

## Disclaimer

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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.

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

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## Overview for Request cder\_mpl1r\_wp152, (Report 1 of 2)

**Request ID:** cder\_mpl1r\_wp152

**Request Description:** Our objectives were 1) to obtain counts of prevalent long-acting injectable antipsychotic (LAIA) users and episodes in the Sentinel Distributed Database (SDD), and 2) to examine the feasibility of capturing evidence of death subsequent to LAIA exposures (i.e., treatment episodes that were censored due to death). We included data from eight Sentinel Data Partners (DPs) in our query request. This is report 1 of 2, which includes data from seven DPs that routinely match to state death records. Report #2 includes results provided by the Centers for Medicare and Medicaid Services (CMS) for patients enrolled in the traditional Medicare fee-for-service program.

**Sentinel Modular Program Tool Used:** Cohort Identification and Descriptive Analysis (CIDA) tool, Version 7.3.4

**Data Source:** We distributed this request on June 26, 2019 to eight DPs with "complete" capture of death information among their members. In this report, we included data from seven of eight DPs that participated in this request. These seven Sentinel DPs routinely attain death information from state death records.

We used censoring information from Sentinel's CIDA tool to characterize death (i.e., treatment episodes that were censored due to death). Sentinel's CIDA tool captures death records from either claims with a discharge status of "expired" or death recorded with a confidence level of "excellent". If a patient is identified in both sources, the tool will use the earliest death date identified.

**Study Design:** We used a retrospective study design to identify prevalent users of eight LAIA medications within the SDD. We conducted two groups of analyses:

- 1) Prevalent LAIA users as defined by National Drug Codes (NDCs):
  - Available data years varied by DP, and state death records may lag for two or more years behind the claims data included in DP databases. Thus, we tailored the study end dates by DP to reflect the date each DP considered their death information "complete".
  - We examined each LAIA medication separately and as a combined, "any LAIA exposure" group.
- 2) Prevalent LAIA users as defined by NDCs or Healthcare Common Procedure Coding System (HCPCS) procedure codes:
  - It was not possible to distinguish paliperidone palmitate (Invega Sustenna, 4-week treatment) and paliperidone palmitate (Invega Trinza, 12-week treatment) as both drugs can be defined using the same HCPCS procedure codes. Thus, the cohorts as defined by NDCs or HCPCS had a study period end date of May 18, 2015, the release date of Invega Trinza. There was no need to tailor the study end dates by DP because all contributing DPs had "complete" death data through May 18, 2015.
  - We examined each LAIA medication separately and as a combined, "any LAIA exposure" group.

Please refer to *Appendix A* for the final study period dates used for both analyses and for each DP.

For each LAIA defined with NDCs, we utilized the days supplied assigned within the Sentinel database. For injectable medications which are generally administered periodically (e.g., every two weeks, four weeks, 12 weeks, etc.), it is possible that days supplied assigned to these codes may not always accurately reflect this administration practice.

For analyses involving NDCs, we bridged consecutive or overlapping dispensings into a single exposure episode if a subsequent dispensing occurred on or before the day after the prior episode's end. For analyses involving HCPCS procedure codes, we bridged consecutive injections into a single exposure episode if they occurred on consecutive days.

Results were stratified by year, sex, age group, and cross-stratified by sex and age group.

**Exposures of Interest:** Our exposures of interest were: aripiprazole extended release, aripiprazole lauroxil, fluphenazine decanoate, haloperidol decanoate, olanzapine pamoate, paliperidone palmitate (Invega Sustenna), paliperidone palmitate (Invega Trinza), and risperidone microspheres. We only reported evidence of death for the "any exposure" group, not for any individual drug of interest.

Please see *Appendix B* for a list of generic and brand drug names used to define exposures in this request. Please see *Appendix C* for a list of HCPCS procedure codes used to define exposures in this request.

**Overview for Request cder\_mpl1r\_wp152, (Report 1 of 2)**

**Cohort Eligibility Criteria:** We examined all patients with LAIA exposures captured at eight DPs (i.e., no exclusions or age restrictions). We required cohort members to be continuously enrolled in plans with medical and drug coverage for at least 183 days prior to their first qualifying code (i.e., index dispensing date, and/or index injection date), during which gaps in coverage of up to 45 days were allowed. We included the following age groups in the analyses: 0-17, 18-49, 50-64, and 65+ years.

**Please see *Appendix D* for the specifications of parameters used in this request.**

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

In this analysis, we utilized the CIDA censoring table to describe deaths in prevalent LAIA users (i.e., treatment episodes that were censored due to death). This approach is imperfect as the censoring table is not explicitly designed to examine death as an outcome.

**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.

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

**Amount Supplied** - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing.

**Blackout Period** - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Exposure Episode Length** - number of days after exposure initiation that is considered "exposed time."

**Exposure Extension Period** - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extensions are added after any episode gaps have been bridged.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

\*all terms may not be used in this report

**Table 1a. Summary of Long-Acting Injectable Antipsychotic (LAIA) Treatment Episodes in the Sentinel Distributed Database (SDD), Overall**

	Number of Patients <sup>1</sup>	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members <sup>2</sup>	Eligible Member-Years <sup>2</sup>
<b>Prevalent Use (1/1/2000 - 3/31/2018), NDCs only</b>						
Aripiprazole extended release	1,222	4,249	9,958	10,041	21,234,258	110,424,825
Aripiprazole lauroxil	164	313	640	640	21,234,258	110,424,825
Fluphenazine decanoate	3,223	28,480	44,365	44,566	21,234,258	110,424,825
Haloperidol decanoate	6,908	68,689	123,303	125,760	21,234,258	110,424,825
Olanzapine pamoate	65	307	583	583	21,234,258	110,424,825
Paliperidone palmitate (Sustenna, 4-week)	2,529	12,555	34,312	34,505	21,234,258	110,424,825
Paliperidone palmitate (Trinza, 12-week)	156	243	462	464	21,234,258	110,424,825
Risperidone microspheres	6,316	34,515	99,236	100,615	21,234,258	110,424,825
<b>Any Prevalent Antipsychotics Use, NDCs only</b>	<b>15,657</b>	<b>146,806</b>	<b>312,649</b>	<b>316,975</b>	<b>21,234,258</b>	<b>110,424,825</b>
<b>Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS</b>						
Aripiprazole extended release	640	1,774	3,744	3,749	19,131,770	93,905,732
Aripiprazole lauroxil	0	0	0	0	19,131,770	93,905,732
Fluphenazine decanoate	3,454	30,288	49,582	49,774	19,131,770	93,905,732
Haloperidol decanoate	7,222	68,370	122,914	125,330	19,131,770	93,905,732
Olanzapine pamoate	257	483	737	737	19,131,770	93,905,732
Paliperidone palmitate (Sustenna, 4-week)	1,862	9,709	24,334	24,438	19,131,770	93,905,732
Risperidone microspheres	6,592	36,933	105,392	106,522	19,131,770	93,905,732
<b>Any Prevalent Antipsychotics Use, NDCs or HCPCS</b>	<b>15,760</b>	<b>145,490</b>	<b>306,469</b>	<b>310,316</b>	<b>19,131,770</b>	<b>93,905,732</b>

<sup>1</sup>Some users may have had dispensings of multiple medications of interest during the study period. Thus, totaling the number of users for each individual drug overestimates the number of LAIA users.

<sup>2</sup>Eligible Members and Member-Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

**Table 1b. Summary of Reasons for Episode Censoring in the Sentinel Distributed Database (SDD), Overall**

	Number of Episodes	Reason(s) for Censoring <sup>1</sup>				
		Eligibility	Death	DP Data End Date	Query End Date	Episode End
<b>Prevalent Use (1/1/2000 - 3/31/2018), NDCs only</b>						
<i>Any Prevalent Antipsychotics Use, NDCs only</i>	146,806	1,632	354	12	2,242	144,525
<b>Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS</b>						
<i>Any Prevalent Antipsychotics Use, NDCs or HCPCS</i>	145,490	1,732	329	0	2,412	142,810

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

**Table 1c. Summary of Follow-up Time for Users Censored due to Death in the Sentinel Distributed Database (SDD), Overall**

	Number of Episodes Censored at Death	Summary Statistics for Lengths of Follow-up Time (Days)						Distribution of Lengths of Follow-up Time (Number of Episodes)							
		Mean	Minimum	Q1	Median	Q3	Maximum	0-7 days	8-14 days	15-21 days	22-30 days	31-60 days	61-90 days	91-183 days	>6 months
<b>Prevalent Use (1/1/2000 - 3/31/2018), NDCs only</b>															
<i>Any Prevalent Antipsychotics Use, NDCs only</i>	354	154.29	1	11	26	99	3,716	55	57	40	44	43	20	36	59
<b>Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS</b>															
<i>Any Prevalent Antipsychotics Use, NDCs or HCPCS</i>	329	140.97	1	10	24	88	3,716	55	55	36	43	39	19	35	47

**Table 2a. Summary of Long-Acting Injectable Antipsychotic (LAIA) Treatment Episodes in the Sentinel Distributed Database (SDD), by Calendar Year**

Year	Number of Patients <sup>1</sup>	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members <sup>2</sup>	Eligible Member-Years <sup>2</sup>
<b>Prevalent Use (1/1/2000 - 3/31/2018), NDCs only</b>						
<b>Aripiprazole extended release</b>						
2000	0	0	0	0	6,180,278	2,860,007
2001	0	0	0	0	6,719,630	5,673,987
2002	0	0	0	0	6,867,336	5,767,540
2003	0	0	0	0	6,860,521	5,754,966
2004	0	0	0	0	7,322,315	6,025,203
2005	0	0	0	0	7,450,395	6,295,266
2006	0	0	0	0	7,292,027	6,152,960
2007	0	0	0	0	7,277,269	6,186,290
2008	0	0	0	0	7,364,286	6,248,657
2009	0	0	0	0	7,493,874	6,339,099
2010	0	0	0	0	7,628,877	6,508,147
2011	0	0	0	0	7,797,888	6,683,547
2012	0	0	0	0	7,857,258	6,782,095
2013	157	258	724	724	7,887,432	6,809,727
2014	420	988	2,519	2,522	8,243,482	7,056,780
2015	604	1,418	3,627	3,668	8,707,811	7,539,596
2016	622	1,559	3,047	3,086	8,373,124	7,305,649
2017	15	**	**	**	5,967,889	4,309,981
2018	**	**	**	**	522,167	125,327
<b>Aripiprazole lauroxil</b>						
2000	0	0	0	0	6,180,278	2,860,007
2001	0	0	0	0	6,719,630	5,673,987
2002	0	0	0	0	6,867,336	5,767,540
2003	0	0	0	0	6,860,521	5,754,966
2004	0	0	0	0	7,322,315	6,025,203
2005	0	0	0	0	7,450,395	6,295,266
2006	0	0	0	0	7,292,027	6,152,960
2007	0	0	0	0	7,277,269	6,186,290
2008	0	0	0	0	7,364,286	6,248,657
2009	0	0	0	0	7,493,874	6,339,099
2010	0	0	0	0	7,628,877	6,508,147
2011	0	0	0	0	7,797,888	6,683,547
2012	0	0	0	0	7,857,258	6,782,095
2013	0	0	0	0	7,887,432	6,809,727
2014	0	0	0	0	8,243,482	7,056,780
2015	**	**	**	**	8,707,811	7,539,596
2016	159	301	608	608	8,373,124	7,305,649
2017	**	**	**	**	5,967,889	4,309,981
2018	0	0	0	0	522,167	125,327
<b>Fluphenazine decanoate</b>						
2000	476	1,197	1,498	1,498	6,180,278	2,860,007
2001	655	2,425	3,023	3,027	6,719,630	5,673,987
2002	716	2,692	3,734	3,749	6,867,336	5,767,540
2003	855	3,678	4,472	4,478	6,860,521	5,754,966
2004	722	2,830	3,238	3,241	7,322,315	6,025,203
2005	646	2,770	3,269	3,279	7,450,395	6,295,266
2006	318	**	**	**	7,292,027	6,152,960

**Table 2a. Summary of Long-Acting Injectable Antipsychotic (LAIA) Treatment Episodes in the Sentinel Distributed Database (SDD), by Calendar Year**

Year	Number of Patients <sup>1</sup>	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members <sup>2</sup>	Eligible Member-Years <sup>2</sup>
2007	440	1,382	2,442	2,494	7,277,269	6,186,290
2008	417	1,269	3,163	3,234	7,364,286	6,248,657
2009	350	1,220	2,318	2,335	7,493,874	6,339,099
2010	344	1,245	2,075	2,075	7,628,877	6,508,147
2011	345	1,153	1,863	1,863	7,797,888	6,683,547
2012	253	910	1,527	1,527	7,857,258	6,782,095
2013	347	1,003	1,760	1,760	7,887,432	6,809,727
2014	420	1,282	3,284	3,285	8,243,482	7,056,780
2015	410	1,333	3,221	3,227	8,707,811	7,539,596
2016	377	1,232	2,292	2,296	8,373,124	7,305,649
2017	**	**	**	**	5,967,889	4,309,981
2018	0	0	0	0	522,167	125,327
<b>Haloperidol decanoate</b>						
2000	1,779	4,335	6,117	6,271	6,180,278	2,860,007
2001	2,284	8,619	12,668	12,958	6,719,630	5,673,987
2002	2,176	8,176	12,307	12,679	6,867,336	5,767,540
2003	1,997	7,334	10,176	10,492	6,860,521	5,754,966
2004	1,851	6,930	10,203	10,554	7,322,315	6,025,203
2005	1,781	6,168	9,510	9,742	7,450,395	6,295,266
2006	940	2,671	4,973	5,139	7,292,027	6,152,960
2007	776	2,316	4,562	4,656	7,277,269	6,186,290
2008	842	2,449	7,268	7,393	7,364,286	6,248,657
2009	733	2,305	4,924	4,950	7,493,874	6,339,099
2010	718	2,228	5,034	5,241	7,628,877	6,508,147
2011	695	2,248	5,224	5,266	7,797,888	6,683,547
2012	679	2,267	4,831	4,847	7,857,258	6,782,095
2013	843	2,635	6,061	6,068	7,887,432	6,809,727
2014	904	2,836	7,203	7,219	8,243,482	7,056,780
2015	863	2,689	7,138	7,167	8,707,811	7,539,596
2016	823	2,441	5,056	5,070	8,373,124	7,305,649
2017	24	**	**	**	5,967,889	4,309,981
2018	**	**	**	**	522,167	125,327
<b>Olanzapine pamoate</b>						
2000	0	0	0	0	6,180,278	2,860,007
2001	0	0	0	0	6,719,630	5,673,987
2002	0	0	0	0	6,867,336	5,767,540
2003	0	0	0	0	6,860,521	5,754,966
2004	0	0	0	0	7,322,315	6,025,203
2005	0	0	0	0	7,450,395	6,295,266
2006	0	0	0	0	7,292,027	6,152,960
2007	0	0	0	0	7,277,269	6,186,290
2008	0	0	0	0	7,364,286	6,248,657
2009	0	0	0	0	7,493,874	6,339,099
2010	16	32	51	51	7,628,877	6,508,147
2011	27	79	156	156	7,797,888	6,683,547
2012	23	67	137	137	7,857,258	6,782,095
2013	21	58	98	98	7,887,432	6,809,727
2014	**	38	74	74	8,243,482	7,056,780
2015	**	**	39	39	8,707,811	7,539,596

**Table 2a. Summary of Long-Acting Injectable Antipsychotic (LAIA) Treatment Episodes in the Sentinel Distributed Database (SDD), by Calendar Year**

Year	Number of Patients <sup>1</sup>	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members <sup>2</sup>	Eligible Member-Years <sup>2</sup>
2016	**	**	**	**	8,373,124	7,305,649
2017	**	**	**	**	5,967,889	4,309,981
2018	0	0	0	0	522,167	125,327
<b>Paliperidone palmitate (Sustenna, 4-week)</b>						
2000	0	0	0	0	6,180,278	2,860,007
2001	0	0	0	0	6,719,630	5,673,987
2002	0	0	0	0	6,867,336	5,767,540
2003	0	0	0	0	6,860,521	5,754,966
2004	0	0	0	0	7,322,315	6,025,203
2005	0	0	0	0	7,450,395	6,295,266
2006	0	0	0	0	7,292,027	6,152,960
2007	0	0	0	0	7,277,269	6,186,290
2008	0	0	0	0	7,364,286	6,248,657
2009	83	135	304	304	7,493,874	6,339,099
2010	293	861	2,337	2,340	7,628,877	6,508,147
2011	441	1,190	4,437	4,456	7,797,888	6,683,547
2012	456	1,421	3,938	3,963	7,857,258	6,782,095
2013	548	1,545	4,171	4,185	7,887,432	6,809,727
2014	743	2,072	6,094	6,123	8,243,482	7,056,780
2015	951	2,409	6,742	6,781	8,707,811	7,539,596
2016	1,131	2,736	5,974	6,027	8,373,124	7,305,649
2017	81	**	**	**	5,967,889	4,309,981
2018	**	**	**	**	522,167	125,327
<b>Paliperidone palmitate (Trinza, 12-week)</b>						
2000	0	0	0	0	6,180,278	2,860,007
2001	0	0	0	0	6,719,630	5,673,987
2002	0	0	0	0	6,867,336	5,767,540
2003	0	0	0	0	6,860,521	5,754,966
2004	0	0	0	0	7,322,315	6,025,203
2005	0	0	0	0	7,450,395	6,295,266
2006	0	0	0	0	7,292,027	6,152,960
2007	0	0	0	0	7,277,269	6,186,290
2008	0	0	0	0	7,364,286	6,248,657
2009	0	0	0	0	7,493,874	6,339,099
2010	0	0	0	0	7,628,877	6,508,147
2011	0	0	0	0	7,797,888	6,683,547
2012	0	0	0	0	7,857,258	6,782,095
2013	0	0	0	0	7,887,432	6,809,727
2014	0	0	0	0	8,243,482	7,056,780
2015	53	**	167	168	8,707,811	7,539,596
2016	117	174	283	284	8,373,124	7,305,649
2017	**	**	12	12	5,967,889	4,309,981
2018	0	0	0	0	522,167	125,327
<b>Risperidone microspheres</b>						
2000	0	0	0	0	6,180,278	2,860,007
2001	0	0	0	0	6,719,630	5,673,987
2002	0	0	0	0	6,867,336	5,767,540
2003	36	36	282	286	6,860,521	5,754,966
2004	1,472	5,668	14,723	14,967	7,322,315	6,025,203

**Table 2a. Summary of Long-Acting Injectable Antipsychotic (LAIA) Treatment Episodes in the Sentinel Distributed Database (SDD), by Calendar Year**

Year	Number of Patients <sup>1</sup>	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members <sup>2</sup>	Eligible Member-Years <sup>2</sup>
2005	1,674	5,957	15,930	16,090	7,450,395	6,295,266
2006	835	1,977	8,726	8,818	7,292,027	6,152,960
2007	804	1,962	8,889	8,987	7,277,269	6,186,290
2008	763	1,852	7,565	7,664	7,364,286	6,248,657
2009	760	1,997	5,129	5,138	7,493,874	6,339,099
2010	858	2,668	5,878	5,983	7,628,877	6,508,147
2011	937	2,790	7,100	7,238	7,797,888	6,683,547
2012	797	2,515	5,875	5,962	7,857,258	6,782,095
2013	796	2,221	5,846	5,989	7,887,432	6,809,727
2014	708	1,963	5,648	5,778	8,243,482	7,056,780
2015	562	1,604	4,594	4,646	8,707,811	7,539,596
2016	430	1,239	2,900	2,918	8,373,124	7,305,649
2017	28	**	**	**	5,967,889	4,309,981
2018	**	**	**	**	522,167	125,327
<b>Any Prevalent Antipsychotics Use, NDCs only</b>						
2000	2,235	5,518	7,614	7,768	6,180,278	2,860,007
2001	2,905	11,030	15,690	15,984	6,719,630	5,673,987
2002	2,864	10,854	16,048	16,435	6,867,336	5,767,540
2003	2,823	11,027	14,943	15,269	6,860,521	5,754,966
2004	3,720	15,253	28,429	29,031	7,322,315	6,025,203
2005	3,880	14,729	29,243	29,652	7,450,395	6,295,266
2006	2,008	5,456	15,207	15,489	7,292,027	6,152,960
2007	1,921	5,581	15,845	16,084	7,277,269	6,186,290
2008	1,939	5,482	18,294	18,575	7,364,286	6,248,657
2009	1,778	5,526	13,222	13,274	7,493,874	6,339,099
2010	1,978	6,761	15,140	15,455	7,628,877	6,508,147
2011	2,148	7,211	17,447	17,645	7,797,888	6,683,547
2012	2,044	7,047	16,115	16,242	7,857,258	6,782,095
2013	2,410	7,526	18,756	18,921	7,887,432	6,809,727
2014	2,919	8,971	24,857	25,038	8,243,482	7,056,780
2015	3,115	9,244	25,515	25,691	8,707,811	7,539,596
2016	3,236	9,269	19,727	19,855	8,373,124	7,305,649
2017	147	**	**	**	5,967,889	4,309,981
2018	**	**	**	**	522,167	125,327
<b>Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS</b>						
<b>Aripiprazole extended release</b>						
2000	0	0	0	0	6,180,278	2,860,007
2001	0	0	0	0	6,719,630	5,673,987
2002	0	0	0	0	6,867,336	5,767,540
2003	0	0	0	0	6,860,521	5,754,966
2004	0	0	0	0	7,322,315	6,025,203
2005	0	0	0	0	7,450,395	6,295,266
2006	0	0	0	0	7,292,027	6,152,960
2007	0	0	0	0	7,277,269	6,186,290
2008	0	0	0	0	7,364,286	6,248,657
2009	0	0	0	0	7,493,874	6,339,099
2010	0	0	0	0	7,628,877	6,508,147
2011	0	0	0	0	7,797,888	6,683,547
2012	0	0	0	0	7,857,258	6,782,095

**Table 2a. Summary of Long-Acting Injectable Antipsychotic (LAIA) Treatment Episodes in the Sentinel Distributed Database (SDD), by Calendar Year**

Year	Number of Patients <sup>1</sup>	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members <sup>2</sup>	Eligible Member-Years <sup>2</sup>
2013	157	258	684	684	7,887,432	6,809,727
2014	435	1,014	2,266	2,267	8,243,482	7,056,780
2015	316	502	794	798	7,640,271	2,761,460
<b>Aripiprazole lauroxil</b>						
2000	0	0	0	0	6,180,278	2,860,007
2001	0	0	0	0	6,719,630	5,673,987
2002	0	0	0	0	6,867,336	5,767,540
2003	0	0	0	0	6,860,521	5,754,966
2004	0	0	0	0	7,322,315	6,025,203
2005	0	0	0	0	7,450,395	6,295,266
2006	0	0	0	0	7,292,027	6,152,960
2007	0	0	0	0	7,277,269	6,186,290
2008	0	0	0	0	7,364,286	6,248,657
2009	0	0	0	0	7,493,874	6,339,099
2010	0	0	0	0	7,628,877	6,508,147
2011	0	0	0	0	7,797,888	6,683,547
2012	0	0	0	0	7,857,258	6,782,095
2013	0	0	0	0	7,887,432	6,809,727
2014	0	0	0	0	8,243,482	7,056,780
2015	0	0	0	0	7,640,271	2,761,460
<b>Fluphenazine decanoate</b>						
2000	527	1,320	1,762	1,762	6,180,278	2,860,007
2001	809	2,817	4,104	4,108	6,719,630	5,673,987
2002	780	2,979	4,516	4,531	6,867,336	5,767,540
2003	926	3,929	5,104	5,110	6,860,521	5,754,966
2004	798	3,133	4,025	4,028	7,322,315	6,025,203
2005	729	3,166	4,021	4,031	7,450,395	6,295,266
2006	379	1,067	1,605	1,617	7,292,027	6,152,960
2007	513	1,662	3,172	3,224	7,277,269	6,186,290
2008	497	1,591	3,945	4,016	7,364,286	6,248,657
2009	419	1,504	3,097	3,114	7,493,874	6,339,099
2010	406	1,487	2,688	2,688	7,628,877	6,508,147
2011	408	1,376	2,596	2,596	7,797,888	6,683,547
2012	316	1,126	2,214	2,214	7,857,258	6,782,095
2013	406	1,155	2,455	2,455	7,887,432	6,809,727
2014	457	1,403	3,349	3,350	8,243,482	7,056,780
2015	311	573	929	930	7,640,271	2,761,460
<b>Haloperidol decanoate</b>						
2000	1,800	4,368	6,242	6,395	6,180,278	2,860,007
2001	2,322	8,718	13,053	13,343	6,719,630	5,673,987
2002	2,209	8,268	12,538	12,910	6,867,336	5,767,540
2003	2,032	7,411	10,502	10,818	6,860,521	5,754,966
2004	1,900	6,967	10,731	11,083	7,322,315	6,025,203
2005	1,844	6,228	10,166	10,397	7,450,395	6,295,266
2006	1,006	2,826	5,482	5,648	7,292,027	6,152,960
2007	899	2,588	5,368	5,462	7,277,269	6,186,290
2008	980	2,790	8,098	8,223	7,364,286	6,248,657
2009	869	2,613	5,800	5,826	7,493,874	6,339,099
2010	862	2,611	6,029	6,236	7,628,877	6,508,147

**Table 2a. Summary of Long-Acting Injectable Antipsychotic (LAIA) Treatment Episodes in the Sentinel Distributed Database (SDD), by Calendar Year**

Year	Number of Patients <sup>1</sup>	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members <sup>2</sup>	Eligible Member-Years <sup>2</sup>
2011	855	2,642	6,203	6,245	7,797,888	6,683,547
2012	839	2,666	5,947	5,963	7,857,258	6,782,095
2013	988	3,018	6,940	6,946	7,887,432	6,809,727
2014	1,103	3,323	7,605	7,619	8,243,482	7,056,780
2015	747	1,333	2,210	2,216	7,640,271	2,761,460
<b>Olanzapine pamoate</b>						
2000	0	0	0	0	6,180,278	2,860,007
2001	0	0	0	0	6,719,630	5,673,987
2002	0	0	0	0	6,867,336	5,767,540
2003	0	0	0	0	6,860,521	5,754,966
2004	0	0	0	0	7,322,315	6,025,203
2005	0	0	0	0	7,450,395	6,295,266
2006	0	0	0	0	7,292,027	6,152,960
2007	0	0	0	0	7,277,269	6,186,290
2008	0	0	0	0	7,364,286	6,248,657
2009	0	0	0	0	7,493,874	6,339,099
2010	16	32	51	51	7,628,877	6,508,147
2011	44	96	174	174	7,797,888	6,683,547
2012	76	122	192	192	7,857,258	6,782,095
2013	66	103	145	145	7,887,432	6,809,727
2014	71	100	140	140	8,243,482	7,056,780
2015	26	30	35	35	7,640,271	2,761,460
<b>Paliperidone palmitate (Sustenna, 4-week)</b>						
2000	0	0	0	0	6,180,278	2,860,007
2001	0	0	0	0	6,719,630	5,673,987
2002	0	0	0	0	6,867,336	5,767,540
2003	0	0	0	0	6,860,521	5,754,966
2004	0	0	0	0	7,322,315	6,025,203
2005	0	0	0	0	7,450,395	6,295,266
2006	0	0	0	0	7,292,027	6,152,960
2007	0	0	0	0	7,277,269	6,186,290
2008	0	0	0	0	7,364,286	6,248,657
2009	84	137	309	309	7,493,874	6,339,099
2010	301	890	2,361	2,364	7,628,877	6,508,147
2011	476	1,291	4,448	4,467	7,797,888	6,683,547
2012	522	1,637	4,162	4,187	7,857,258	6,782,095
2013	670	1,939	4,759	4,773	7,887,432	6,809,727
2014	936	2,680	6,375	6,402	8,243,482	7,056,780
2015	631	1,135	1,920	1,936	7,640,271	2,761,460
<b>Risperidone microspheres</b>						
2000	0	0	0	0	6,180,278	2,860,007
2001	0	0	0	0	6,719,630	5,673,987
2002	0	0	0	0	6,867,336	5,767,540
2003	36	36	282	286	6,860,521	5,754,966
2004	1,474	5,675	14,701	14,945	7,322,315	6,025,203
2005	1,709	6,186	16,560	16,720	7,450,395	6,295,266
2006	873	2,176	9,250	9,342	7,292,027	6,152,960
2007	882	2,283	9,753	9,851	7,277,269	6,186,290
2008	840	2,132	8,388	8,487	7,364,286	6,248,657

**Table 2a. Summary of Long-Acting Injectable Antipsychotic (LAIA) Treatment Episodes in the Sentinel Distributed Database (SDD), by Calendar Year**

Year	Number of Patients <sup>1</sup>	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members <sup>2</sup>	Eligible Member-Years <sup>2</sup>
2009	832	2,298	5,980	5,989	7,493,874	6,339,099
2010	912	2,898	6,482	6,577	7,628,877	6,508,147
2011	1,005	3,054	7,814	7,923	7,797,888	6,683,547
2012	958	2,988	7,405	7,469	7,857,258	6,782,095
2013	1,019	3,105	8,532	8,624	7,887,432	6,809,727
2014	954	2,995	8,103	8,162	8,243,482	7,056,780
2015	546	1,107	2,142	2,147	7,640,271	2,761,460
<b>Any Prevalent Antipsychotics Use, NDCs or HCPCS</b>						
2000	2,304	5,671	7,939	8,092	6,180,278	2,860,007
2001	3,087	11,513	17,130	17,424	6,719,630	5,673,987
2002	2,954	11,220	17,044	17,431	6,867,336	5,767,540
2003	2,924	11,351	15,907	16,233	6,860,521	5,754,966
2004	3,838	15,584	29,718	30,321	7,322,315	6,025,203
2005	4,043	15,393	31,255	31,663	7,450,395	6,295,266
2006	2,167	6,015	16,638	16,920	7,292,027	6,152,960
2007	2,181	6,447	18,223	18,462	7,277,269	6,186,290
2008	2,221	6,413	20,676	20,957	7,364,286	6,248,657
2009	2,047	6,417	15,636	15,687	7,493,874	6,339,099
2010	2,239	7,640	17,349	17,654	7,628,877	6,508,147
2011	2,476	8,203	20,070	20,240	7,797,888	6,683,547
2012	2,531	8,390	19,750	19,853	7,857,258	6,782,095
2013	2,973	9,362	23,514	23,626	7,887,432	6,809,727
2014	3,631	11,290	27,679	27,780	8,243,482	7,056,780
2015	2,484	4,581	7,941	7,973	7,640,271	2,761,460

<sup>1</sup>Some users may have had dispensings of multiple medications of interest during the study period. Thus, totaling the number of users for each individual drug overestimates the number of LAIA users.

<sup>2</sup>Eligible Members and Member-Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

\*\*These cells were suppressed to mask small counts

**Table 2b. Summary of Reasons for Episode Censoring in the Sentinel Distributed Database (SDD), by Calendar Year**

Year	Number of Episodes	Reason(s) for Censoring <sup>1</sup>					Episode End
		Eligibility	Death	DP Data End Date	Query End Date		
<b>Prevalent Use (1/1/2000 - 3/31/2018), NDCs only</b>							
<i>Any Prevalent Antipsychotics Use, NDCs only</i>							
2000	5,518	**	**	0	0	5,517	
2001	11,030	23	13	0	0	11,028	
2002	10,854	31	23	0	0	10,851	
2003	11,027	37	25	0	0	11,024	
2004	15,253	108	45	0	**	15,247	
2005	14,729	559	38	0	**	14,711	
2006	5,456	95	17	0	**	5,452	
2007	5,581	86	21	0	**	5,575	
2008	5,482	91	17	0	11	5,469	
2009	5,526	88	**	0	**	5,520	
2010	6,761	66	17	0	12	6,743	
2011	7,211	79	17	0	**	7,198	
2012	7,047	76	21	**	16	7,027	
2013	7,526	69	11	**	25	7,500	
2014	8,971	64	27	**	90	8,878	
2015	9,244	66	25	**	246	8,992	
2016	9,269	74	17	**	1,761	7,525	
2017	**	**	0	**	47	**	
2018	**	0	0	0	**	**	
<b>Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS</b>							
<i>Any Prevalent Antipsychotics Use, NDCs or HCPCS</i>							
2000	5,671	17	**	0	0	5,667	
2001	11,513	26	13	0	0	11,508	
2002	11,220	36	24	0	0	11,211	
2003	11,351	47	25	0	0	11,338	
2004	15,584	111	45	0	**	15,573	
2005	15,393	622	40	0	**	15,296	
2006	6,015	105	17	0	**	5,999	
2007	6,447	95	21	0	**	6,430	
2008	6,413	101	19	0	17	6,382	
2009	6,417	108	**	0	**	6,387	
2010	7,640	77	20	0	17	7,603	
2011	8,203	93	16	0	16	8,168	
2012	8,390	97	21	0	28	8,337	
2013	9,362	82	13	0	75	9,270	
2014	11,290	82	26	0	483	10,779	
2015	4,581	33	**	0	1,742	2,862	

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

\*\*These cells were suppressed to mask small counts

**Table 2c. Summary of Follow-up Time for Users Censored due to Death in the Sentinel Distributed Database (SDD), by Calendar Year**

Year	Distribution of Lengths of Follow-up Time (Number of Episodes)								
	Number of Episodes Censored at Death	0-7 days	8-14 days	15-21 days	22-30 days	31-60 days	61-90 days	91-183 days	>6 months
<b>Prevalent Use (1/1/2000 - 3/31/2018), NDCs only</b>									
<i>Any Prevalent Antipsychotics Use, NDCs only</i>									
2000	**	**	**	**	**	0	0	0	**
2001	13	**	**	**	**	**	0	**	0
2002	23	**	**	**	**	**	**	0	**
2003	25	**	**	0	**	**	**	**	**
2004	45	**	13	**	**	**	0	**	**
2005	38	**	**	**	**	**	**	**	**
2006	17	**	0	**	**	0	**	**	**
2007	21	**	**	**	0	**	**	**	**
2008	17	0	**	**	**	**	**	**	**
2009	**	**	**	**	**	**	0	**	**
2010	17	**	**	**	**	**	**	0	**
2011	17	0	**	**	**	**	**	**	**
2012	21	**	**	**	**	**	0	**	**
2013	11	**	**	**	0	**	0	**	**
2014	27	**	**	**	**	0	**	**	**
2015	25	**	**	**	**	**	**	**	**
2016	17	**	**	**	**	**	**	**	**
2017	0	0	0	0	0	0	0	0	0
2018	0	0	0	0	0	0	0	0	0
<b>Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS</b>									
<i>Any Prevalent Antipsychotics Use, NDCs or HCPCS</i>									
2000	**	**	**	**	**	0	0	0	**
2001	13	**	**	**	**	**	0	**	0
2002	24	**	**	**	**	**	**	**	**
2003	25	**	**	0	**	**	**	**	**
2004	45	**	13	**	**	**	0	**	**
2005	40	**	**	**	**	**	**	**	**
2006	17	**	0	**	**	0	**	**	**
2007	21	**	**	**	0	**	**	**	**
2008	19	0	**	**	**	**	**	**	**
2009	**	**	**	**	**	**	0	**	**
2010	20	**	**	**	**	**	**	0	**
2011	16	0	**	**	**	**	**	**	**
2012	21	**	**	**	**	**	0	**	**
2013	13	**	**	**	0	**	0	**	**
2014	26	**	**	**	**	0	**	**	**
2015	**	**	**	0	0	**	**	0	0

\*\*These cells were suppressed to mask small counts

**Table 3a. Summary of Long-Acting Injectable Antipsychotic (LAIA) Treatment Episodes in the Sentinel Distributed Database (SDD), by Sex**

Sex	Number of Patients <sup>1</sup>	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members <sup>2</sup>	Eligible Member-Years <sup>2</sup>
<b>Prevalent Use (1/1/2000 - 3/31/2018), NDCs only</b>						
<b>Aripiprazole extended release</b>						
Female	648	2,215	5,297	5,336	10,959,603	58,532,405
Male	574	2,034	4,661	4,705	10,273,455	51,887,144
Other	0	0	0	0	1,200	5,276
<b>Aripiprazole lauroxil</b>						
Female	96	195	381	381	10,959,603	58,532,405
Male	68	118	259	259	10,273,455	51,887,144
Other	0	0	0	0	1,200	5,276
<b>Fluphenazine decanoate</b>						
Female	1,502	13,110	20,208	20,307	10,959,603	58,532,405
Male	1,721	15,370	24,157	24,259	10,273,455	51,887,144
Other	0	0	0	0	1,200	5,276
<b>Haloperidol decanoate</b>						
Female	3,028	27,941	49,273	50,269	10,959,603	58,532,405
Male	3,880	40,748	74,030	75,491	10,273,455	51,887,144
Other	0	0	0	0	1,200	5,276
<b>Olanzapine pamoate</b>						
Female	35	151	286	286	10,959,603	58,532,405
Male	30	156	297	297	10,273,455	51,887,144
Other	0	0	0	0	1,200	5,276
<b>Paliperidone palmitate (Sustenna, 4-week)</b>						
Female	1,114	5,513	14,141	14,241	10,959,603	58,532,405
Male	1,415	7,042	20,171	20,264	10,273,455	51,887,144
Other	0	0	0	0	1,200	5,276
<b>Paliperidone palmitate (Trinza, 12-week)</b>						
Female	60	93	181	182	10,959,603	58,532,405
Male	96	150	281	282	10,273,455	51,887,144
Other	0	0	0	0	1,200	5,276
<b>Risperidone microspheres</b>						
Female	2,961	16,202	45,170	45,757	10,959,603	58,532,405
Male	3,355	18,313	54,066	54,858	10,273,455	51,887,144
Other	0	0	0	0	1,200	5,276
<b>Any Prevalent Antipsychotics Use, NDCs only</b>						
Female	7,240	64,255	134,849	136,674	10,959,603	58,532,405
Male	8,417	82,551	177,800	180,301	10,273,455	51,887,144
Other	0	0	0	0	1,200	5,276
<b>Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS</b>						
<b>Aripiprazole extended release</b>						
Female	323	891	1,974	1,976	9,914,529	49,838,389
Male	317	883	1,770	1,773	9,216,156	44,062,775
Other	0	0	0	0	1,085	4,568
<b>Aripiprazole lauroxil</b>						
Female	0	0	0	0	9,914,529	49,838,389
Male	0	0	0	0	9,216,156	44,062,775
Other	0	0	0	0	1,085	4,568
<b>Fluphenazine decanoate</b>						
Female	1,630	14,051	22,601	22,699	9,914,529	49,838,389
Male	1,824	16,237	26,981	27,075	9,216,156	44,062,775

**Table 3a. Summary of Long-Acting Injectable Antipsychotic (LAIA) Treatment Episodes in the Sentinel Distributed Database (SDD), by Sex**

Sex	Number of Patients <sup>1</sup>	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members <sup>2</sup>	Eligible Member-Years <sup>2</sup>
Other	0	0	0	0	1,085	4,568
<b>Haloperidol decanoate</b>						
Female	3,143	28,241	50,542	51,519	9,914,529	49,838,389
Male	4,079	40,129	72,372	73,811	9,216,156	44,062,775
Other	0	0	0	0	1,085	4,568
<b>Olanzapine pamoate</b>						
Female	137	253	376	376	9,914,529	49,838,389
Male	120	230	361	361	9,216,156	44,062,775
Other	0	0	0	0	1,085	4,568
<b>Paliperidone palmitate (Sustenna, 4-week)</b>						
Female	780	4,036	9,483	9,541	9,914,529	49,838,389
Male	1,082	5,673	14,851	14,897	9,216,156	44,062,775
Other	0	0	0	0	1,085	4,568
<b>Risperidone microspheres</b>						
Female	3,078	17,150	47,956	48,448	9,914,529	49,838,389
Male	3,514	19,783	57,436	58,074	9,216,156	44,062,775
Other	0	0	0	0	1,085	4,568
<b>Any Prevalent Antipsychotics Use, NDCs or HCPCS</b>						
Female	7,232	63,686	132,743	134,370	9,914,529	49,838,389
Male	8,528	81,804	173,726	175,946	9,216,156	44,062,775
Other	0	0	0	0	1,085	4,568

<sup>1</sup>Some users may have had dispensings of multiple medications of interest during the study period. Thus, totaling the number of users for each individual drug overestimates the number of LAIA users.

<sup>2</sup>Eligible Members and Member-Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

**Table 3b. Summary of Reasons for Episode Censoring in the Sentinel Distributed Database (SDD), by Sex**

Sex	Number of Episodes	Reason(s) for Censoring <sup>1</sup>				
		Eligibility	Death	DP Data End Date	Query End Date	Episode End
<b>Prevalent Use (1/1/2000 - 3/31/2018), NDCs only</b>						
<i>Any Prevalent Antipsychotics Use, NDCs only</i>						
Female	64,255	753	158	**	965	63,267
Male	82,551	879	196	**	1,277	81,258
Other	0	0	0	0	0	0
<b>Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS</b>						
<i>Any Prevalent Antipsychotics Use, NDCs or HCPCS</i>						
Female	63,686	771	148	0	1,039	62,547
Male	81,804	961	181	0	1,373	80,263
Other	0	0	0	0	0	0

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

\*\*These cells were suppressed to mask small counts

**Table 3c. Summary of Follow-up Time for Users Censored due to Death in the Sentinel Distributed Database (SDD), by Sex**

Sex	Number of Episodes Censored at Death	Distribution of Lengths of Follow-up Time (Number of Episodes)							
		0-7 days	8-14 days	15-21 days	22-30 days	31-60 days	61-90 days	91-183 days	>6 months
<b>Prevalent Use (1/1/2000 - 3/31/2018), NDCs only</b>									
<i>Any Prevalent Antipsychotics Use, NDCs only</i>									
Female	158	**	26	22	21	21	**	20	23
Male	196	**	31	18	23	22	**	16	36
Other	0	0	0	0	0	0	0	0	0
<b>Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS</b>									
<i>Any Prevalent Antipsychotics Use, NDCs or HCPCS</i>									
Female	148	**	27	19	21	19	**	18	19
Male	181	**	28	17	22	20	**	17	28
Other	0	0	0	0	0	0	0	0	0

\*\*These cells were suppressed to mask small counts

**Table 4a. Summary of Long-Acting Injectable Antipsychotic (LAIA) Treatment Episodes in the Sentinel Distributed Database (SDD), by Age Group**

Age (Years)	Number of Patients <sup>1</sup>	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members <sup>2</sup>	Eligible Member-Years <sup>2</sup>
<b>Prevalent Use (1/1/2000 - 3/31/2018), NDCs only</b>						
<b>Aripiprazole extended release</b>						
0-17 years	83	**	**	**	6,974,217	29,849,778
18-49 years	946	3,158	7,459	7,522	12,134,991	45,861,709
50-64 years	216	791	1,937	1,948	4,852,918	21,760,831
65 years or older	**	**	**	**	2,271,145	12,952,507
<b>Aripiprazole lauroxil</b>						
0-17 years	**	**	16	16	6,974,217	29,849,778
18-49 years	119	224	441	441	12,134,991	45,861,709
50-64 years	42	**	183	183	4,852,918	21,760,831
65 years or older	0	0	0	0	2,271,145	12,952,507
<b>Fluphenazine decanoate</b>						
0-17 years	23	49	68	69	6,974,217	29,849,778
18-49 years	2,187	16,798	25,747	25,861	12,134,991	45,861,709
50-64 years	1,011	10,016	16,396	16,474	4,852,918	21,760,831
65 years or older	273	1,617	2,154	2,162	2,271,145	12,952,507
<b>Haloperidol decanoate</b>						
0-17 years	82	230	389	406	6,974,217	29,849,778
18-49 years	4,830	44,047	80,370	82,006	12,134,991	45,861,709
50-64 years	1,997	19,565	36,097	36,693	4,852,918	21,760,831
65 years or older	670	4,847	6,447	6,655	2,271,145	12,952,507
<b>Olanzapine pamoate</b>						
0-17 years	0	0	0	0	6,974,217	29,849,778
18-49 years	59	289	556	556	12,134,991	45,861,709
50-64 years	**	18	27	27	4,852,918	21,760,831
65 years or older	0	0	0	0	2,271,145	12,952,507
<b>Paliperidone palmitate (Sustenna, 4-week)</b>						
0-17 years	94	408	832	845	6,974,217	29,849,778
18-49 years	1,950	8,963	24,809	24,954	12,134,991	45,861,709
50-64 years	567	3,152	8,584	8,619	4,852,918	21,760,831
65 years or older	**	32	87	87	2,271,145	12,952,507
<b>Paliperidone palmitate (Trinza, 12-week)</b>						
0-17 years	**	**	**	**	6,974,217	29,849,778
18-49 years	112	171	320	322	12,134,991	45,861,709
50-64 years	42	**	**	**	4,852,918	21,760,831
65 years or older	0	0	0	0	2,271,145	12,952,507
<b>Risperidone microspheres</b>						
0-17 years	549	1,895	5,449	5,455	6,974,217	29,849,778
18-49 years	4,413	22,763	66,653	67,724	12,134,991	45,861,709
50-64 years	1,349	8,331	23,677	23,930	4,852,918	21,760,831
65 years or older	309	1,526	3,457	3,506	2,271,145	12,952,507
<b>Any Prevalent Antipsychotics Use, NDCs only</b>						
0-17 years	750	2,847	7,345	7,391	6,974,217	29,849,778
18-49 years	11,079	94,645	206,487	209,527	12,134,991	45,861,709
50-64 years	4,175	41,363	86,671	87,646	4,852,918	21,760,831
65 years or older	1,175	7,951	12,146	12,411	2,271,145	12,952,507

**Table 4a. Summary of Long-Acting Injectable Antipsychotic (LAIA) Treatment Episodes in the Sentinel Distributed Database (SDD), by Age Group**

Age (Years)	Number of Patients <sup>1</sup>	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members <sup>2</sup>	Eligible Member-Years <sup>2</sup>
<b>Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS</b>						
<b>Aripiprazole extended release</b>						
0-17 years	35	**	**	**	6,341,930	25,806,741
18-49 years	503	1,360	2,878	2,881	10,760,703	38,999,102
50-64 years	106	300	666	667	4,233,349	18,420,657
65 years or older	**	**	**	**	1,992,669	10,679,233
<b>Aripiprazole lauroxil</b>						
0-17 years	0	0	0	0	6,341,930	25,806,741
18-49 years	0	0	0	0	10,760,703	38,999,102
50-64 years	0	0	0	0	4,233,349	18,420,657
65 years or older	0	0	0	0	1,992,669	10,679,233
<b>Fluphenazine decanoate</b>						
0-17 years	30	66	92	93	6,341,930	25,806,741
18-49 years	2,264	17,057	27,129	27,235	10,760,703	38,999,102
50-64 years	1,110	10,798	18,747	18,824	4,233,349	18,420,657
65 years or older	339	2,367	3,614	3,622	1,992,669	10,679,233
<b>Haloperidol decanoate</b>						
0-17 years	96	256	425	442	6,341,930	25,806,741
18-49 years	4,987	43,647	79,571	81,182	10,760,703	38,999,102
50-64 years	2,082	19,187	35,260	35,840	4,233,349	18,420,657
65 years or older	738	5,280	7,658	7,866	1,992,669	10,679,233
<b>Olanzapine pamoate</b>						
0-17 years	**	**	**	**	6,341,930	25,806,741
18-49 years	183	393	630	630	10,760,703	38,999,102
50-64 years	36	51	62	62	4,233,349	18,420,657
65 years or older	32	**	**	**	1,992,669	10,679,233
<b>Paliperidone palmitate (Sustenna, 4-week)</b>						
0-17 years	77	339	696	707	6,341,930	25,806,741
18-49 years	1,449	6,990	17,633	17,707	10,760,703	38,999,102
50-64 years	390	2,305	5,839	5,858	4,233,349	18,420,657
65 years or older	18	75	166	166	1,992,669	10,679,233
<b>Risperidone microspheres</b>						
0-17 years	549	1,881	5,403	5,409	6,341,930	25,806,741
18-49 years	4,602	24,425	70,402	71,290	10,760,703	38,999,102
50-64 years	1,398	8,717	24,678	24,865	4,233,349	18,420,657
65 years or older	348	1,910	4,909	4,958	1,992,669	10,679,233
<b>Any Prevalent Antipsychotics Use, NDCs or HCPCS</b>						
0-17 years	718	2,631	6,848	6,884	6,341,930	25,806,741
18-49 years	10,949	92,465	198,379	201,062	10,760,703	38,999,102
50-64 years	4,219	40,819	84,857	85,720	4,233,349	18,420,657
65 years or older	1,365	9,575	16,385	16,650	1,992,669	10,679,233

<sup>1</sup>Some users may have had dispensings of multiple medications of interest during the study period. Thus, totaling the number of users for each individual drug overestimates the number of LAIA users.

<sup>2</sup>Eligible Members and Member-Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

\*\*These cells were suppressed to mask small counts

**Table 4b. Summary of Reasons for Episode Censoring in the Sentinel Distributed Database (SDD), by Age Group**

Age (Years)	Number of Episodes	Reason(s) for Censoring <sup>1</sup>					Episode End
		Eligibility	Death	DP Data End Date	Query End Date		
<b>Prevalent Use (1/1/2000 - 3/31/2018), NDCs only</b>							
<i>Any Prevalent Antipsychotics Use, NDCs only</i>							
0-17 years	2,847	30	0	0	**	2,809	
18-49 years	94,645	864	121	**	1,517	93,125	
50-64 years	41,363	519	141	**	678	40,679	
65 years or older	7,951	219	92	0	**	7,912	
<b>Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS</b>							
<i>Any Prevalent Antipsychotics Use, NDCs or HCPCS</i>							
0-17 years	2,631	32	0	0	38	2,589	
18-49 years	92,465	945	113	0	1,591	90,720	
50-64 years	40,819	523	122	0	731	40,027	
65 years or older	9,575	232	94	0	52	9,474	

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

\*\*These cells were suppressed to mask small counts

**Table 4c. Summary of Follow-up Time for Users Censored due to Death in the Sentinel Distributed Database (SDD), by Age Group**

Age (Years)	Number of Episodes Censored at Death	Distribution of Lengths of Follow-up Time (Number of Episodes)							
		0-7 days	8-14 days	15-21 days	22-30 days	31-60 days	61-90 days	91-183 days	>6 months
<b>Prevalent Use (1/1/2000 - 3/31/2018), NDCs only</b>									
<i>Any Prevalent Antipsychotics Use, NDCs only</i>									
0-17 years	0	0	0	0	0	0	0	0	0
18-49 years	121	18	16	**	12	13	**	16	27
50-64 years	141	23	22	15	14	15	11	**	**
65 years or older	92	14	19	**	18	15	**	**	**
<b>Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS</b>									
<i>Any Prevalent Antipsychotics Use, NDCs or HCPCS</i>									
0-17 years	0	0	0	0	0	0	0	0	0
18-49 years	113	19	16	**	**	13	**	16	22
50-64 years	122	21	19	**	**	13	**	**	**
65 years or older	94	15	20	13	18	13	**	**	**

\*\*These cells were suppressed to mask small counts

**Table 5. Summary of Long-Acting Injectable Antipsychotic (LAIA) Treatment Episodes and in the Sentinel Distributed Database (SDD), Cross-Stratified by Age and Sex**

Age (Years)	Number of Patients <sup>1</sup>	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members <sup>2</sup>	Eligible Member-Years <sup>2</sup>
<b>Prevalent Use (1/1/2000 - 3/31/2018), NDCs only</b>						
<b>Aripiprazole extended release</b>						
<b>Female</b>						
0-17 years	**	**	**	**	3,413,575	14,590,763
18-49 years	490	1,621	3,828	3,858	6,330,979	25,037,154
50-64 years	139	507	1,291	1,299	2,540,692	11,584,306
65 years or older	**	**	**	**	1,259,167	7,320,184
<b>Male</b>						
0-17 years	55	213	384	392	3,560,313	15,258,003
18-49 years	456	1,537	3,631	3,664	5,803,213	20,821,708
50-64 years	77	284	646	649	2,312,021	10,175,689
65 years or older	0	0	0	0	1,011,865	5,631,743
<b>Other</b>						
0-17 years	0	0	0	0	329	1,012
18-49 years	0	0	0	0	799	2,847
50-64 years	0	0	0	0	205	836
65 years or older	0	0	0	0	113	581
<b>Aripiprazole lauroxil</b>						
<b>Female</b>						
0-17 years	0	0	0	0	3,413,575	14,590,763
18-49 years	63	127	228	228	6,330,979	25,037,154
50-64 years	33	68	153	153	2,540,692	11,584,306
65 years or older	0	0	0	0	1,259,167	7,320,184
<b>Male</b>						
0-17 years	**	**	16	16	3,560,313	15,258,003
18-49 years	56	97	213	213	5,803,213	20,821,708
50-64 years	**	**	30	30	2,312,021	10,175,689
65 years or older	0	0	0	0	1,011,865	5,631,743
<b>Other</b>						
0-17 years	0	0	0	0	329	1,012
18-49 years	0	0	0	0	799	2,847
50-64 years	0	0	0	0	205	836
65 years or older	0	0	0	0	113	581
<b>Fluphenazine decanoate</b>						
<b>Female</b>						
0-17 years	**	16	16	16	3,413,575	14,590,763
18-49 years	862	6,241	9,675	9,725	6,330,979	25,037,154
50-64 years	557	5,486	8,683	8,725	2,540,692	11,584,306
65 years or older	**	1,367	1,834	1,841	1,259,167	7,320,184
<b>Male</b>						
0-17 years	16	33	52	53	3,560,313	15,258,003
18-49 years	1,325	10,557	16,072	16,136	5,803,213	20,821,708
50-64 years	454	4,530	7,713	7,749	2,312,021	10,175,689
65 years or older	67	250	320	321	1,011,865	5,631,743
<b>Other</b>						
0-17 years	0	0	0	0	329	1,012
18-49 years	0	0	0	0	799	2,847
50-64 years	0	0	0	0	205	836
65 years or older	0	0	0	0	113	581

**Table 5. Summary of Long-Acting Injectable Antipsychotic (LAIA) Treatment Episodes and in the Sentinel Distributed Database (SDD), Cross-Stratified by Age and Sex**

Age (Years)	Number of Patients <sup>1</sup>	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members <sup>2</sup>	Eligible Member-Years <sup>2</sup>
<b>Haloperidol decanoate</b>						
<b>Female</b>						
0-17 years	24	58	87	91	3,413,575	14,590,763
18-49 years	1,831	15,185	27,704	28,256	6,330,979	25,037,154
50-64 years	1,007	9,419	17,168	17,466	2,540,692	11,584,306
65 years or older	463	3,279	4,314	4,456	1,259,167	7,320,184
<b>Male</b>						
0-17 years	58	172	302	315	3,560,313	15,258,003
18-49 years	2,999	28,862	52,666	53,750	5,803,213	20,821,708
50-64 years	990	10,146	18,929	19,227	2,312,021	10,175,689
65 years or older	207	1,568	2,133	2,199	1,011,865	5,631,743
<b>Other</b>						
0-17 years	0	0	0	0	329	1,012
18-49 years	0	0	0	0	799	2,847
50-64 years	0	0	0	0	205	836
65 years or older	0	0	0	0	113	581
<b>Olanzapine pamoate</b>						
<b>Female</b>						
0-17 years	0	0	0	0	3,413,575	14,590,763
18-49 years	31	143	272	272	6,330,979	25,037,154
50-64 years	**	**	14	14	2,540,692	11,584,306
65 years or older	**	0	0	0	1,259,167	7,320,184
<b>Male</b>						
0-17 years	0	0	0	0	3,560,313	15,258,003
18-49 years	28	**	284	284	5,803,213	20,821,708
50-64 years	**	**	13	13	2,312,021	10,175,689
65 years or older	**	0	0	0	1,011,865	5,631,743
<b>Other</b>						
0-17 years	0	0	0	0	329	1,012
18-49 years	0	0	0	0	799	2,847
50-64 years	0	0	0	0	205	836
65 years or older	0	0	0	0	113	581
<b>Paliperidone palmitate (Sustenna, 4-week)</b>						
<b>Female</b>						
0-17 years	**	153	300	305	3,413,575	14,590,763
18-49 years	808	3,444	9,224	9,295	6,330,979	25,037,154
50-64 years	316	1,900	4,564	4,588	2,540,692	11,584,306
65 years or older	**	16	53	53	1,259,167	7,320,184
<b>Male</b>						
0-17 years	**	255	532	540	3,560,313	15,258,003
18-49 years	1,142	5,519	15,585	15,659	5,803,213	20,821,708
50-64 years	251	1,252	4,020	4,031	2,312,021	10,175,689
65 years or older	**	16	34	34	1,011,865	5,631,743
<b>Other</b>						
0-17 years	0	0	0	0	329	1,012
18-49 years	0	0	0	0	799	2,847
50-64 years	0	0	0	0	205	836
65 years or older	0	0	0	0	113	581

**Table 5. Summary of Long-Acting Injectable Antipsychotic (LAIA) Treatment Episodes and in the Sentinel Distributed Database (SDD), Cross-Stratified by Age and Sex**

Age (Years)	Number of Patients <sup>1</sup>	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members <sup>2</sup>	Eligible Member-Years <sup>2</sup>
<b>Paliperidone palmitate (Trinza, 12-week)</b>						
<b>Female</b>						
0-17 years	**	**	**	**	3,413,575	14,590,763
18-49 years	44	62	134	135	6,330,979	25,037,154
50-64 years	15	**	**	**	2,540,692	11,584,306
65 years or older	**	0	0	0	1,259,167	7,320,184
<b>Male</b>						
0-17 years	**	**	**	**	3,560,313	15,258,003
18-49 years	68	109	186	187	5,803,213	20,821,708
50-64 years	27	**	**	**	2,312,021	10,175,689
65 years or older	**	0	0	0	1,011,865	5,631,743
<b>Other</b>						
0-17 years	0	0	0	0	329	1,012
18-49 years	0	0	0	0	799	2,847
50-64 years	0	0	0	0	205	836
65 years or older	0	0	0	0	113	581
<b>Risperidone microspheres</b>						
<b>Female</b>						
0-17 years	210	675	1,799	1,801	3,413,575	14,590,763
18-49 years	1,900	9,597	27,040	27,435	6,330,979	25,037,154
50-64 years	764	4,838	13,594	13,742	2,540,692	11,584,306
65 years or older	224	1,092	2,737	2,779	1,259,167	7,320,184
<b>Male</b>						
0-17 years	339	1,220	3,650	3,654	3,560,313	15,258,003
18-49 years	2,513	13,166	39,613	40,289	5,803,213	20,821,708
50-64 years	585	3,493	10,083	10,188	2,312,021	10,175,689
65 years or older	85	434	720	727	1,011,865	5,631,743
<b>Other</b>						
0-17 years	0	0	0	0	329	1,012
18-49 years	0	0	0	0	799	2,847
50-64 years	0	0	0	0	205	836
65 years or older	0	0	0	0	113	581
<b>Any Prevalent Antipsychotics Use, NDCs only</b>						
<b>Female</b>						
0-17 years	269	972	2,394	2,406	3,413,575	14,590,763
18-49 years	4,586	35,711	78,170	79,272	6,330,979	25,037,154
50-64 years	2,252	21,887	45,346	45,866	2,540,692	11,584,306
65 years or older	826	5,685	8,939	9,130	1,259,167	7,320,184
<b>Male</b>						
0-17 years	481	1,875	4,951	4,985	3,560,313	15,258,003
18-49 years	6,493	58,934	128,317	130,255	5,803,213	20,821,708
50-64 years	1,923	19,476	41,325	41,780	2,312,021	10,175,689
65 years or older	349	2,266	3,207	3,281	1,011,865	5,631,743
<b>Other</b>						
0-17 years	0	0	0	0	329	1,012
18-49 years	0	0	0	0	799	2,847
50-64 years	0	0	0	0	205	836
65 years or older	0	0	0	0	113	581

**Table 5. Summary of Long-Acting Injectable Antipsychotic (LAIA) Treatment Episodes and in the Sentinel Distributed Database (SDD), Cross-Stratified by Age and Sex**

Age (Years)	Number of Patients <sup>1</sup>	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members <sup>2</sup>	Eligible Member-Years <sup>2</sup>
<b>Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS</b>						
<b>Aripiprazole extended release</b>						
<b>Female</b>						
0-17 years	**	**	**	**	3,104,252	12,613,752
18-49 years	249	662	1,453	1,455	5,651,141	21,349,111
50-64 years	66	197	464	464	2,221,217	9,815,743
65 years or older	**	**	**	**	1,110,695	6,059,783
<b>Male</b>						
0-17 years	25	82	143	144	3,237,370	13,192,074
18-49 years	254	698	1,425	1,426	5,108,855	17,647,619
50-64 years	40	103	202	203	2,011,952	8,604,174
65 years or older	0	0	0	0	881,867	4,618,908
<b>Other</b>						
0-17 years	0	0	0	0	308	915
18-49 years	0	0	0	0	707	2,372
50-64 years	0	0	0	0	180	739
65 years or older	0	0	0	0	107	542
<b>Aripiprazole lauroxil</b>						
<b>Female</b>						
0-17 years	0	0	0	0	3,104,252	12,613,752
18-49 years	0	0	0	0	5,651,141	21,349,111
50-64 years	0	0	0	0	2,221,217	9,815,743
65 years or older	0	0	0	0	1,110,695	6,059,783
<b>Male</b>						
0-17 years	0	0	0	0	3,237,370	13,192,074
18-49 years	0	0	0	0	5,108,855	17,647,619
50-64 years	0	0	0	0	2,011,952	8,604,174
65 years or older	0	0	0	0	881,867	4,618,908
<b>Other</b>						
0-17 years	0	0	0	0	308	915
18-49 years	0	0	0	0	707	2,372
50-64 years	0	0	0	0	180	739
65 years or older	0	0	0	0	107	542
<b>Fluphenazine decanoate</b>						
<b>Female</b>						
0-17 years	**	18	18	18	3,104,252	12,613,752
18-49 years	907	6,215	9,737	9,786	5,651,141	21,349,111
50-64 years	597	5,853	9,928	9,970	2,221,217	9,815,743
65 years or older	**	1,965	2,918	2,925	1,110,695	6,059,783
<b>Male</b>						
0-17 years	21	48	74	75	3,237,370	13,192,074
18-49 years	1,357	10,842	17,392	17,449	5,108,855	17,647,619
50-64 years	513	4,945	8,819	8,854	2,011,952	8,604,174
65 years or older	87	402	696	697	881,867	4,618,908
<b>Other</b>						
0-17 years	0	0	0	0	308	915
18-49 years	0	0	0	0	707	2,372
50-64 years	0	0	0	0	180	739
65 years or older	0	0	0	0	107	542

**Table 5. Summary of Long-Acting Injectable Antipsychotic (LAIA) Treatment Episodes and in the Sentinel Distributed Database (SDD), Cross-Stratified by Age and Sex**

Age (Years)	Number of Patients <sup>1</sup>	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members <sup>2</sup>	Eligible Member-Years <sup>2</sup>
<b>Haloperidol decanoate</b>						
<b>Female</b>						
0-17 years	24	54	78	82	3,104,252	12,613,752
18-49 years	1,865	15,256	27,968	28,514	5,651,141	21,349,111
50-64 years	1,052	9,294	17,186	17,471	2,221,217	9,815,743
65 years or older	508	3,637	5,310	5,452	1,110,695	6,059,783
<b>Male</b>						
0-17 years	72	202	347	360	3,237,370	13,192,074
18-49 years	3,122	28,391	51,603	52,668	5,108,855	17,647,619
50-64 years	1,030	9,893	18,074	18,369	2,011,952	8,604,174
65 years or older	230	1,643	2,348	2,414	881,867	4,618,908
<b>Other</b>						
0-17 years	0	0	0	0	308	915
18-49 years	0	0	0	0	707	2,372
50-64 years	0	0	0	0	180	739
65 years or older	0	0	0	0	107	542
<b>Olanzapine pamoate</b>						
<b>Female</b>						
0-17 years	**	**	**	**	3,104,252	12,613,752
18-49 years	95	206	319	319	5,651,141	21,349,111
50-64 years	**	22	28	28	2,221,217	9,815,743
65 years or older	20	**	**	**	1,110,695	6,059,783
<b>Male</b>						
0-17 years	**	**	**	**	3,237,370	13,192,074
18-49 years	88	187	311	311	5,108,855	17,647,619
50-64 years	18	29	34	34	2,011,952	8,604,174
65 years or older	**	**	**	**	881,867	4,618,908
<b>Other</b>						
0-17 years	0	0	0	0	308	915
18-49 years	0	0	0	0	707	2,372
50-64 years	0	0	0	0	180	739
65 years or older	0	0	0	0	107	542
<b>Paliperidone palmitate (Sustenna, 4-week)</b>						
<b>Female</b>						
0-17 years	26	122	232	236	3,104,252	12,613,752
18-49 years	563	2,490	6,122	6,161	5,651,141	21,349,111
50-64 years	217	1,389	3,051	3,066	2,221,217	9,815,743
65 years or older	12	35	78	78	1,110,695	6,059,783
<b>Male</b>						
0-17 years	**	217	464	471	3,237,370	13,192,074
18-49 years	886	4,500	11,511	11,546	5,108,855	17,647,619
50-64 years	173	916	2,788	2,792	2,011,952	8,604,174
65 years or older	**	40	88	88	881,867	4,618,908
<b>Other</b>						
0-17 years	0	0	0	0	308	915
18-49 years	0	0	0	0	707	2,372
50-64 years	0	0	0	0	180	739
65 years or older	0	0	0	0	107	542

**Table 5. Summary of Long-Acting Injectable Antipsychotic (LAIA) Treatment Episodes and in the Sentinel Distributed Database (SDD), Cross-Stratified by Age and Sex**

Age (Years)	Number of Patients <sup>1</sup>	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members <sup>2</sup>	Eligible Member-Years <sup>2</sup>
<b>Risperidone microspheres</b>						
<b>Female</b>						
0-17 years	212	672	1,781	1,783	3,104,252	12,613,752
18-49 years	1,952	9,978	27,964	28,296	5,651,141	21,349,111
50-64 years	793	5,075	14,273	14,389	2,221,217	9,815,743
65 years or older	255	1,425	3,938	3,980	1,110,695	6,059,783
<b>Male</b>						
0-17 years	337	1,209	3,622	3,626	3,237,370	13,192,074
18-49 years	2,650	14,447	42,438	42,994	5,108,855	17,647,619
50-64 years	605	3,642	10,405	10,476	2,011,952	8,604,174
65 years or older	93	485	971	978	881,867	4,618,908
<b>Other</b>						
0-17 years	0	0	0	0	308	915
18-49 years	0	0	0	0	707	2,372
50-64 years	0	0	0	0	180	739
65 years or older	0	0	0	0	107	542
<b>Any Prevalent Antipsychotics Use, NDCs or HCPCS</b>						
<b>Female</b>						
0-17 years	260	890	2,185	2,195	3,104,252	12,613,752
18-49 years	4,438	34,264	73,595	74,564	5,651,141	21,349,111
50-64 years	2,252	21,537	44,695	45,152	2,221,217	9,815,743
65 years or older	955	6,995	12,268	12,459	1,110,695	6,059,783
<b>Male</b>						
0-17 years	458	1,741	4,663	4,689	3,237,370	13,192,074
18-49 years	6,511	58,201	124,784	126,498	5,108,855	17,647,619
50-64 years	1,967	19,282	40,162	40,568	2,011,952	8,604,174
65 years or older	410	2,580	4,117	4,191	881,867	4,618,908
<b>Other</b>						
0-17 years	0	0	0	0	308	915
18-49 years	0	0	0	0	707	2,372
50-64 years	0	0	0	0	180	739
65 years or older	0	0	0	0	107	542

<sup>1</sup>Some users may have had dispensings of multiple medications of interest during the study period. Thus, totaling the number of users for each individual drug overestimates the number of LAIA users.

<sup>2</sup>Eligible Members and Member-Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

\*\*These cells were suppressed to mask small counts

**Appendix A. Dates of Most Recent Available Data for Each Data Partner (DP)**

Masked DP ID	DP Death Data Availability Start Date	DP Death Data Availability End Date	Actual Dates Used	
			Query Period Start Date	Query Period End Date
<b>Analyses Defining Prevalent LAIA Use by National Drug Codes (NDCs):</b>				
DP02	01/01/2000	10/31/2017	01/01/2000	10/31/2017
DP03	01/01/2000	12/31/2016	01/01/2000	12/31/2016
DP04	01/01/2000	12/31/2016	01/01/2000	12/31/2016
DP05	01/01/2000	12/31/2017	01/01/2000	10/31/2017
DP06	01/01/2000	12/31/2017	01/01/2000	10/31/2017
DP07	01/01/2004	05/31/2018	01/01/2004	03/31/2018
DP08	01/01/2000	12/31/2015	01/01/2000	12/31/2015
<b>Analyses Defining Prevalent LAIA Use by NDCs or Healthcare Common Procedure Coding System (HCPCS) procedure codes:</b>				
DP02	01/01/2000	10/31/2017	01/01/2000	05/18/2015
DP03	01/01/2000	12/31/2016	01/01/2000	05/18/2015
DP04	01/01/2000	12/31/2016	01/01/2000	05/18/2015
DP05	01/01/2000	12/31/2017	01/01/2000	05/18/2015
DP06	01/01/2000	12/31/2017	01/01/2000	05/18/2015
DP07	01/01/2004	05/31/2018	01/01/2004	05/18/2015
DP08	01/01/2000	12/31/2015	01/01/2000	05/18/2015

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

<b>Generic Name</b>	<b>Brand Name</b>
<b>Aripiprazol Extended Release</b>	
Aripiprazole	Abilify Maintena
<b>Aripiprazole Lauroxil</b>	
Aripiprazole Lauroxil	Aristada
<b>Fluphenazine Decanoate</b>	
Fluphenazine Decanoate	Fluphenazine Decanoate
<b>Haloperidol Decanoate</b>	
Haloperidol Decanoate	Haldol Decanoate
Haloperidol Decanoate	Haloperidol Decanoate
<b>Olanzapine Pamoate</b>	
Olanzapine Pamoate	Zyprexa Relprevv
<b>Paliperidone Palmitate (4 Week)</b>	
Paliperidone Palmitate	Invega Sustenna
<b>Paliperidone Palmitate (12 Week)</b>	
Paliperidone Palmitate	Invega Trinza
<b>Risperidone Microspheres</b>	
Risperidone Microspheres	Risperdal Consta

**Appendix C. List of Health Care Procedural Coding System (HCPCS) Codes Used to Define Exposures in This Request**

<b>Code</b>	<b>Description</b>	<b>Code Type</b>
<b>Aripiprazol Extended Release</b>		
J0401	Injection, aripiprazole, extended release, 1 mg	HCPCS
<b>Aripiprazole Lauroxil</b>		
C9470	Injection, aripiprazole lauroxil, 1 mg	HCPCS
J1942	Injection, aripiprazole lauroxil, 1 mg	HCPCS
<b>Fluphenazine Decanoate</b>		
J2680	Injection, fluphenazine decanoate, up to 25 mg	HCPCS
<b>Haloperidol Decanoate</b>		
J1631	Injection, haloperidol decanoate, per 50 mg	HCPCS
<b>Olanzapine Pamoate</b>		
J2358	Injection, olanzapine, long-acting, 1 mg	HCPCS
<b>Paliperidone Palmitate (ALL)</b>		
C9255	Injection, paliperidone palmitate, 1 mg	HCPCS
J2426	Injection, paliperidone palmitate extended release, 1 mg	HCPCS
<b>Risperidone Microspheres</b>		
J2794	Injection, risperidone, long acting, 0.5 mg	HCPCS
C9125	Injection, risperidone, per 12.5 mg	HCPCS
S0163	Injection, risperidone, long acting, 12.5 mg	HCPCS

**Appendix D. Specifications for Type 2 Request [cder\_mpl1r\_wp152]**

This request executed the Cohort Identification and Descriptive Analysis (CIDA) tool, version 7.3.4, to 1) obtain counts of prevalent long-acting injectable antipsychotic (LAIA) users and episodes in the Sentinel Distributed Database (SDD), and 2) examine the feasibility of capturing evidence of death subsequent to LAIA exposures (i.e., treatment episodes that were censored due to death).

**Coverage requirement:** Medical & Drug Coverage

**Data Partner-Specific Query Period Start/End Dates:** See Appendix A

**Pre-index enrollment requirement:** 183 days

**Enrollment gap:** 45 days

**Age groups:** 0 - 17 years, 18 - 49, 50 - 64, 65 or greater

**Stratifications:** Age group, Sex, Calendar year, Age group\*Sex

**Data Source:** Sentinel Distributed Database

Scenario	Group	Query period	Pre-index enrollment requirement	Index exposure	Exposure care setting	Cohort definition	Exposure							Outcome	
							Incident exposure washout period	Episode gap	Episode extension	Minimum episode duration	Minimum days supplied	Maximum episode duration	Forced Days Supplied	Censor episode at evidence of:	Outcome
1	p_Ari_ext_ndc	Start of DP Data-End of DP death data	183 days	Aripiprazole extended release (Abilify Maintena), NDCs	Any	All valid exposure episodes during query period	0 days	0 days	0 days	1	1	N/A	N/A	Death; Data Partner End Date; Query Period End Date	N/A
2	p_Ari_lau_ndc	Start of DP Data-End of DP death data	183 days	Aripiprazole lauroxil (Aristada), NDCs	Any	All valid exposure episodes during query period	0 days	0 days	0 days	1	1	N/A	N/A	Death; Data Partner End Date; Query Period End Date	N/A
3	p_Flu_ndc	Start of DP Data-End of DP death data	183 days	Fluphenazine decanoate, NDCs	Any	All valid exposure episodes during query period	0 days	0 days	0 days	1	1	N/A	N/A	Death; Data Partner End Date; Query Period End Date	N/A
4	p_Halo_ndc	Start of DP Data-End of DP death data	183 days	Haloperidol decanoate, NDCs	Any	All valid exposure episodes during query period	0 days	0 days	0 days	1	1	N/A	N/A	Death; Data Partner End Date; Query Period End Date	N/A
5	p_Olan_ndc	Start of DP Data-End of DP death data	183 days	Olanzapine pamoate (Zyprexa Relprevv), NDCs	Any	All valid exposure episodes during query period	0 days	0 days	0 days	1	1	N/A	N/A	Death; Data Partner End Date; Query Period End Date	N/A

Appendix D. Specifications for Type 2 Request [cder_mpl1r_wp152]															
Scenario	Group	Query period	Pre-index enrollment requirement	Index exposure	Exposure care setting	Cohort definition	Exposure						Outcome		
							Incident exposure washout period	Episode gap	Episode extension	Minimum episode duration	Minimum days supplied	Maximum episode duration	Forced Days Supplied	Censor episode at evidence of:	Outcome
9	p_ALL_ndc	Start of DP Data-End of DP death data	183 days	All Injectable Antipsychotics, NDCs	Any	All valid exposure episodes during query period	0 days	0 days	0 days	1	1	N/A	N/A	Death; Data Partner End Date; Query Period End Date	N/A
10	p_Ari_ext_all	Start of DP Data-5/18/2015	183 days	Aripiprazole extended release	Any	All valid exposure episodes during query period	0 days	0 days	0 days	1	1	N/A	Px codes: 30 days NDC codes: N/A	Death; Data Partner End Date; Query Period End Date	N/A
11	p_Ari_lau_all	Start of DP Data-5/18/2015	183 days	Aripiprazole lauroxil	Any	All valid exposure episodes during query period	0 days	0 days	0 days	1	1	N/A	Px codes: 28 days NDC codes: N/A	Death; Data Partner End Date; Query Period End Date	N/A
12	p_Flu_all	Start of DP Data-5/18/2015	183 days	Fluphenazine decanoate	Any	All valid exposure episodes during query period	0 days	0 days	0 days	1	1	N/A	Px codes: 21 days NDC codes: N/A	Death; Data Partner End Date; Query Period End Date	N/A
13	p_Halo_al	Start of DP Data-5/18/2015	183 days	Haloperidol decanoate	Any	All valid exposure episodes during query period	0 days	0 days	0 days	1	1	N/A	Px codes: 30 days NDC codes: N/A	Death; Data Partner End Date; Query Period End Date	N/A
14	p_Olan_al	Start of DP Data-5/18/2015	183 days	Olanzapine pamoate	Any	All valid exposure episodes during query period	0 days	0 days	0 days	1	1	N/A	Px codes: 21 days NDC codes: N/A	Death; Data Partner End Date; Query Period End Date	N/A

Appendix D. Specifications for Type 2 Request [cder\_mpl1r\_wp152]

Scenario	Group	Query period	Pre-index enrollment requirement	Index exposure	Exposure care setting	Cohort definition	Exposure						Outcome		
							Incident exposure washout period	Episode gap	Episode extension	Minimum episode duration	Minimum days supplied	Maximum episode duration	Forced Days Supplied	Censor episode at evidence of:	Outcome
15	p_Pali_all	Start of DP Data-5/18/2015	183 days	Paliperidone palmitate	Any	All valid exposure episodes during query period	0 days	0 days	0 days	1	1	N/A	Px codes: 28 days NDC codes: N/A	Death; Data Partner End Date; Query Period End Date	N/A
16	p_Ris_all	Start of DP Data-5/18/2015	183 days	Risperidone microspheres	Any	All valid exposure episodes during query period	0 days	0 days	0 days	1	1	N/A	Px codes: 14 days NDC codes: N/A	Death; Data Partner End Date; Query Period End Date	N/A
17	p_ALL_all	Start of DP Data-5/18/2015	183 days	All Injectable Antipsychotics, Both NDCs or HCPCS, Prevalent Use	Any	All valid exposure episodes during query period	0 days	0 days	0 days	1	1	N/A	Px codes: Code-specific NDC codes: N/A	Death; Data Partner End Date	N/A

ICD-9, ICD-10, HCPCS, and CPT codes are provided by Optum360.  
NDC codes are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."