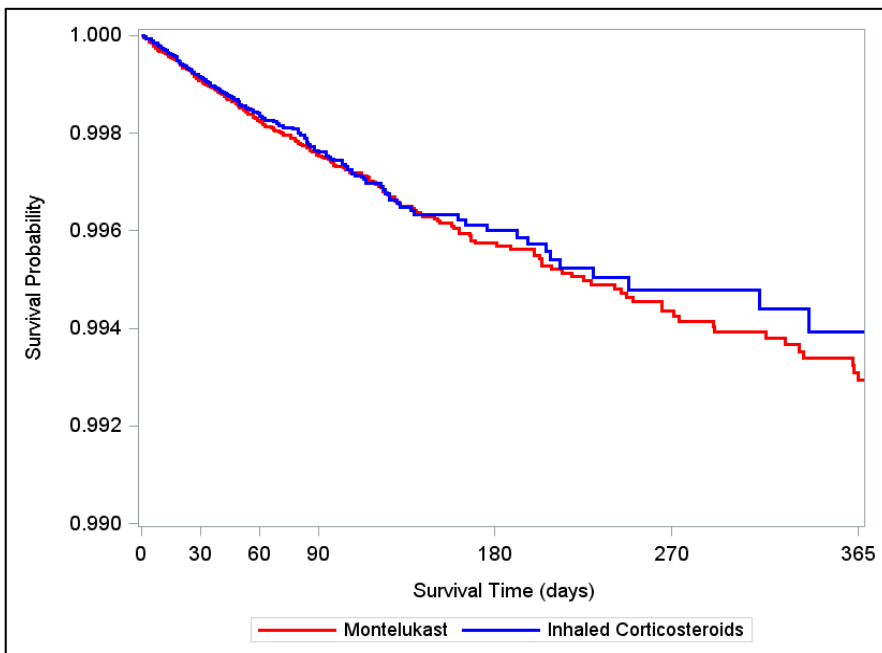
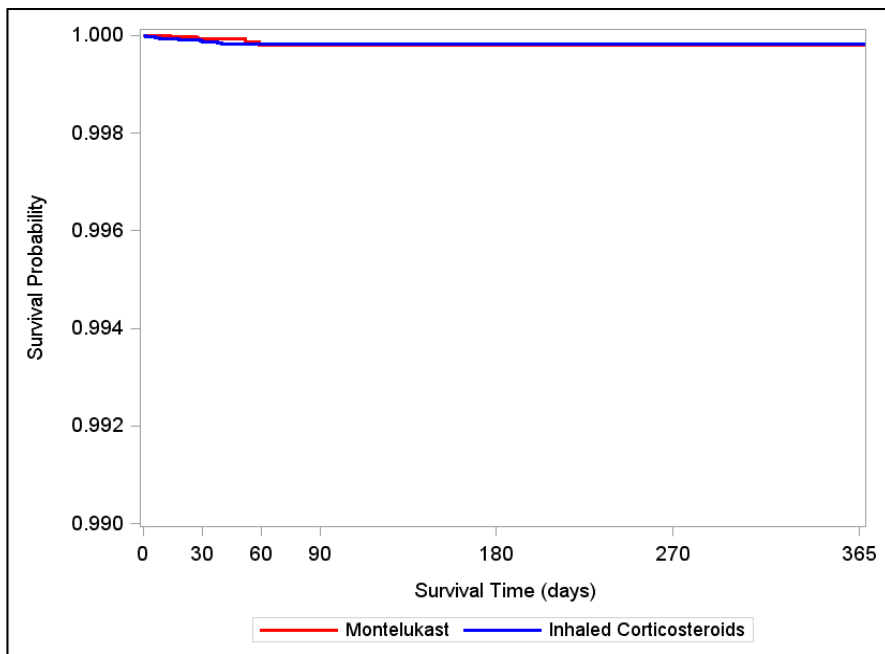


Figure 3e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, ICS 30 day Extension and Gap, Conditional Matched Cohort, Follow-Up Truncated to 365 Days

Ages 6-11 years



Ages 12-17 years

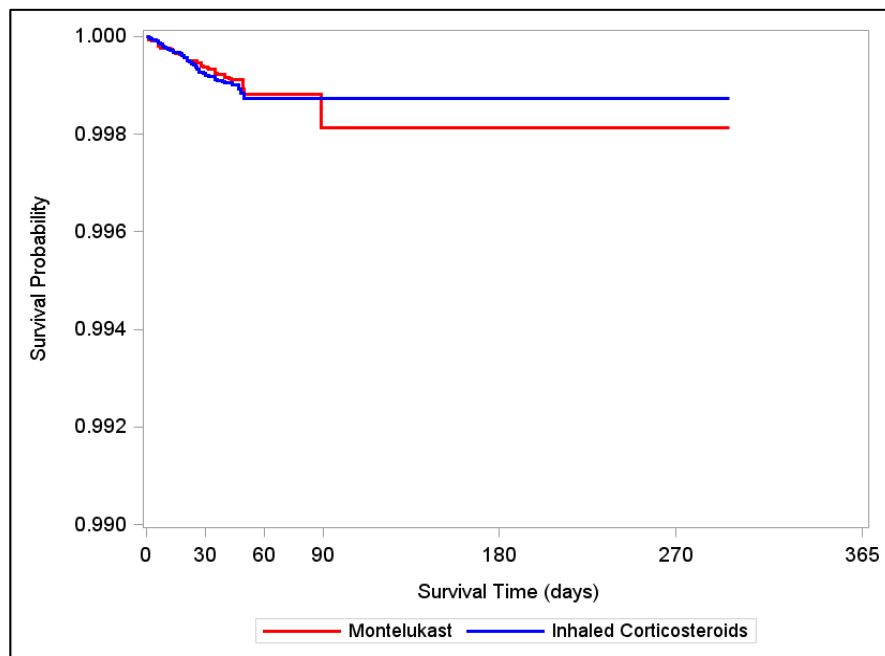


Figure 3e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, ICS 30 day Extension and Gap, Conditional Matched Cohort, Follow-Up Truncated to 365 Days

Ages 18+ years

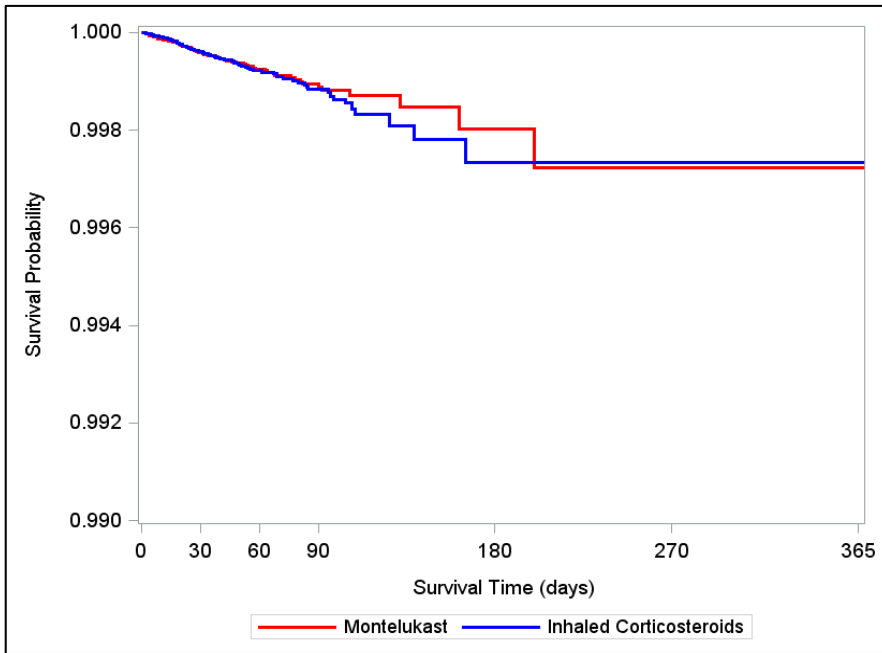
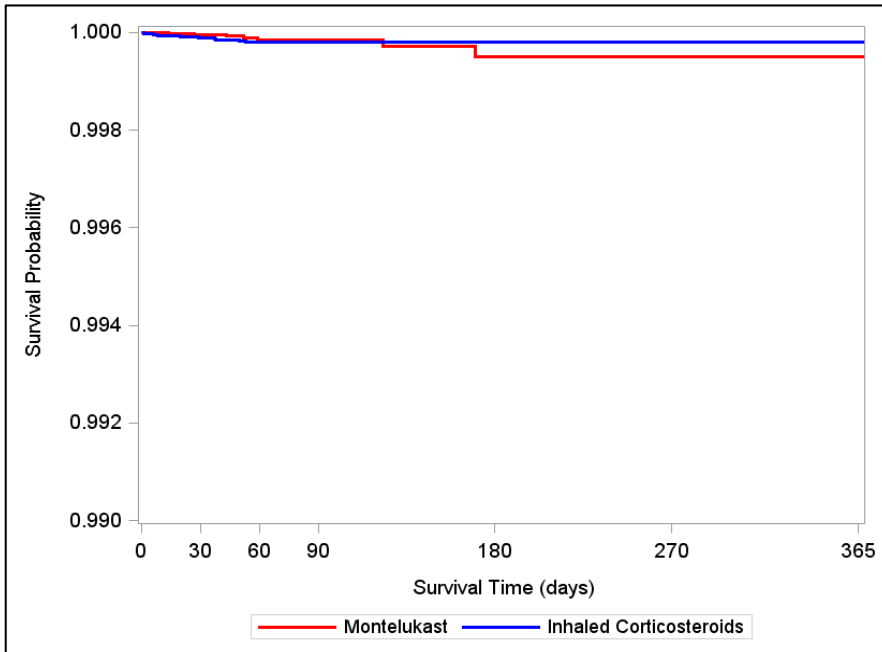


Figure 3f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, ICS 30 day Extension and Gap, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days

Ages 6-11 years



Ages 12-17 years

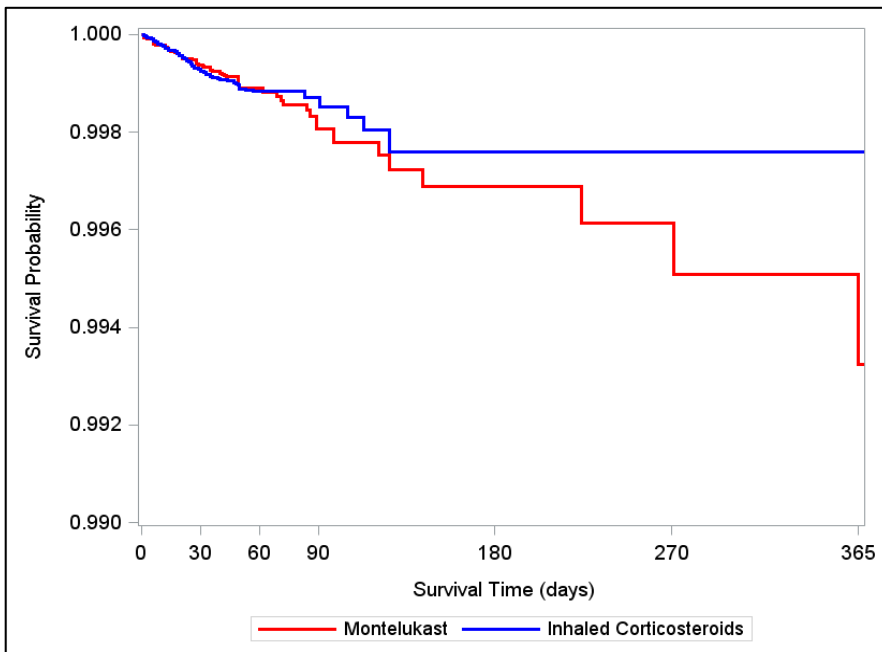
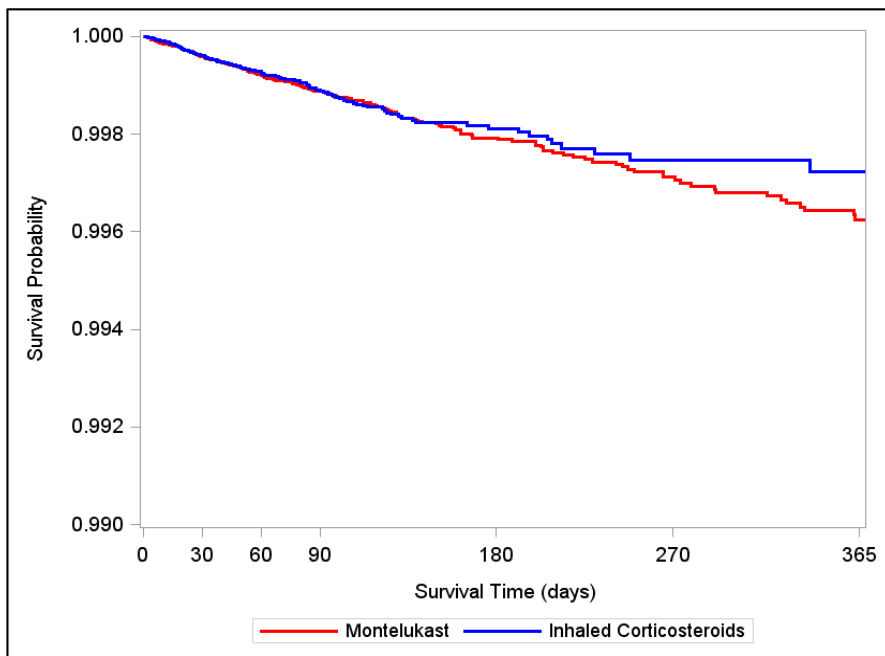


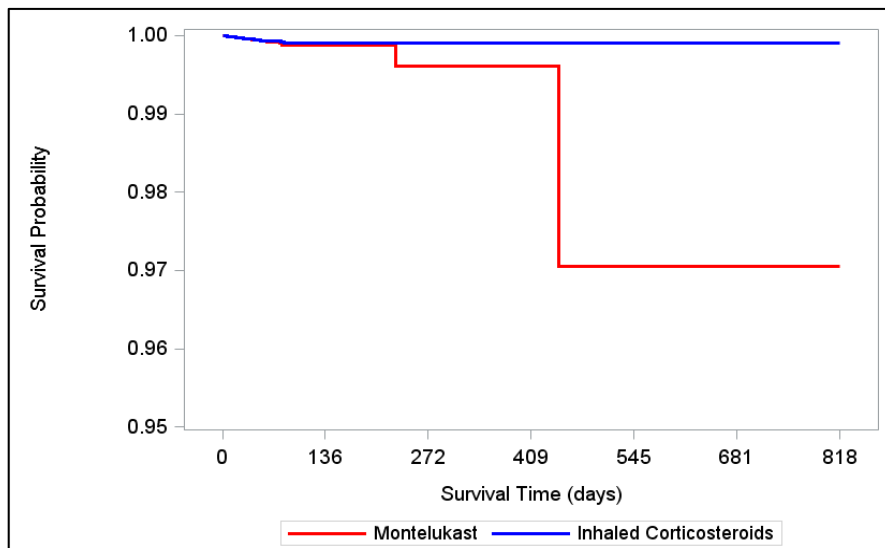
Figure 3f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, ICS 30 day Extension and Gap, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days

Ages 18+ years

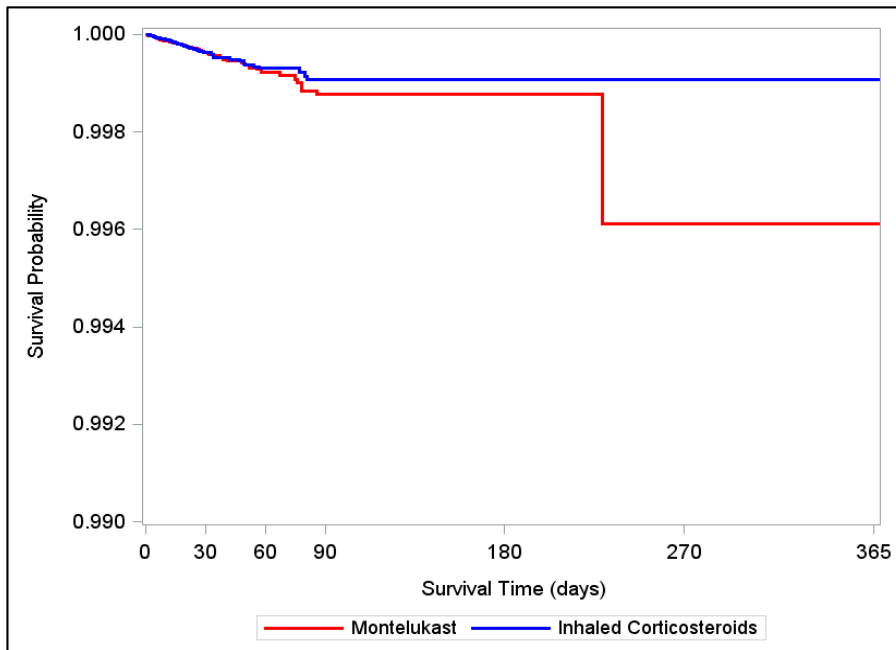


**Figure 4a. Kaplan Meier Survival Curves of Informative Events and Followup Time for Inpatient Depressive Disorder, No Episode Extension, Conditional Matched Cohort**

**All Available Follow-Up**

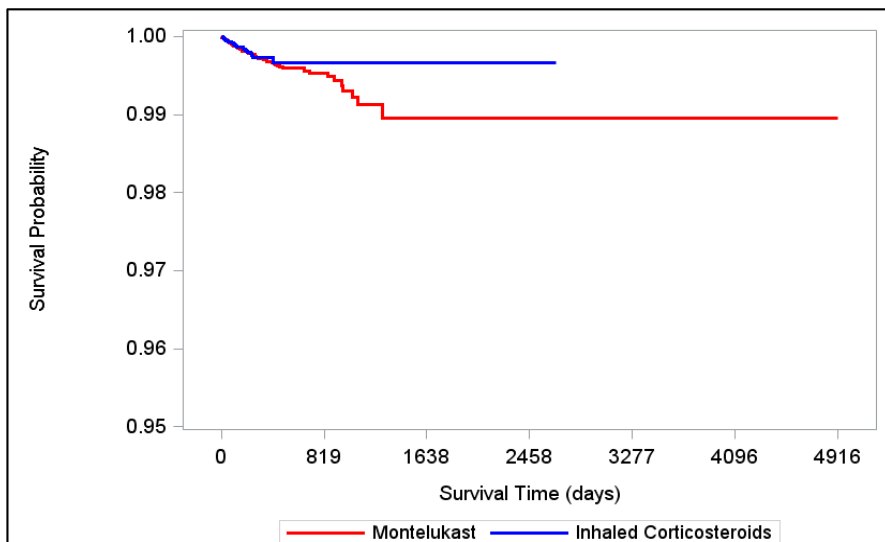


**Follow-Up Truncated at 365 Days**



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

**All Available Follow-Up**



**Follow-Up Truncated at 365 Days**

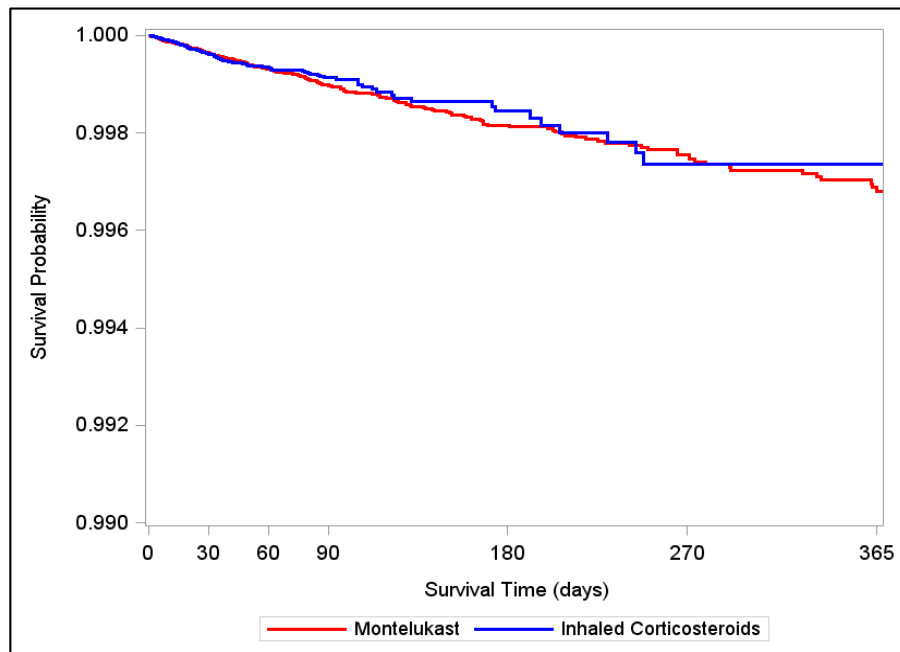
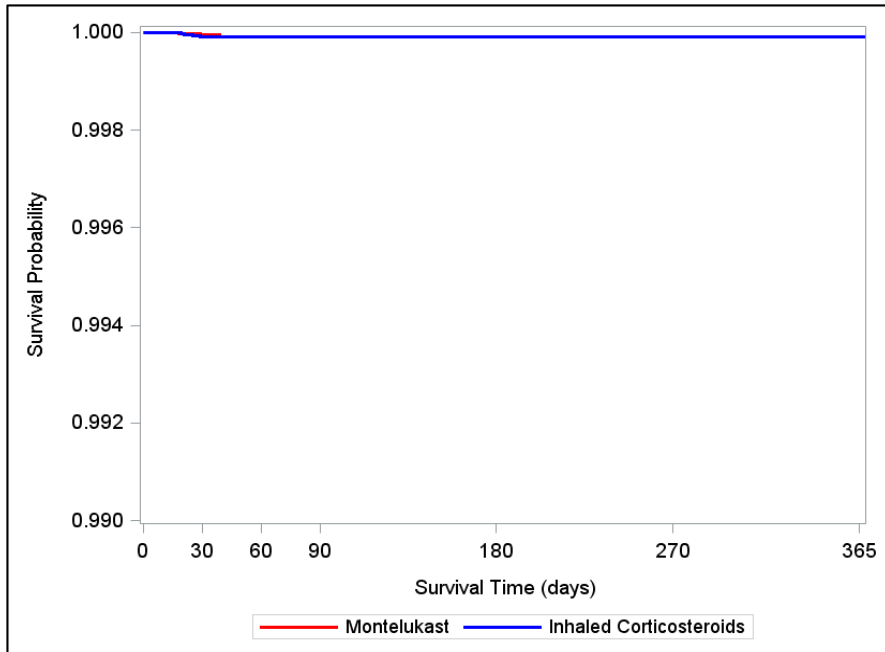


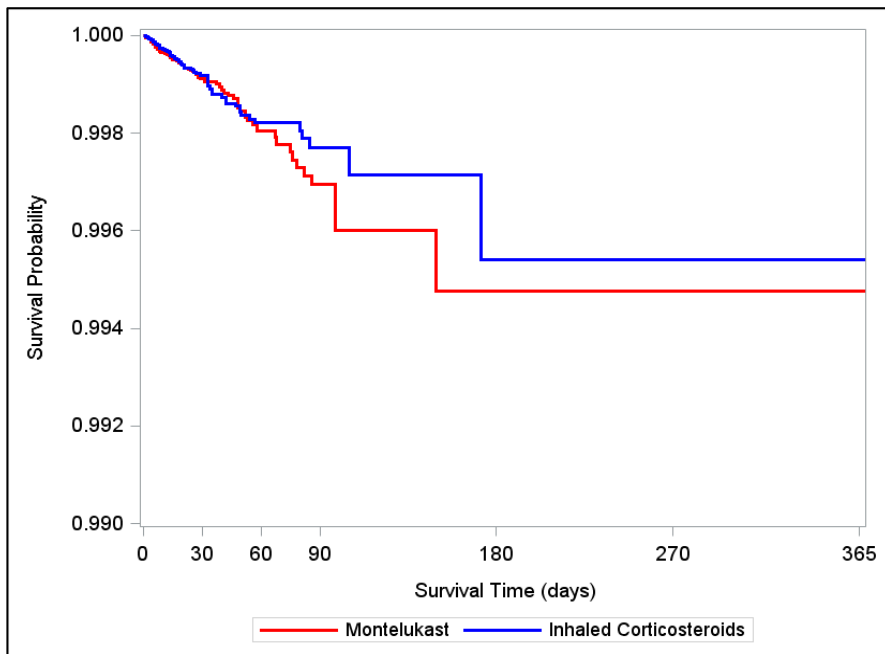


Figure 4c. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by History of Psychiatric Disorder, No Episode Extension, Conditional Matched Cohort, Follow-Up Truncated to 365 Days

No History of Psychiatric Disorder

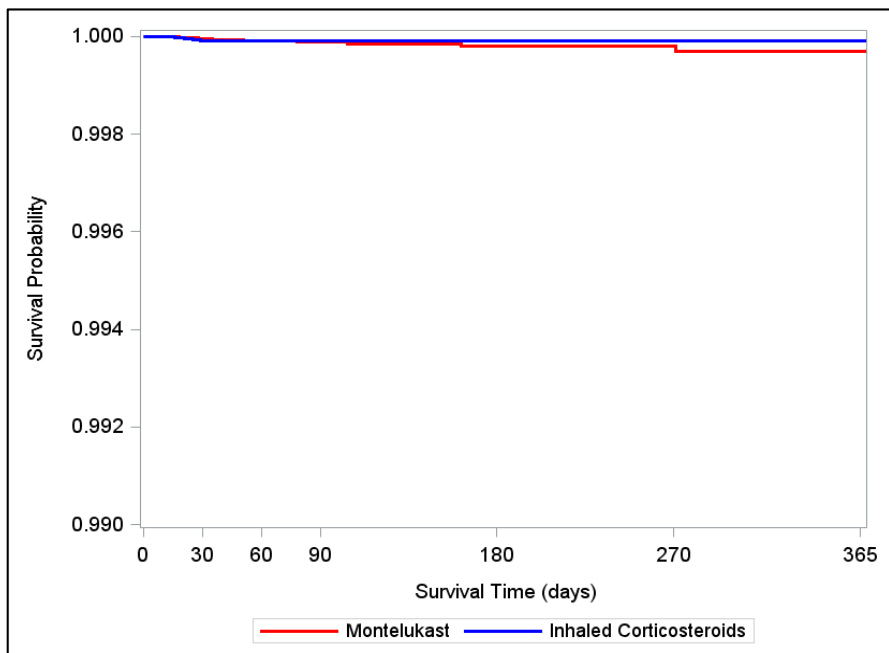


History of Psychiatric Disorder



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

**No History of Psychiatric Disorder**



**History of Psychiatric Disorder**

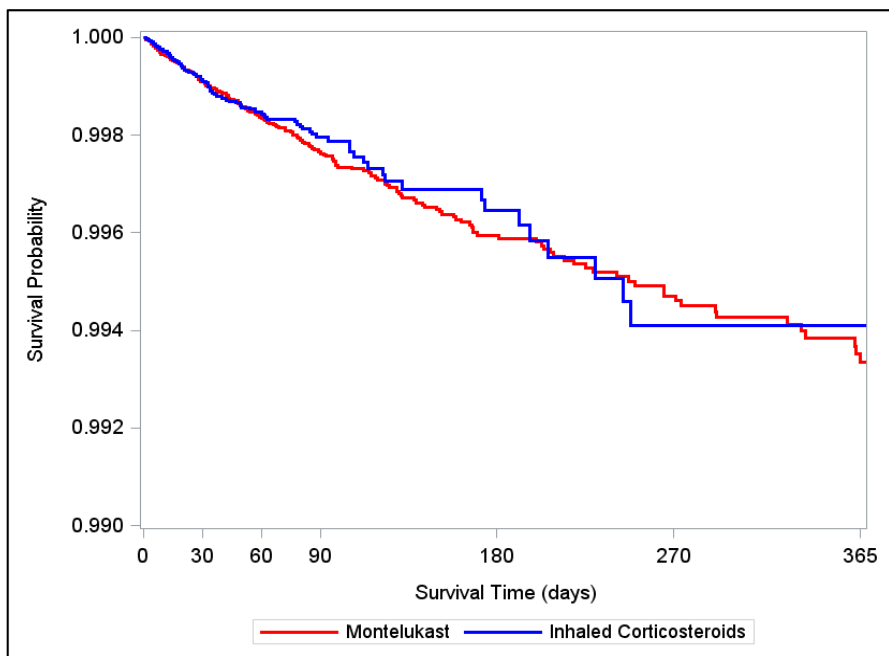
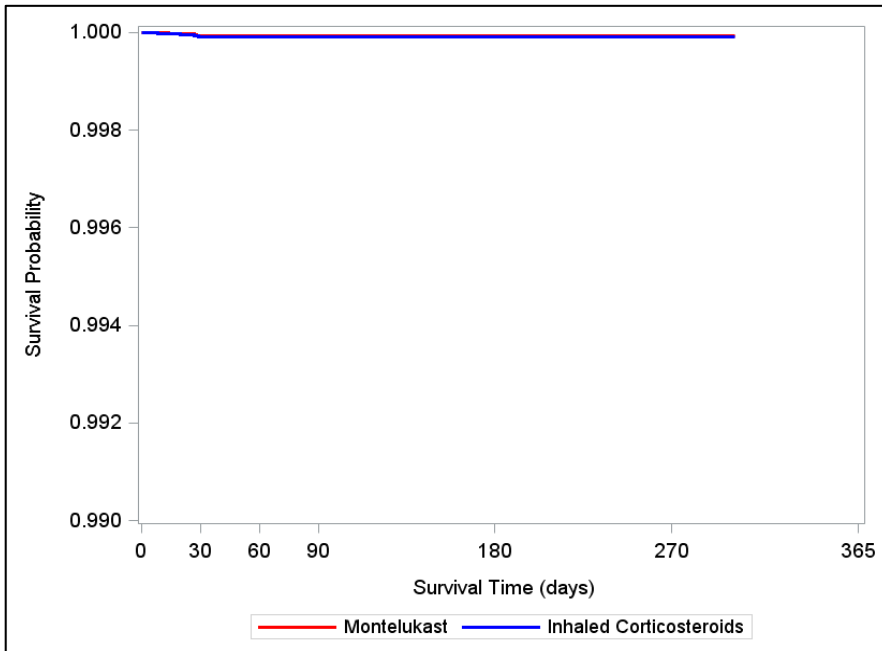


Figure 4e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, No Episode Extension, Conditional Matched Cohort, Follow-Up Truncated to 365 Days

Ages 6-11 years



Ages 12-17 years

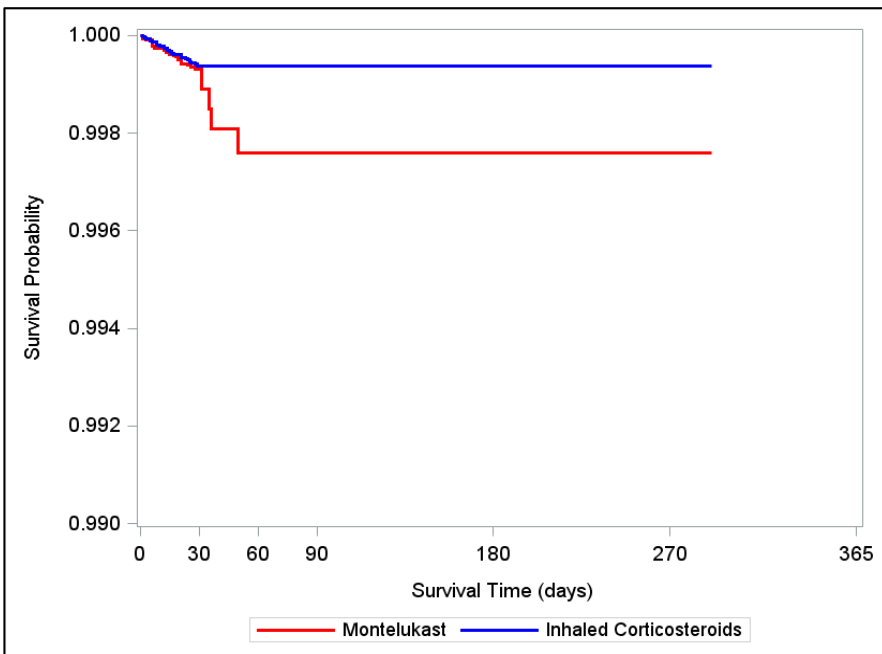
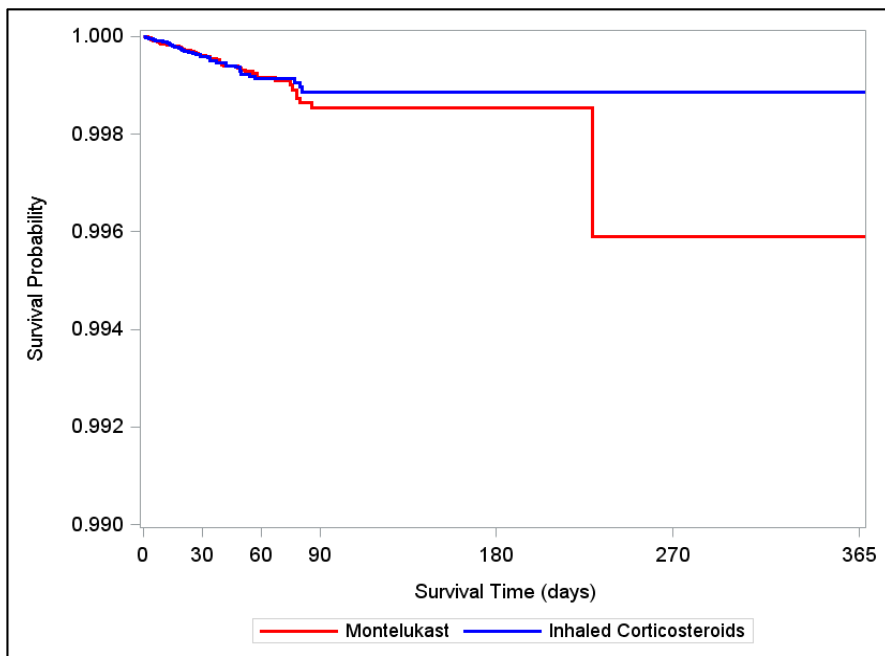


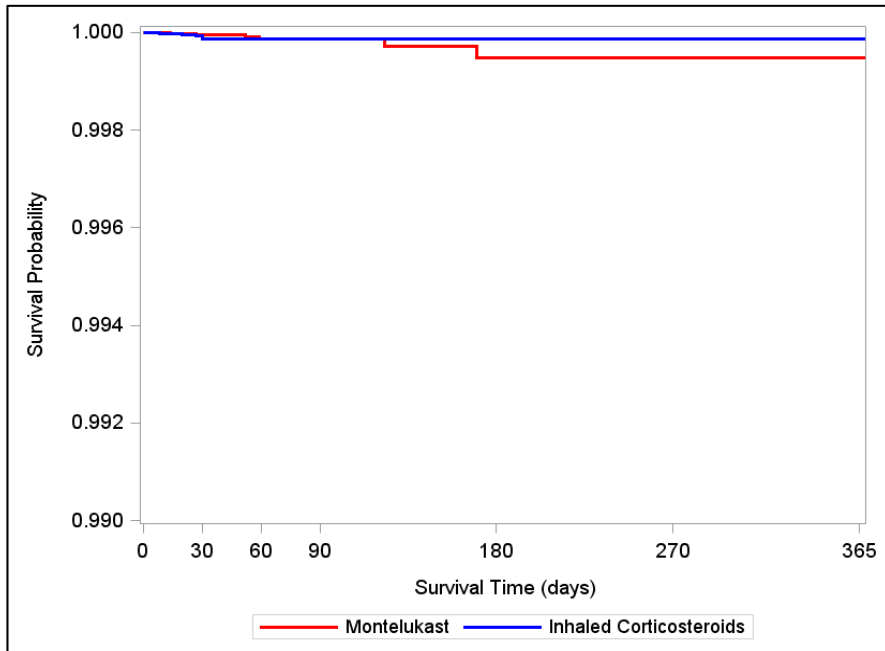
Figure 4e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, No Episode Extension, Conditional Matched Cohort, Follow-Up Truncated to 365 Days

Ages 18+ years



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

**Ages 6-11 years**



**Ages 12-17 years**

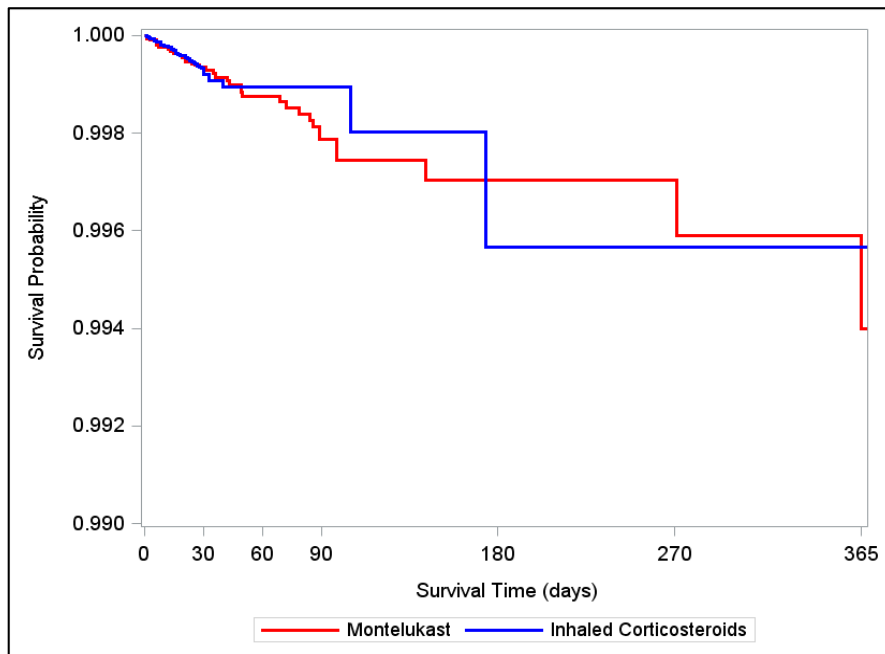
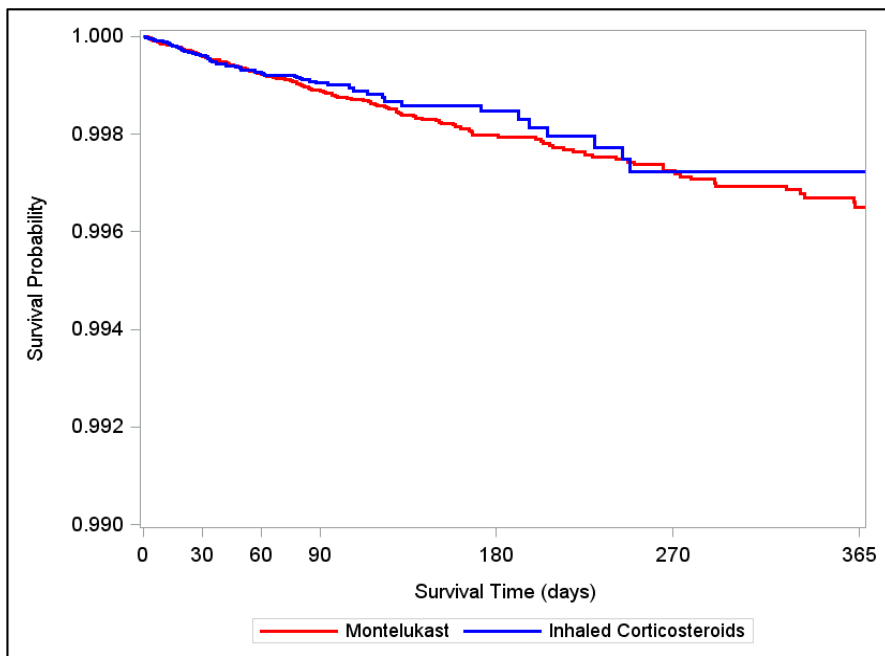


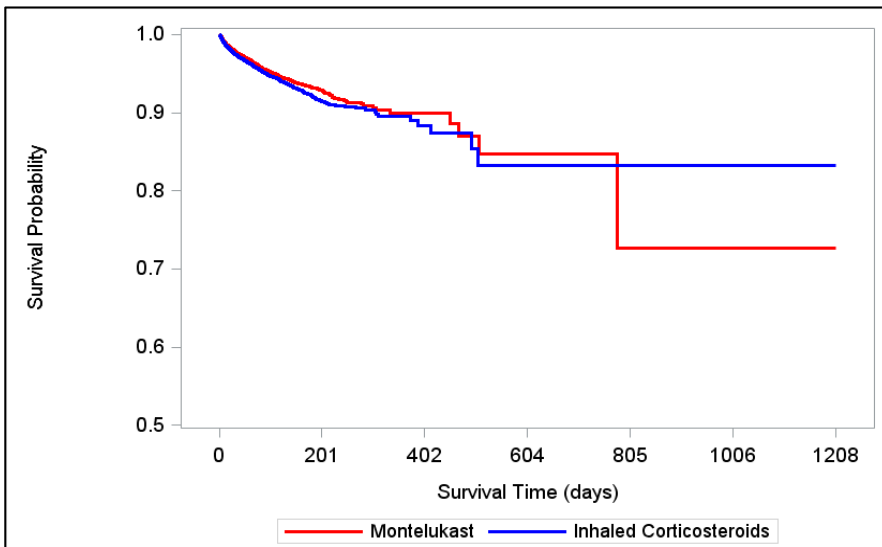
Figure 4f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Inpatient Depressive Disorder, by Age Group, No Episode Extension, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days

Ages 18+ years

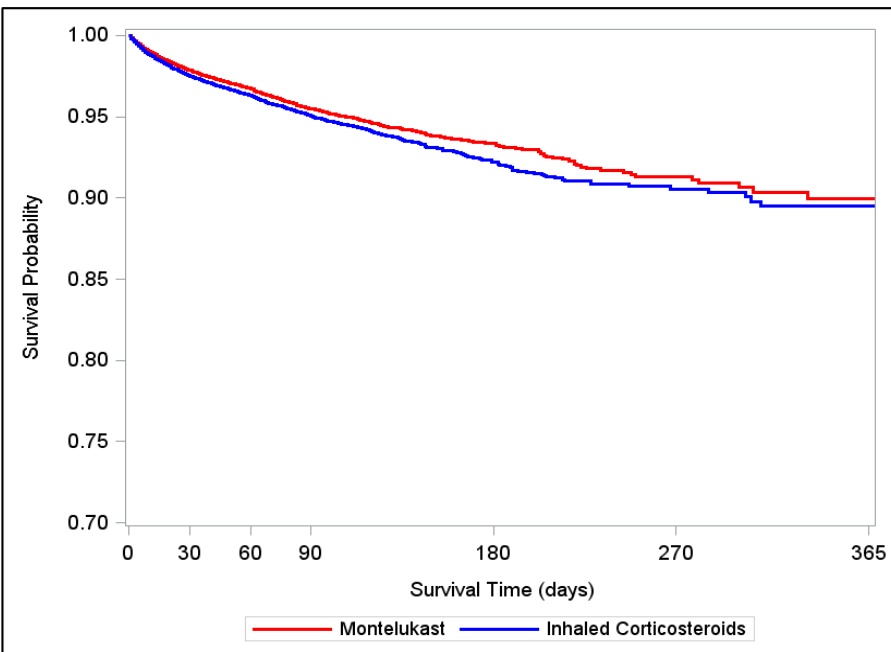


**Figure 5a. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Outpatient Depressive Disorder, Conditional Matched Cohort**

**All Available Follow-Up**

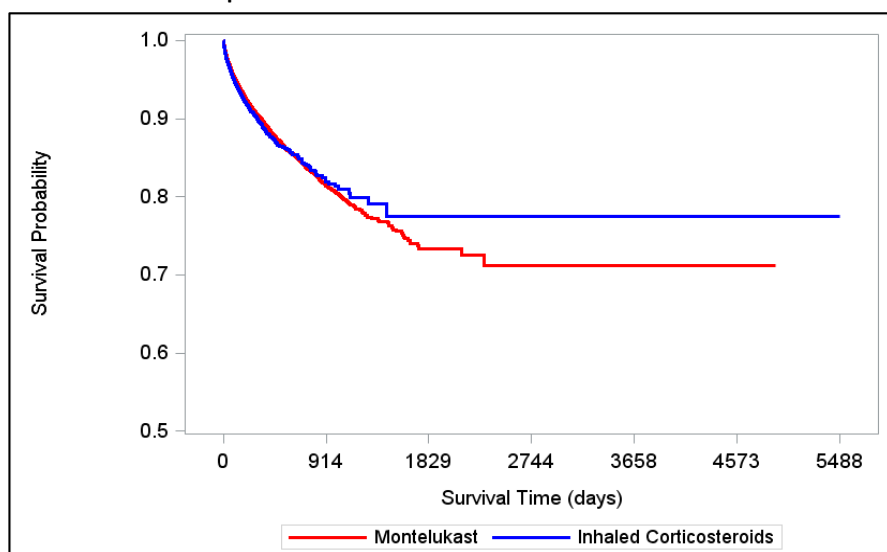


**Follow-Up Truncated at 365 Days**



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

**All Available Follow-Up**



**Follow-Up Truncated at 365 Days**

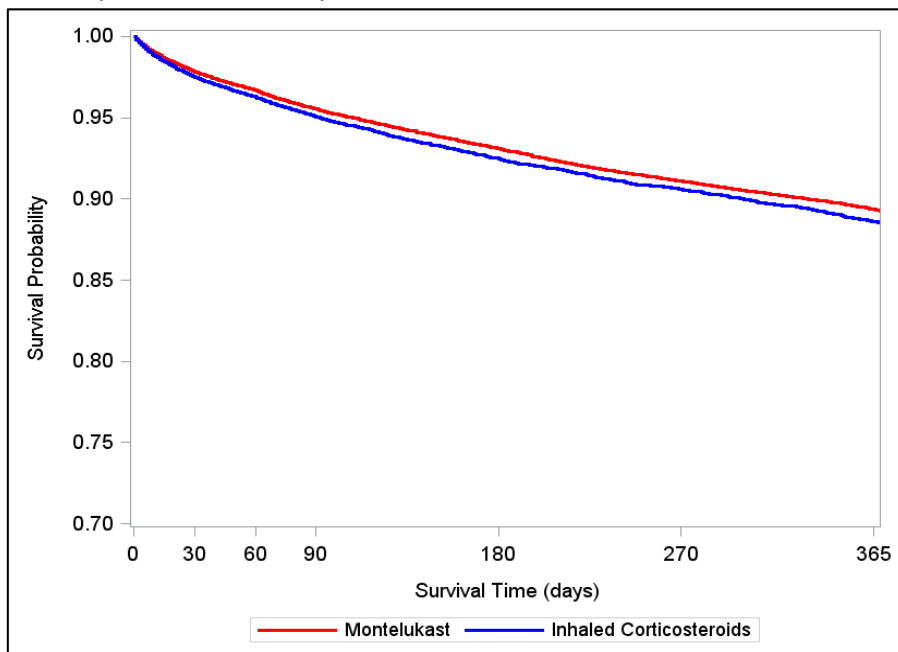
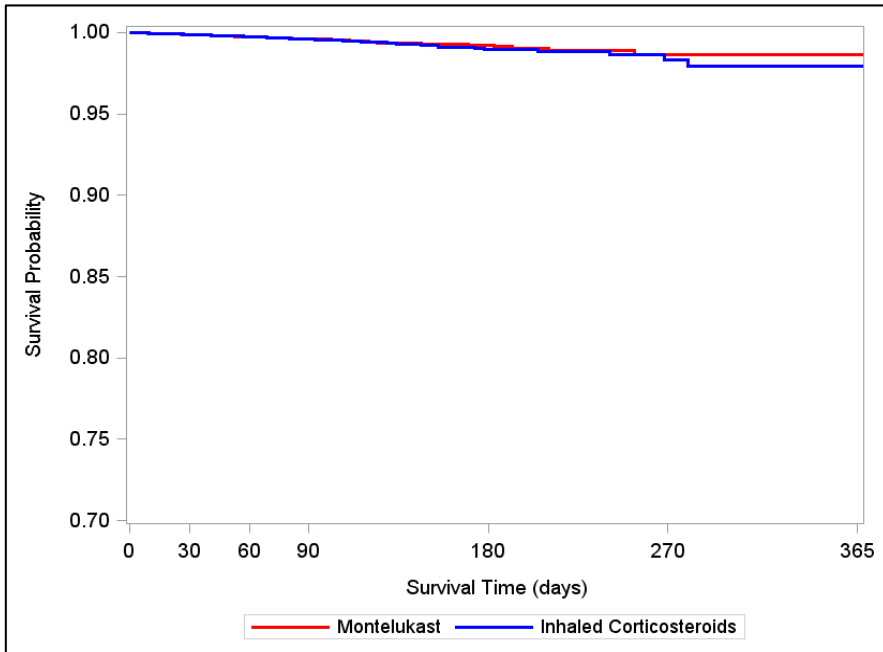




Figure 5c. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Outpatient Depressive Disorder, by History of Psychiatric Disorder, Conditional Matched Cohort, Follow-Up Truncated to 365 Days

No History of Psychiatric Disorder



History of Psychiatric Disorder

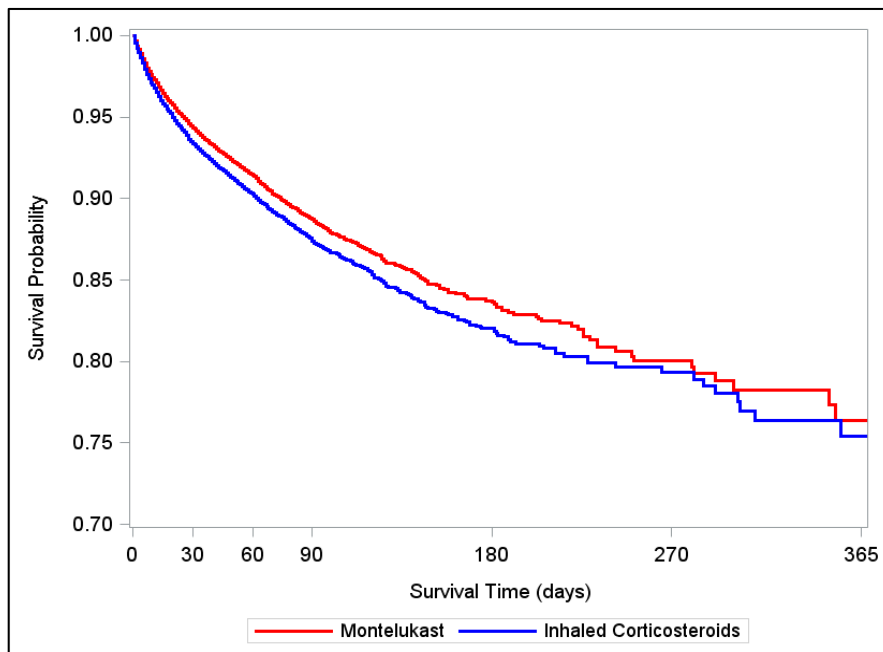
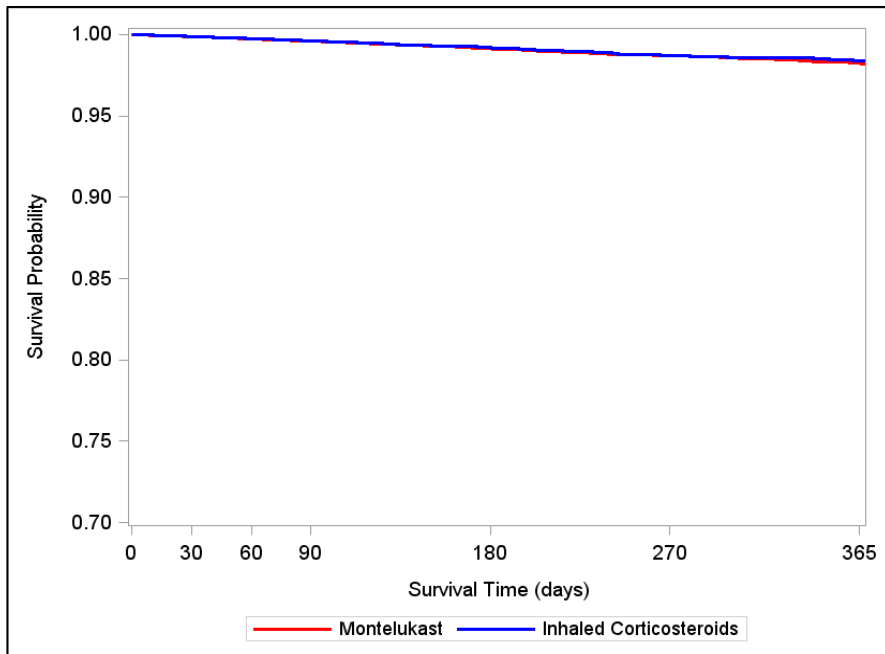


Figure 5d. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Outpatient Depressive Disorder, by History of Psychiatric Disorder, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days

No History of Psychiatric Disorder



History of Psychiatric Disorder

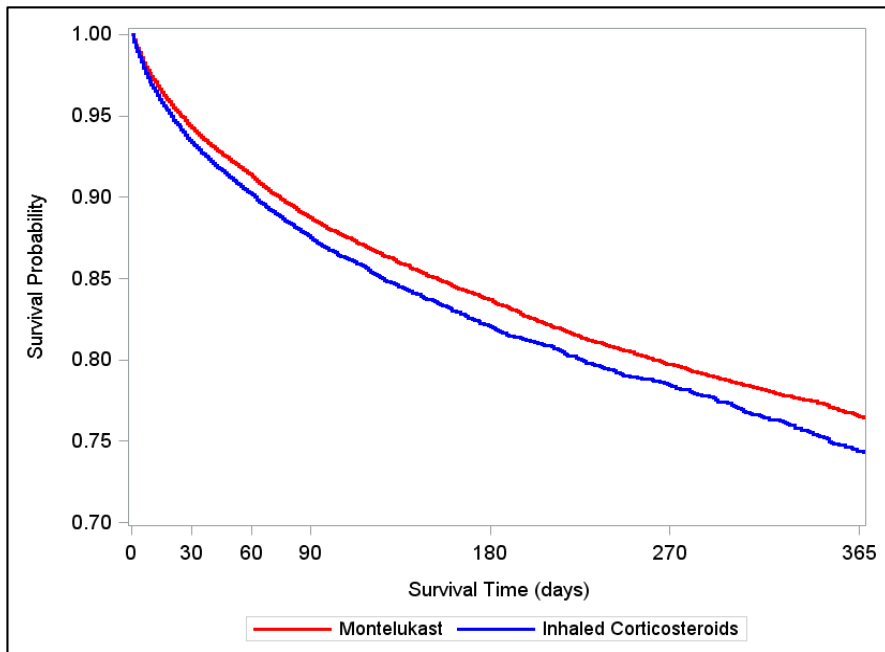
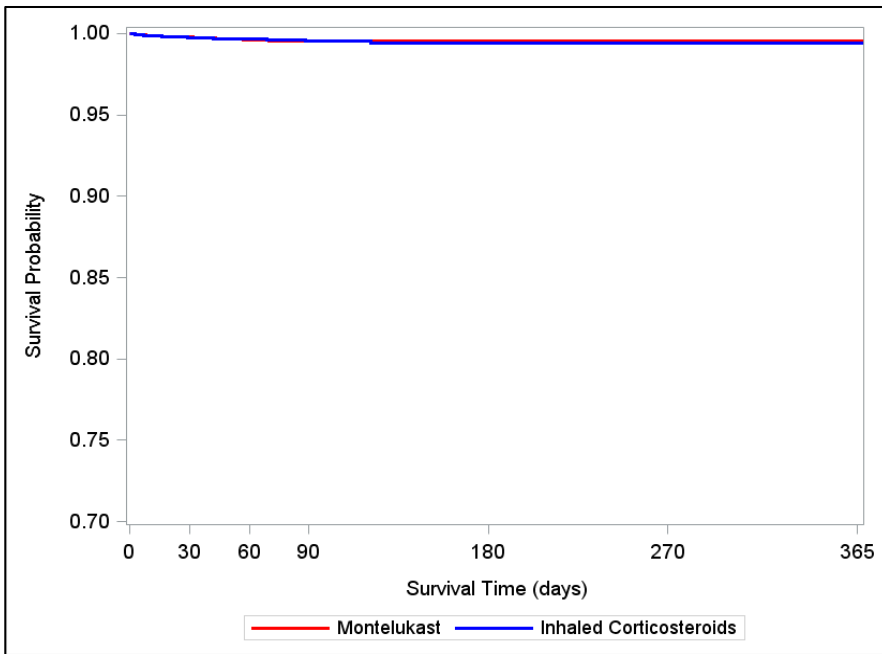


Figure 5e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Outpatient Depressive Disorder, by Age Group, Conditional Matched Cohort, Follow-Up Truncated to 365 Days

Ages 6-11 years



Ages 12-17 years

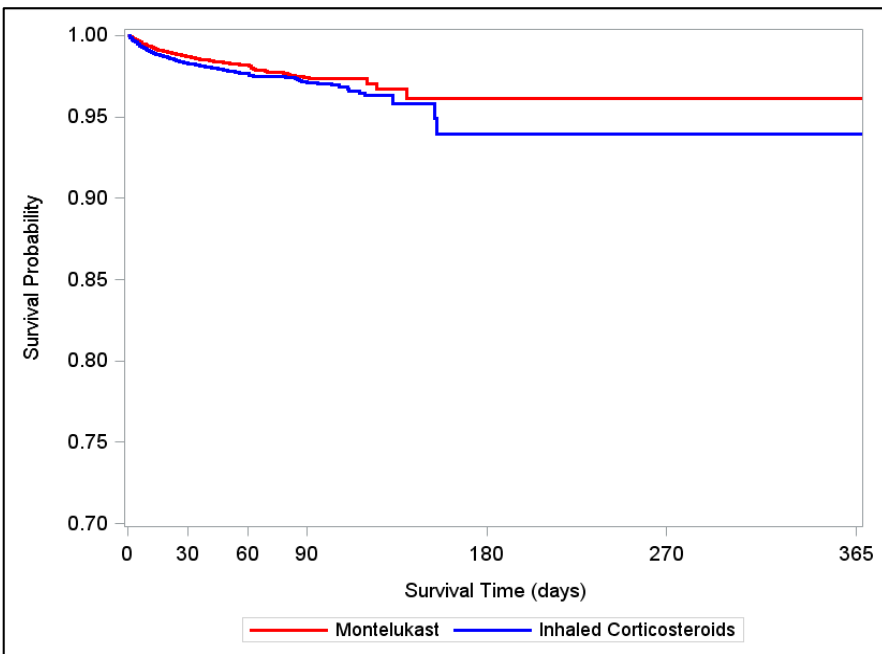
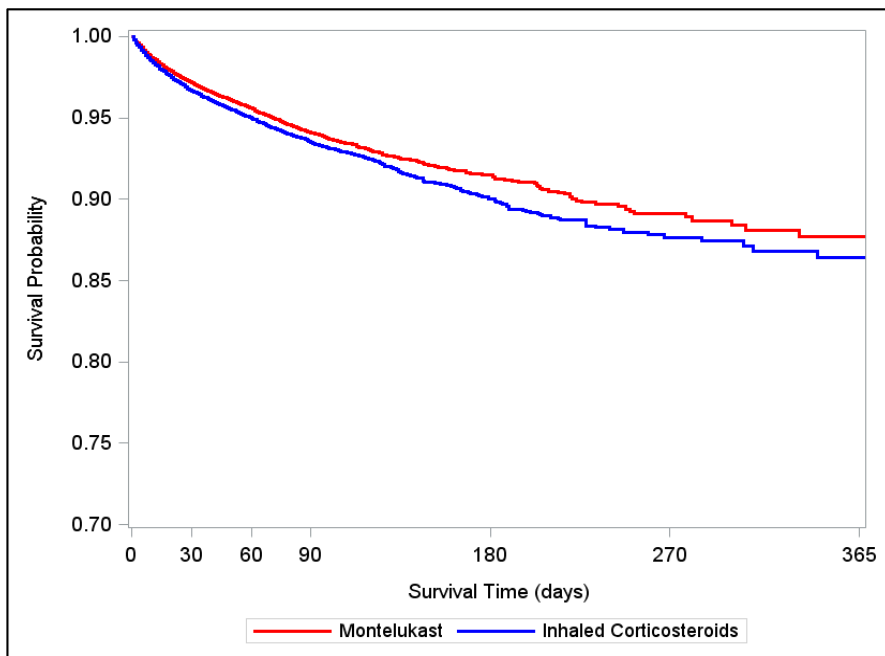


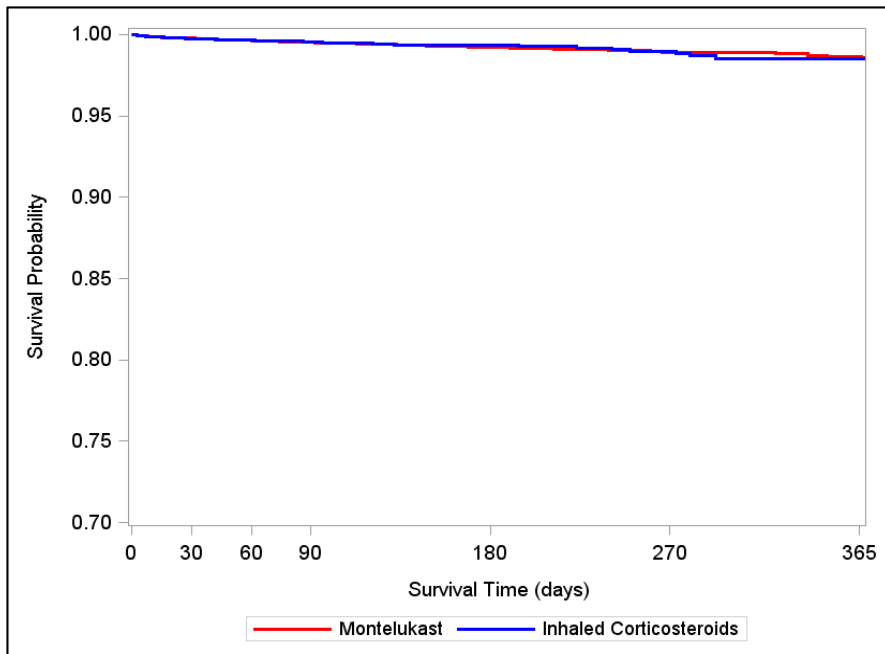
Figure 5e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Outpatient Depressive Disorder, by Age Group, Conditional Matched Cohort, Follow-Up Truncated to 365 Days

Ages 18+ years



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

**Ages 6-11 years**



**Ages 12-17 years**

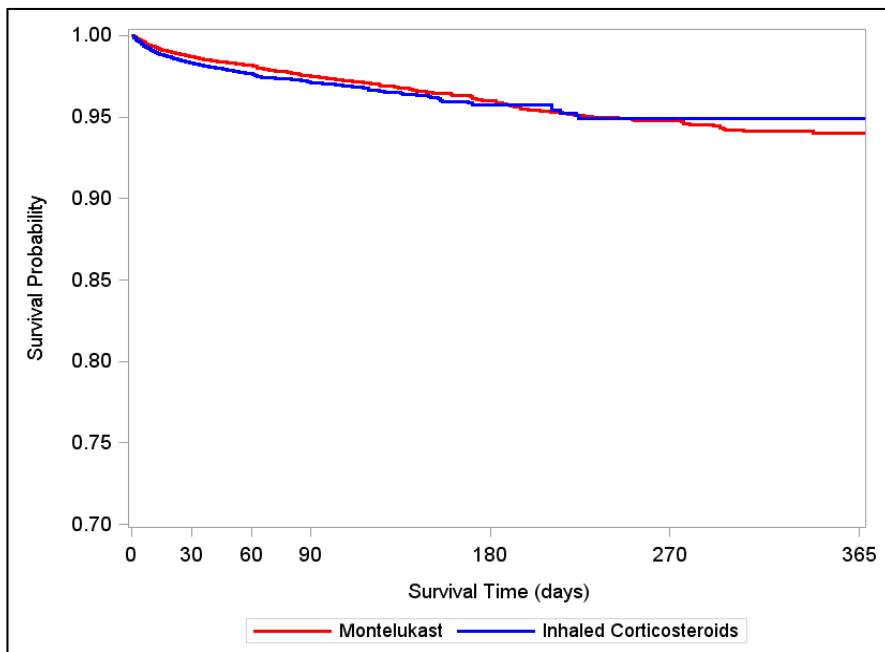


Figure 5f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Outpatient Depressive Disorder, by Age Group, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days

Ages 18+ years

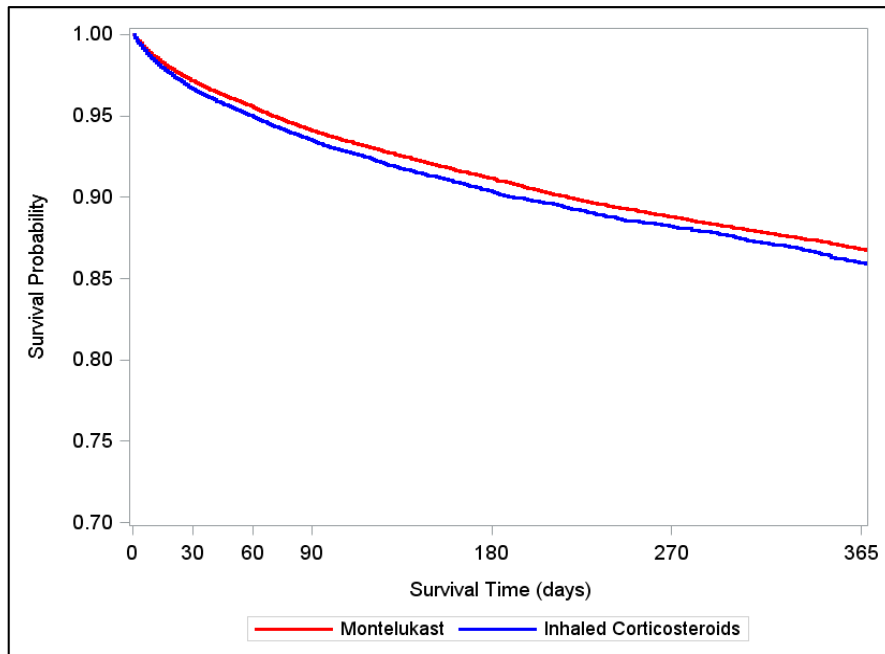
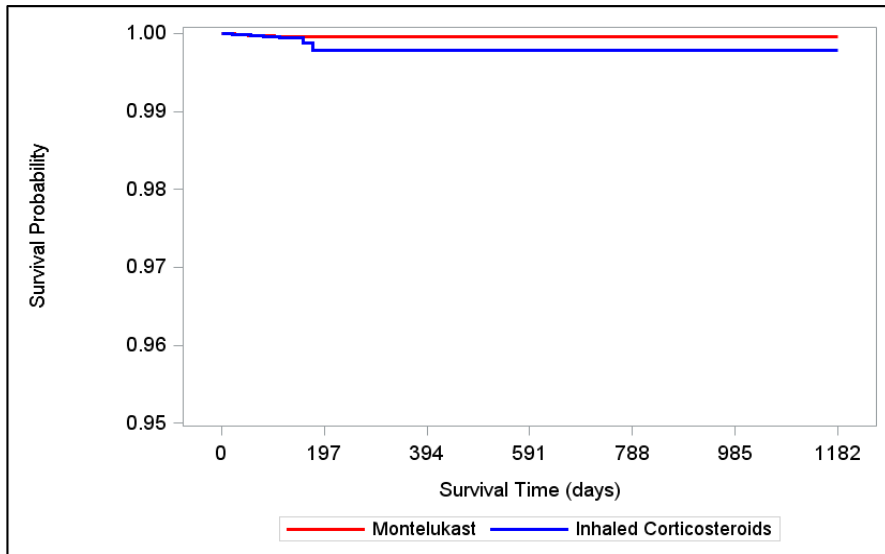


Figure 6a. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm, Conditional Matched Cohort

All Available Follow-Up



Follow-Up Truncated at 365 Days

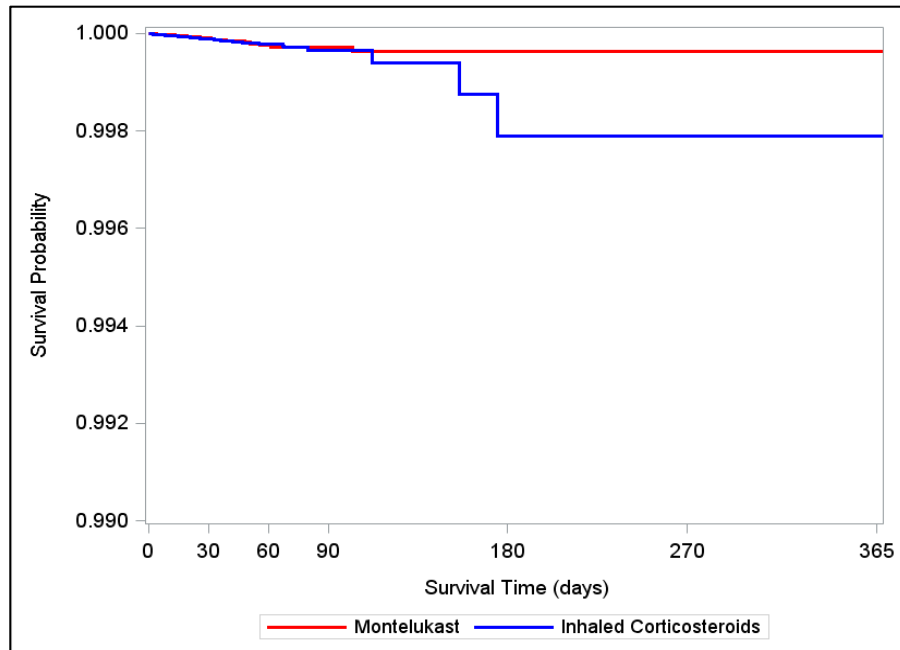
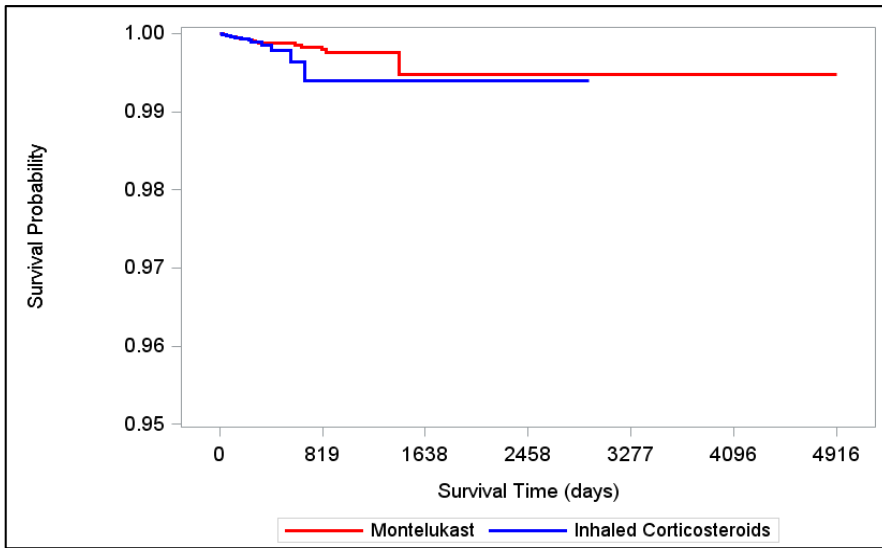


Figure 6b. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm, Unconditional Matched Cohort

All Available Follow-Up



Follow-Up Truncated at 365 Days

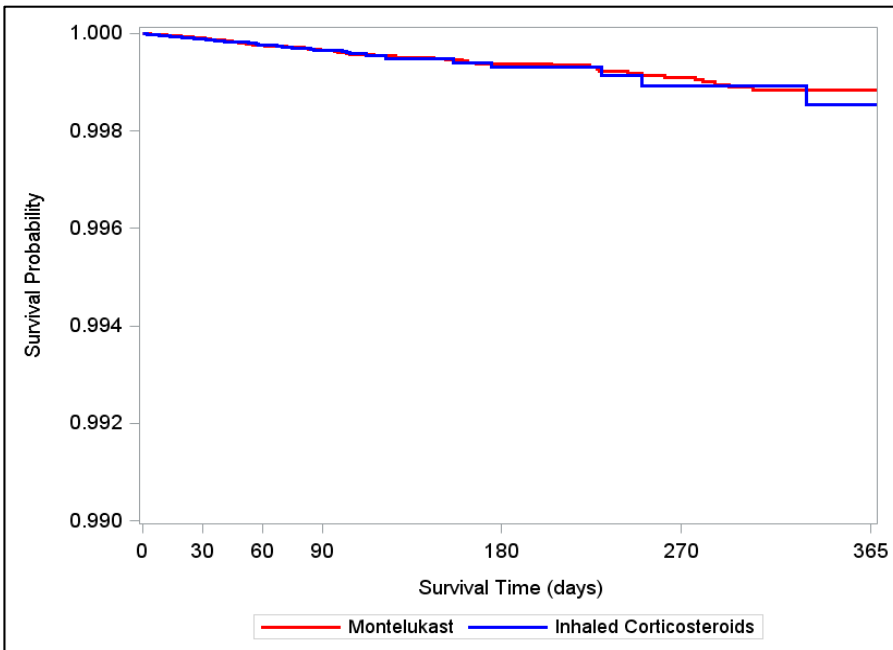
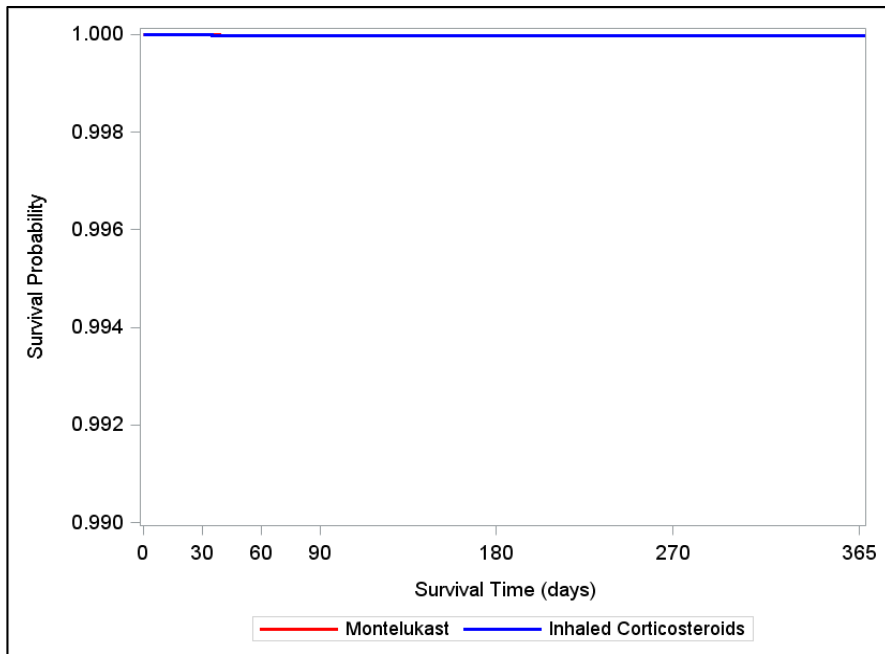


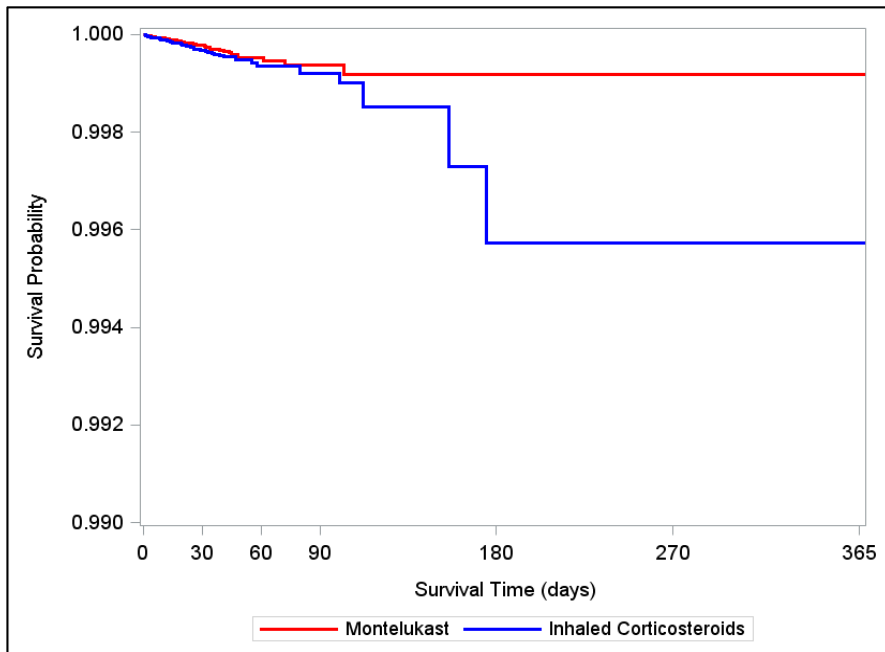


Figure 6c. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm, by History of Psychiatric Disorder, Conditional Matched Cohort, Follow-Up Truncated to 365 Days

No History of Psychiatric Disorder

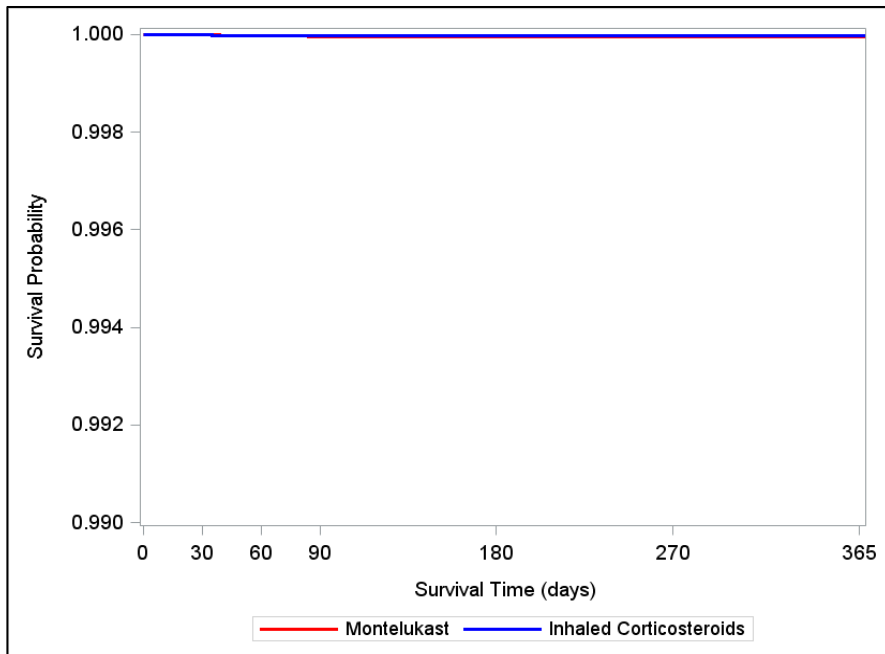


History of Psychiatric Disorder



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

**No History of Psychiatric Disorder**



**History of Psychiatric Disorder**

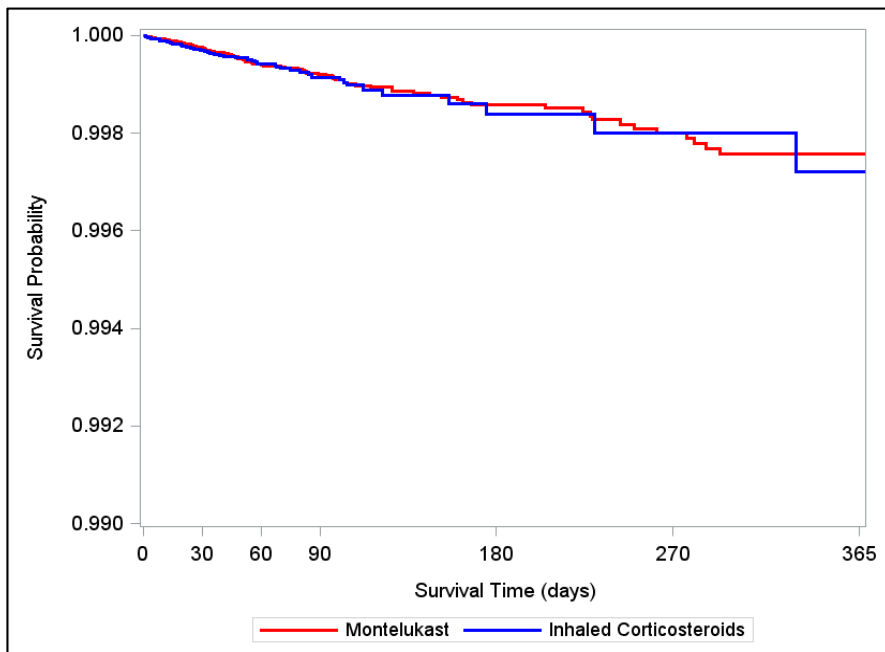
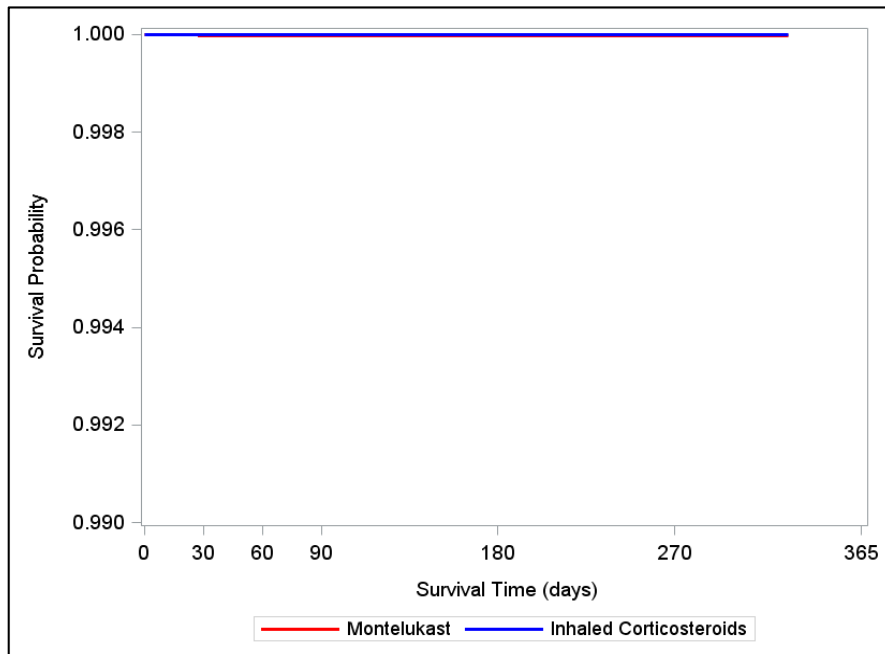


Figure 6e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm, by Age Group, Conditional Matched Cohort, Follow-Up Truncated to 365 Days

Ages 6-11 years



Ages 12-17 years

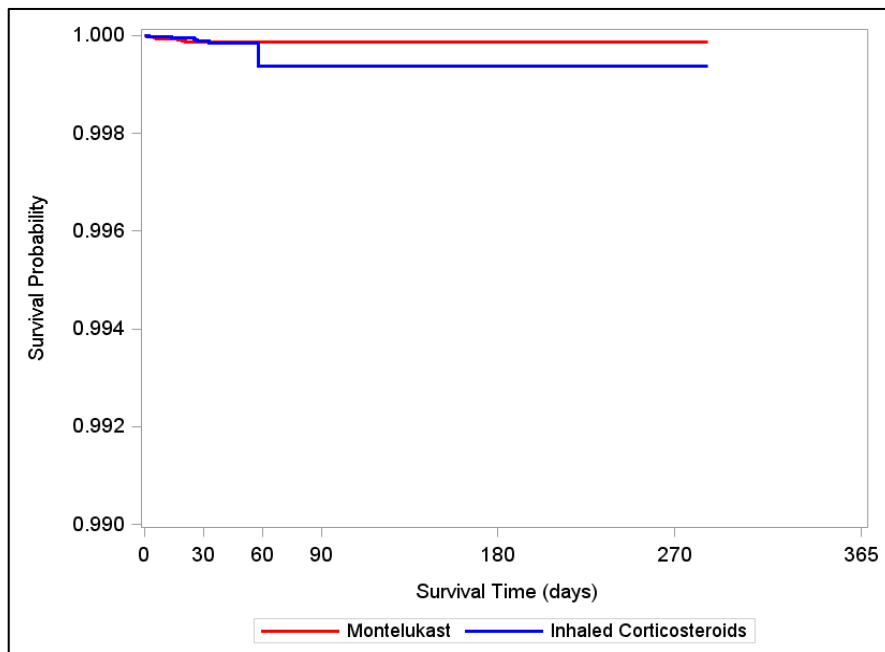


Figure 6e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm, by Age Group, Conditional Matched Cohort, Follow-Up Truncated to 365 Days

Ages 18+ years

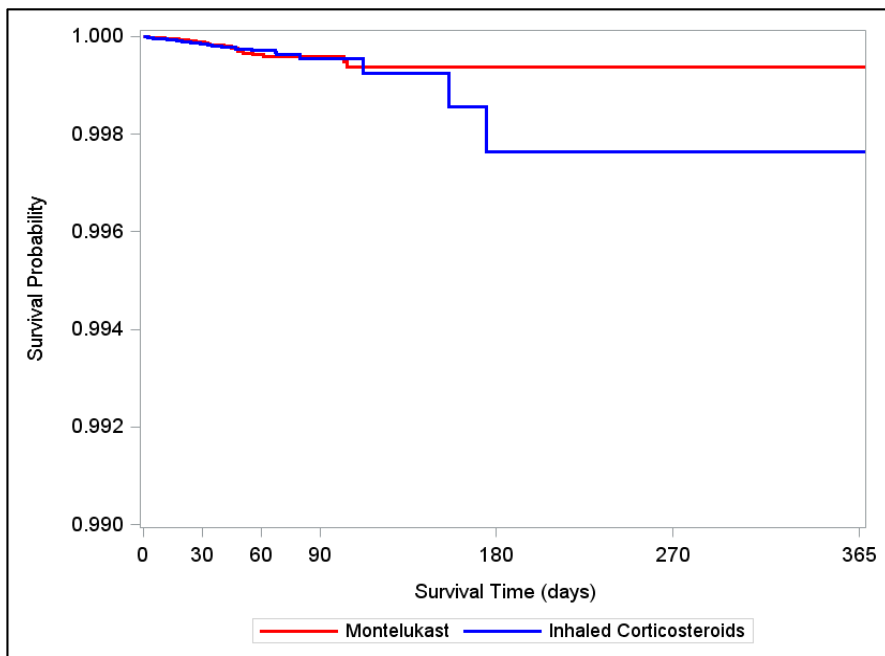
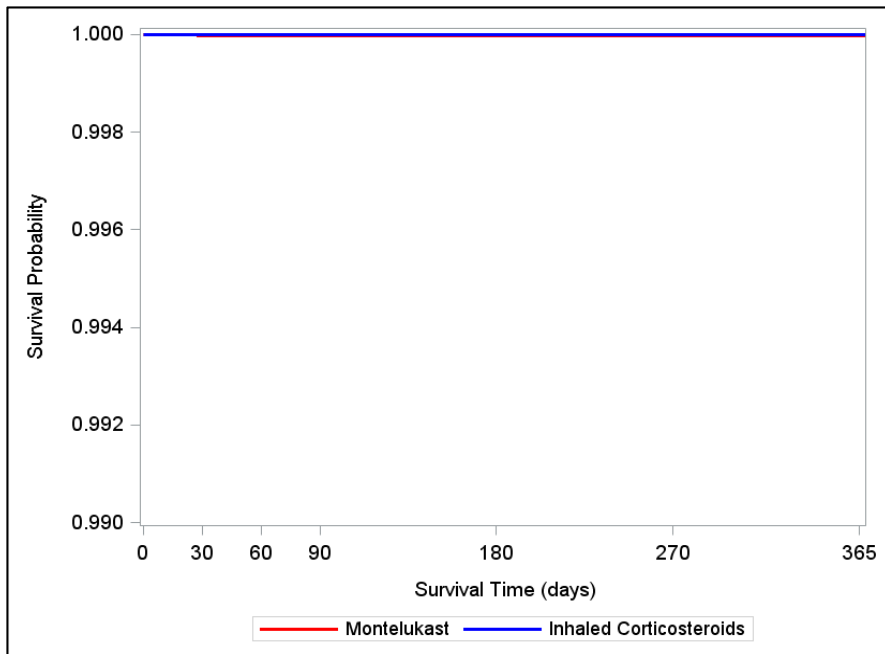


Figure 6f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm, by Age Group, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days

Ages 6-11 years



Ages 12-17 years

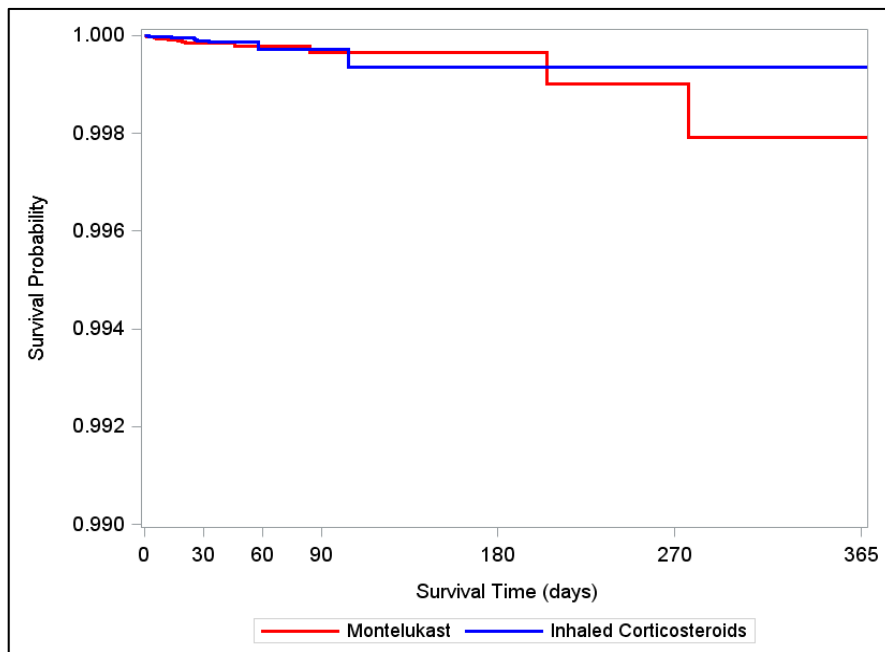


Figure 6f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm, by Age Group, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days

Ages 18+ years

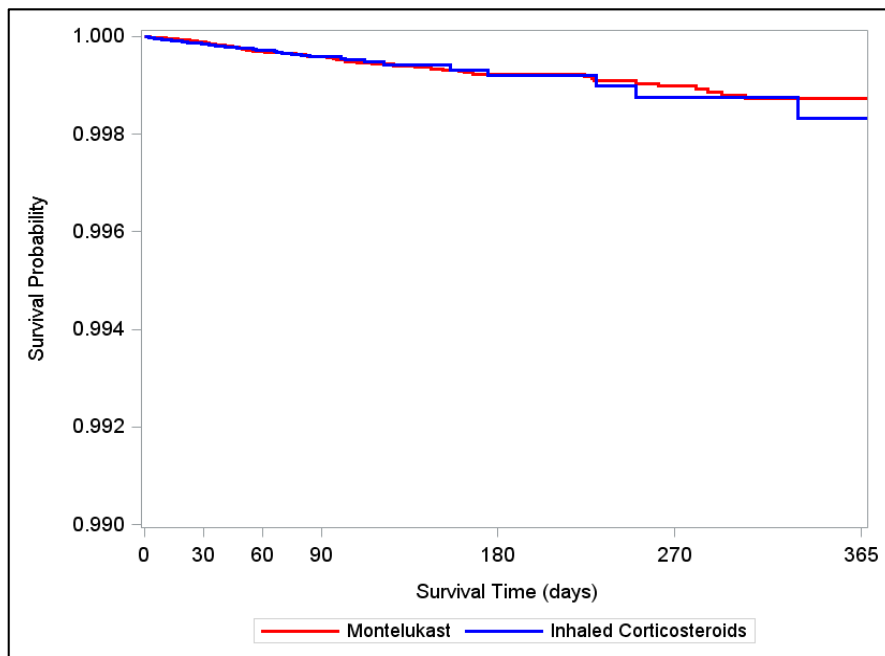
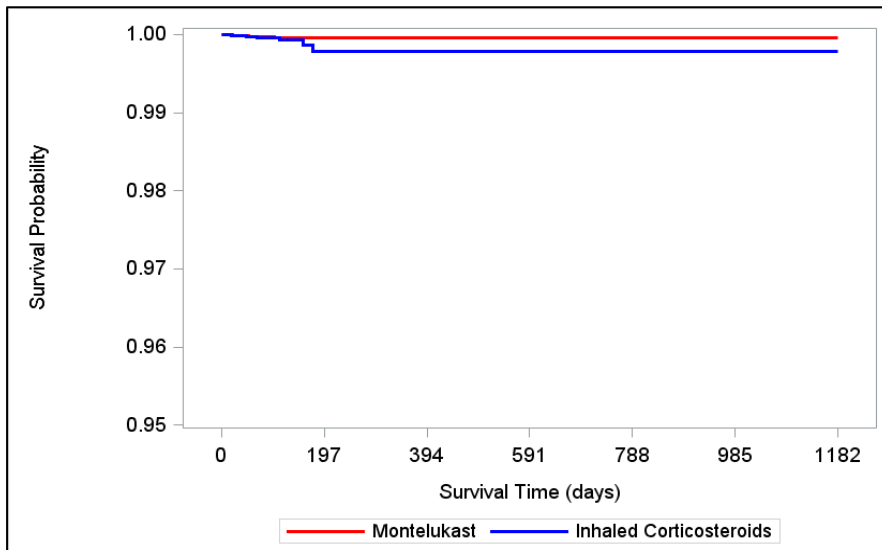
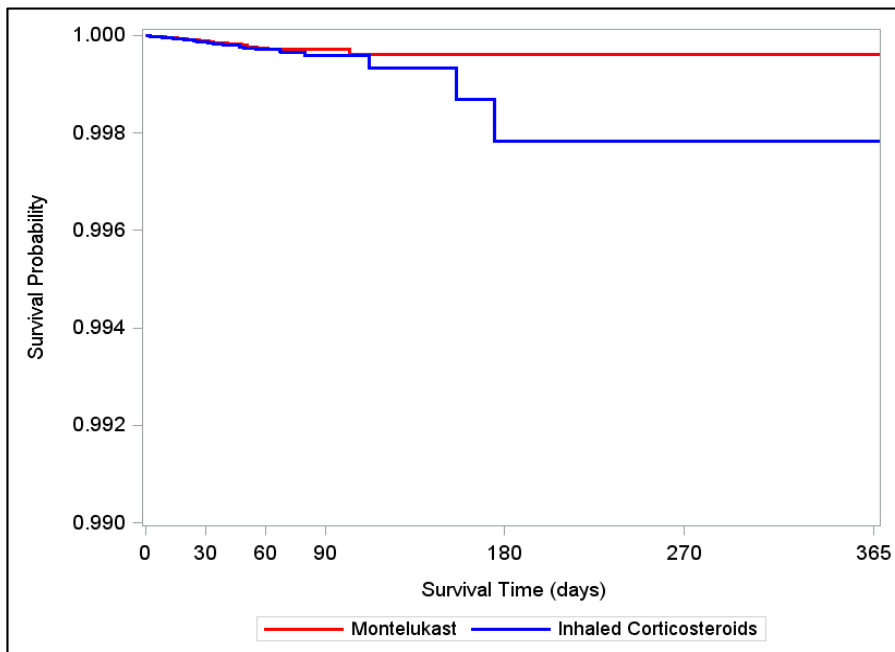


Figure 7a. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm with E-Code, Conditional Matched Cohort

All Available Follow-Up

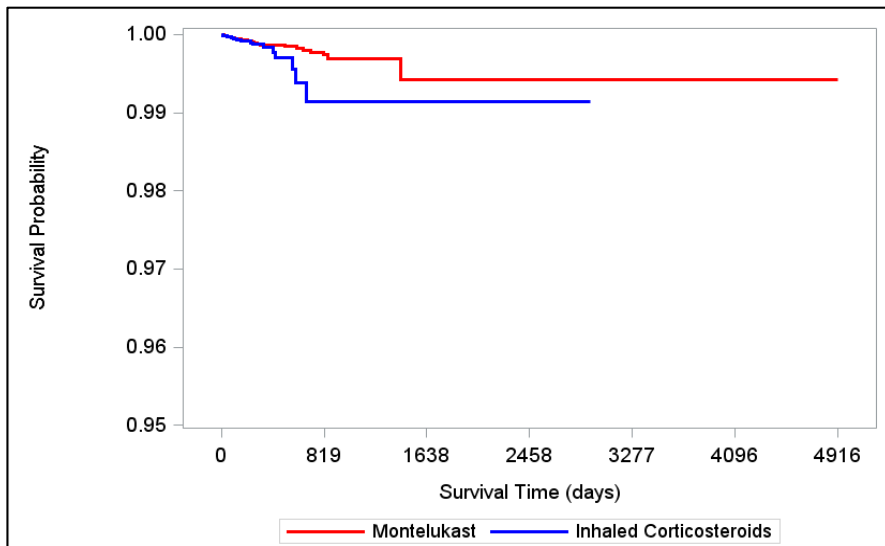


Follow-Up Truncated at 365 Days



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

**All Available Follow-Up**



**Follow-Up Truncated at 365 Days**

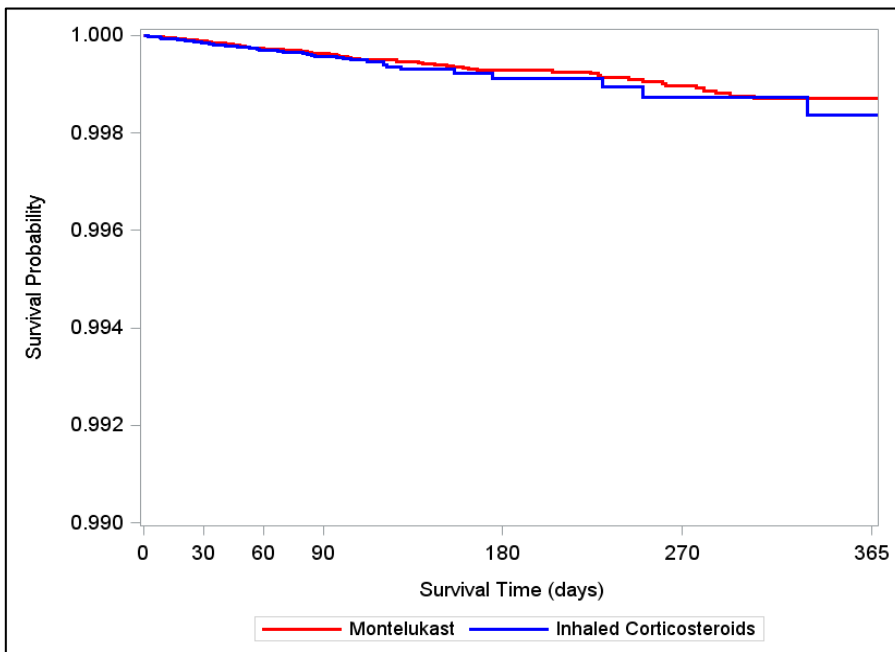
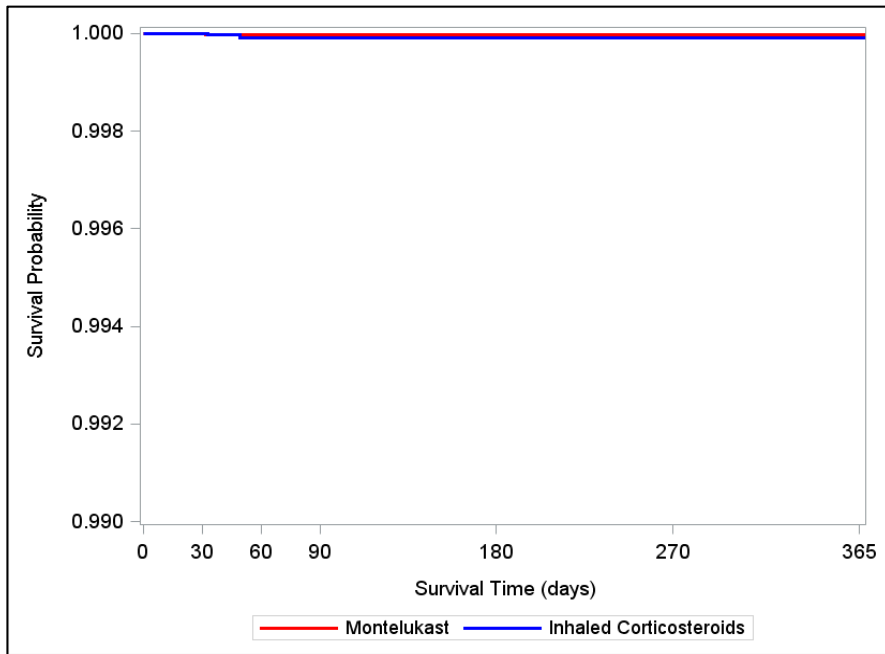


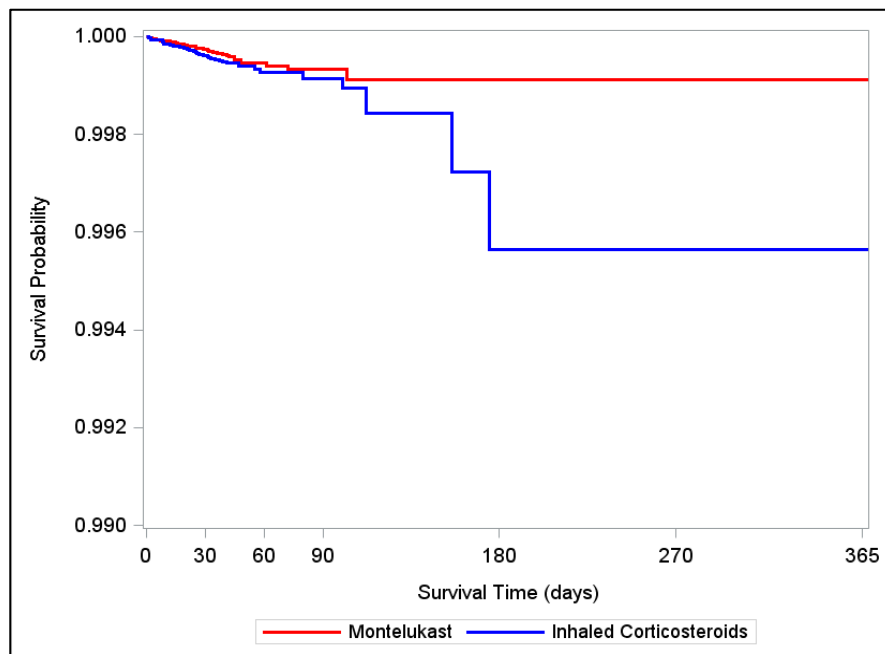


Figure 7c. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm or E-code, by History of Psychiatric Disorder, Conditional Matched Cohort, Follow-Up Truncated to 365 Days

No History of Psychiatric Disorder

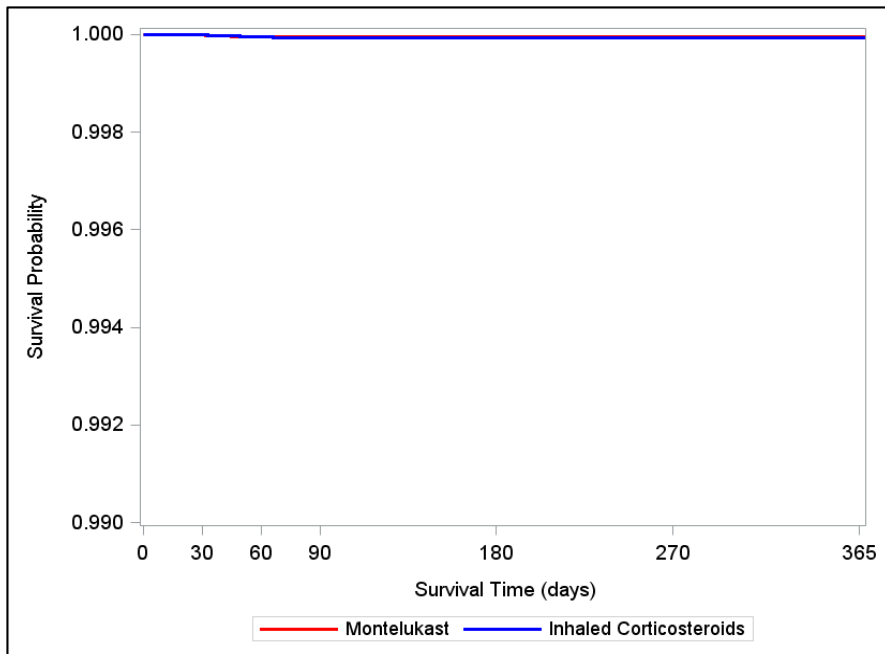


History of Psychiatric Disorder

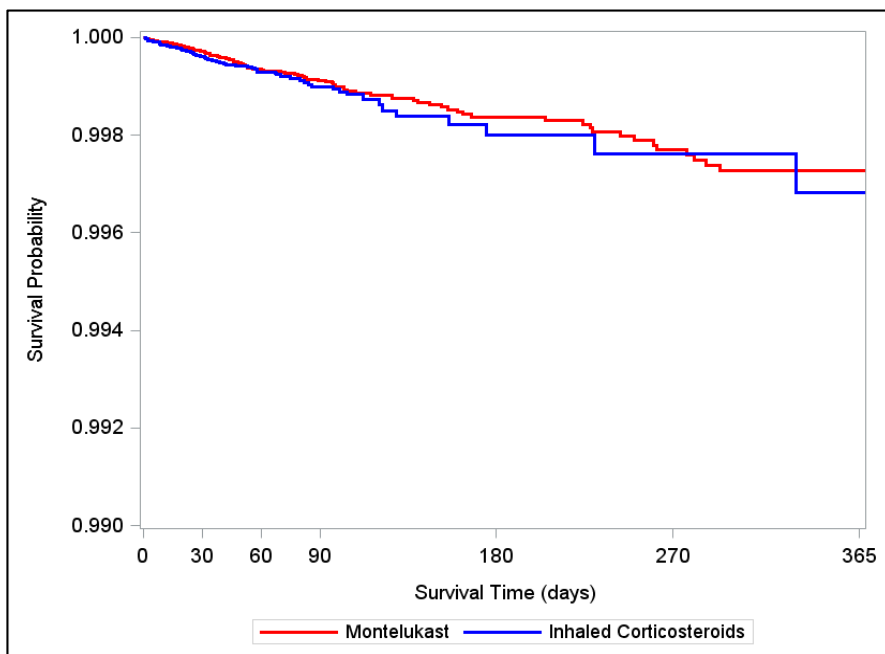


**Figure 7d. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm or E-code, by History of Psychiatric Disorder, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days**

**No History of Psychiatric Disorder**

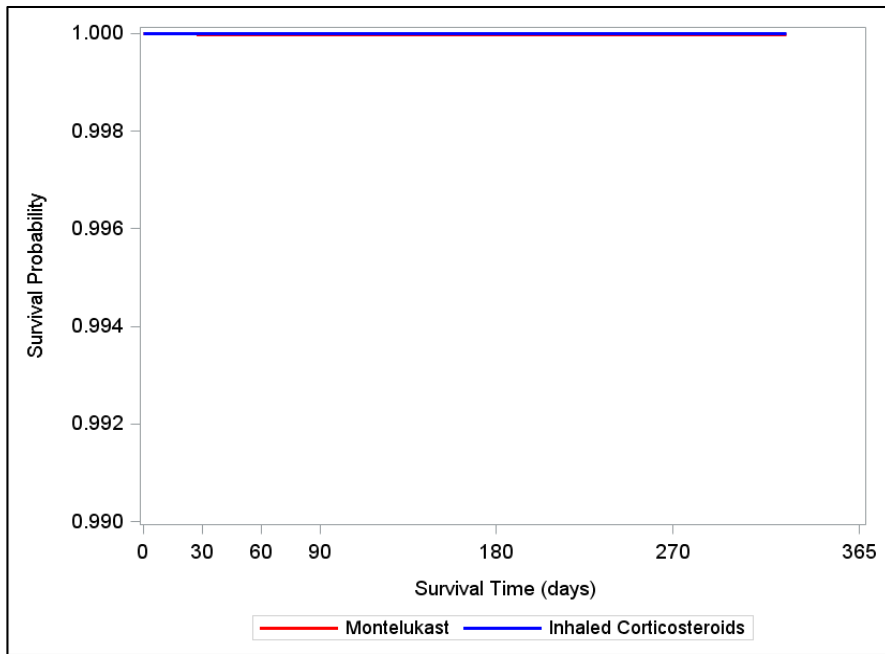


**History of Psychiatric Disorder**



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

**Ages 6-11 years**



**Ages 12-17 years**

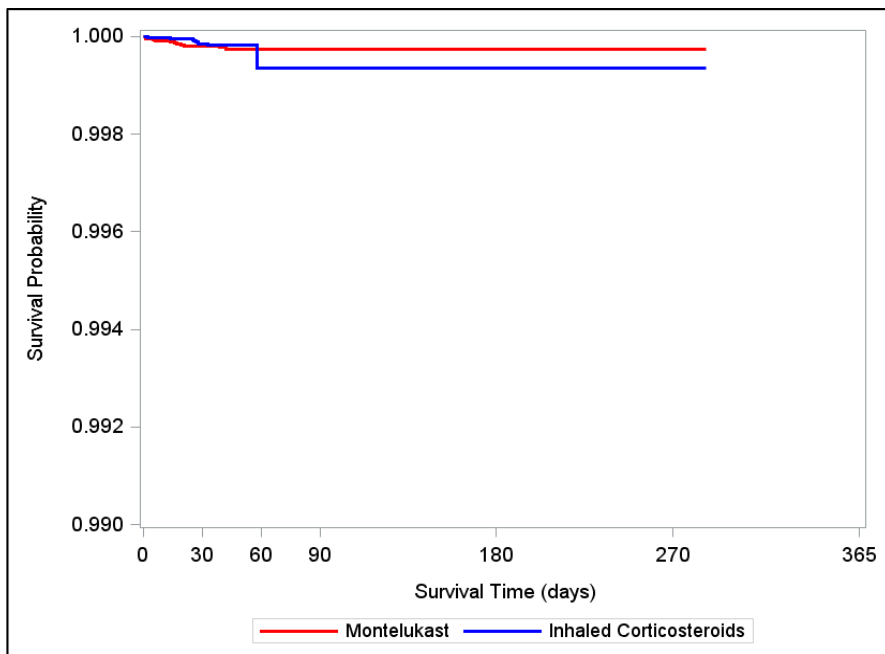
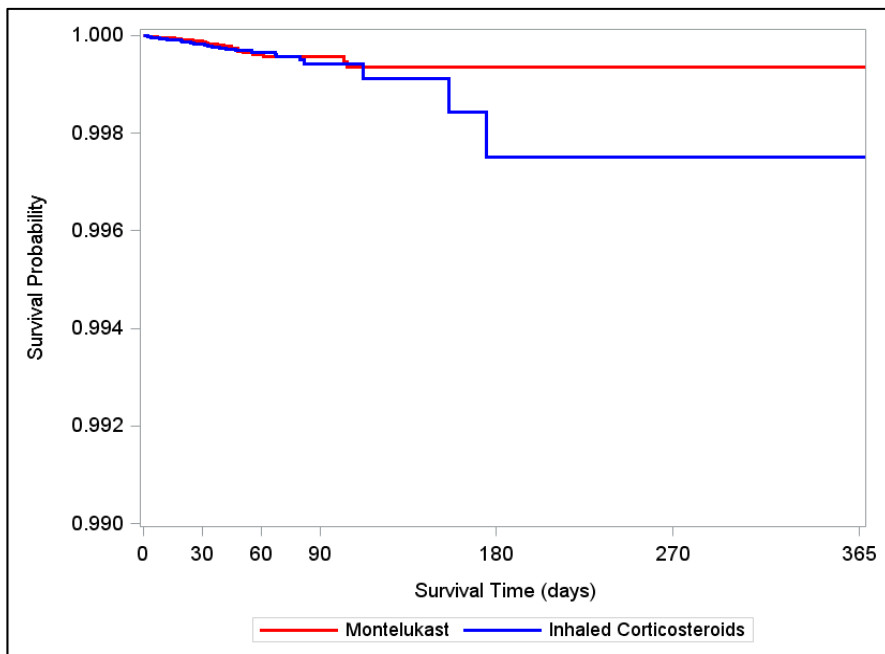


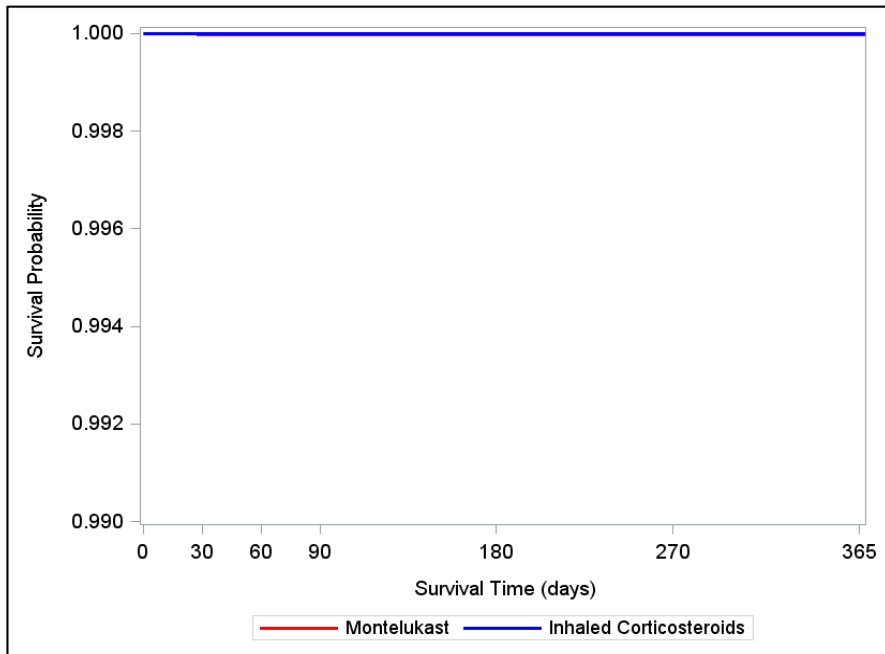
Figure 7e. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm or E-code, by Age Group, Conditional Matched Cohort, Follow-Up Truncated to 365 Days

Ages 18+ years



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

**Ages 6-11 years**



**Ages 12-17 years**

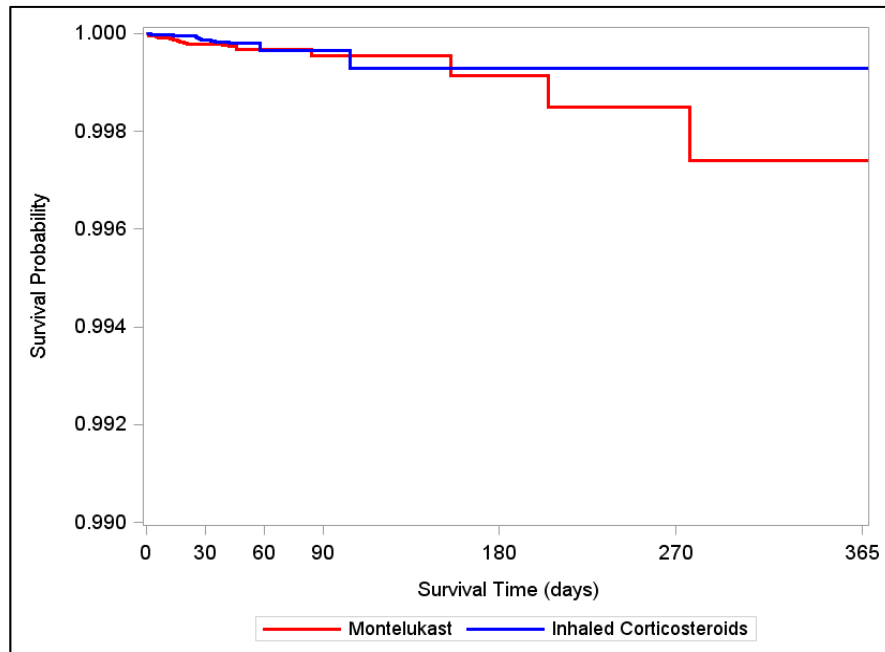
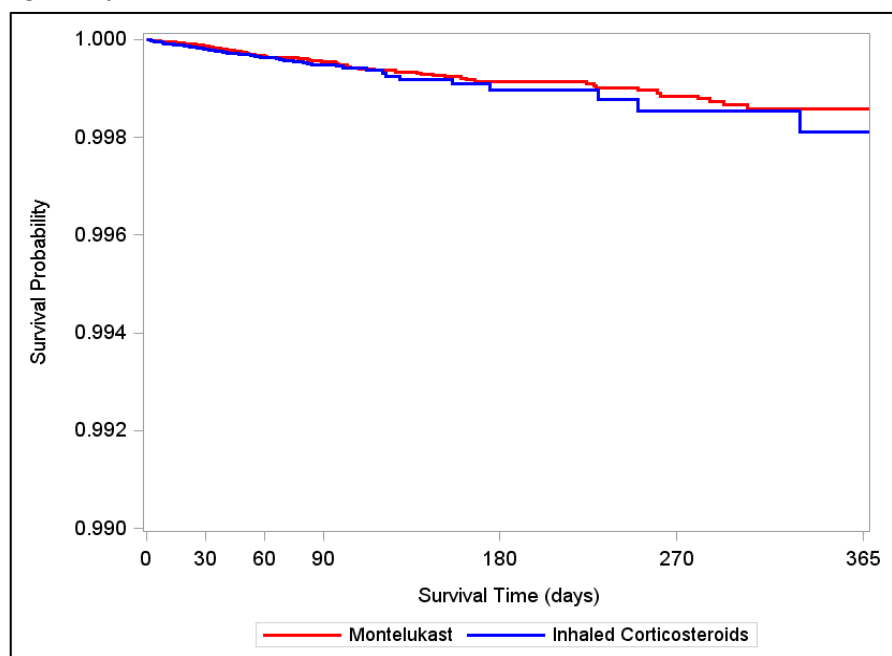


Figure 7f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for Self-Harm or E-code, by Age Group, Unconditional Matched Cohort, Follow-Up Truncated to 365 Days

Ages 18+ years



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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

**Query Period:** January 1, 2000 - September 30, 2015

**Coverage Requirement:** Medical and Drug Coverage

**Pre-index Enrollment Requirement:** 183 days

**Post-index Enrollment Requirement:** None

**Restrictions:** Male and Female only

**Age:** 6-11, 12-17, 18+ years

**Enrollment Gap:** 45 days

**Envelope Macro:** \*On: Reclassify encounters during inpatient stay as inpatient;

**Never-exposed Cohort:** None

**Additional Output (Dist of Index, MFU):** Censoring

**Freeze Data:** Yes

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

Appendix K. Specifications for Parameters for this Request, Part 1						
Inclusion/Exclusion Criteria						
<b>Criteria</b>	Asthma	Asthma	Asthma	Asthma	Asthma	Asthma
<b>Type</b>	Inclusion	Inclusion	Inclusion	Inclusion	Inclusion	Inclusion
<b>Evaluation Window</b>	-183, 0	-183, 0	-183, 0	-183, 0	-183, 0	-183, 0
<b>Care Setting/PDX</b>	Any	Any	Any	Any	Any	Any
<b>Criteria</b>	Chronic obstructive pulmonary disease (COPD)	COPD	COPD	COPD	COPD	COPD
<b>Type</b>	Exclusion	Exclusion	Exclusion	Exclusion	Exclusion	Exclusion
<b>Evaluation Window</b>	-183, 0	-183, 0	-183, 0	-183, 0	-183, 0	-183, 0
<b>Care Setting/PDX</b>	Any	Any	Any	Any	Any	Any
<b>Criteria</b>	ICS Monotherapy	Montelukast	ICS Monotherapy	Montelukast	ICS Monotherapy	Montelukast
<b>Type</b>	Exclusion	Exclusion	Exclusion	Exclusion	Exclusion	Exclusion
<b>Evaluation Window</b>	0,0	0,0	0,0	0,0	0,0	0,0
<b>Care Setting/PDX</b>	Any	Any	Any	Any	Any	Any
<b>Criteria</b>	Primary outcomes: Inpatient Primary Depressive Disorder, Outpatient Depressive Disorder, Self-harm hospitalizations (Patrick et al.), E-codes for Self-Harm	Primary outcomes: Inpatient Primary Depressive Disorder, Outpatient Depressive Disorder, Self-harm hospitalizations (Patrick et al.), E-codes for Self-Harm	Primary outcomes: Inpatient Primary Depressive Disorder, Outpatient Depressive Disorder, Self-harm hospitalizations (Patrick et al.), E-codes for Self-Harm	Primary outcomes: Inpatient Primary Depressive Disorder, Outpatient Depressive Disorder, Self-harm hospitalizations (Patrick et al.), E-codes for Self-Harm	Primary outcomes: Inpatient Primary Depressive Disorder, Outpatient Depressive Disorder, Self-harm hospitalizations (Patrick et al.), E-codes for Self-Harm	Primary outcomes: Inpatient Primary Depressive Disorder, Outpatient Depressive Disorder, Self-harm hospitalizations (Patrick et al.), E-codes for Self-Harm
<b>Type</b>	Exclusion	Exclusion	Exclusion	Exclusion	Exclusion	Exclusion
<b>Evaluation Window</b>	0,0	0,0	0,0	0,0	0,0	0,0
<b>At Risk Time</b>						
<b>Minimum exposure episode duration</b>	----	----	----	----	----	----
<b>Maximum exposure episode duration</b>	----	----	----	----	----	----

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

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

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

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

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

**Appendix M. Specifications Defining Outcomes in this Request**

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



### Appendix N. Specifications Defining Covariates in this Request

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

### Appendix N. Specifications Defining Covariates in this Request

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

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

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

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

Appendix O. Design Diagram for this Request

