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

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

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Overview for Request cder_mpl1r_wp152, (Report 2 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 this query request. This is report 2 of 2, which includes results provided by the Centers for Medicare and Medicaid Services (CMS) for patients enrolled in the traditional Medicare fee-for-service program. Report 1 includes data from seven DPs that routinely match to state death records.

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 only included results provided by the Centers for Medicare and Medicaid Services (CMS) for patients enrolled in the traditional Medicare fee-for-service program.

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, four 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 2 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) 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.

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).

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 ¹	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members ²	Eligible Member-Years ²
Prevalent Use (1/1/2000 - 3/31/2018), NDCs only						
Aripiprazole lauroxil	5,514	15,015	39,149	39,156	36,020,432	149,535,978
Fluphenazine decanoate	37,177	316,055	528,074	528,087	36,020,432	149,535,978
Haloperidol decanoate	76,237	653,764	1,568,746	1,578,692	36,020,432	149,535,978
Olanzapine pamoate	1,826	10,223	37,309	37,318	36,020,432	149,535,978
Paliperidone palmitate (Sustenna, 4-week)	92,332	510,827	1,777,768	1,790,309	36,020,432	149,535,978
Paliperidone palmitate (Trinza, 12-week)	11,812	26,265	55,323	55,367	36,020,432	149,535,978
Risperidone microspheres	63,303	411,162	1,674,396	1,688,135	36,020,432	149,535,978
Any Prevalent Antipsychotics Use, NDCs only	233,134	1,973,803	5,952,062	5,988,272	36,020,432	149,535,978
Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS						
Aripiprazole extended release	10,475	27,756	73,086	73,097	28,955,314	88,206,989
Aripiprazole lauroxil	**	**	**	**	28,955,314	88,206,989
Fluphenazine decanoate	34,363	265,339	427,763	427,768	28,955,314	88,206,989
Haloperidol decanoate	65,036	481,746	1,067,121	1,072,831	28,955,314	88,206,989
Olanzapine pamoate	3,855	10,533	28,594	28,602	28,955,314	88,206,989
Paliperidone palmitate (Sustenna, 4-week)	59,072	298,236	952,416	959,658	28,955,314	88,206,989
Risperidone microspheres	56,132	351,794	1,254,360	1,262,665	28,955,314	88,206,989
Any Prevalent Antipsychotics Use, NDCs or HCPCS	182,896	1,398,301	3,781,219	3,802,327	28,955,314	88,206,989

¹Some 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.

²Eligible 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 1b. Summary of Reasons for Episode Censoring in the Sentinel Distributed Database (SDD), Overall

	Number of Episodes	Reason(s) for Censoring ¹				
		Eligibility	Death	Data Partner Data End Date	Query End Date	Episode End
Prevalent Use (1/1/2000 - 3/31/2018), NDCs only						
<i>Any Prevalent Antipsychotics Use, NDCs only</i>	1,973,803	95,282	10,483	69,514	69,514	1,963,974
Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS						
<i>Any Prevalent Antipsychotics Use, NDCs or HCPCS</i>	1,398,301	14,013	6,223	0	62,926	1,329,273

¹An 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, 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
Prevalent Use (1/1/2000 - 3/31/2018), NDCs only															
<i>Any Prevalent Antipsychotics Use, NDCs only</i>	10,483	160.59	1	20	54	162	2,681	798	1,071	1,004	1,068	1,642	1,026	1,487	2,387
Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS															
<i>Any Prevalent Antipsychotics Use, NDCs or HCPCS</i>	6,223	120.20	1	18	45	124	1,693	569	716	638	702	1,031	587	851	1,129

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

Year	Number of Patients ¹	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members ²	Eligible Member-Years ²
Prevalent Use (1/1/2000 - 3/31/2018), NDCs only						
2000	0	0	0	0	0	0
2001	0	0	0	0	0	0
2002	0	0	0	0	0	0
2003	0	0	0	0	0	0
2004	0	0	0	0	0	0
2005	0	0	0	0	0	0
2006	0	0	0	0	0	0
2007	0	0	0	0	0	0
2008	0	0	0	0	0	0
2009	0	0	0	0	0	0
2010	0	0	0	0	16,864,454	8,011,593
2011	0	0	0	0	18,287,424	16,382,637
2012	0	0	0	0	19,322,790	17,268,487
2013	3,083	5,400	21,750	21,758	21,756,274	18,804,345
2014	6,742	14,821	53,992	53,996	22,470,547	20,111,473
2015	8,712	20,757	69,245	69,285	23,063,358	20,617,470
2016	10,285	24,993	78,606	78,634	23,753,615	21,439,660
2017	11,092	27,168	71,184	71,216	23,929,509	21,617,144
2018	5,535	7,445	11,210	11,212	21,790,732	5,283,170
Aripiprazole lauroxil						
2000	0	0	0	0	0	0
2001	0	0	0	0	0	0
2002	0	0	0	0	0	0
2003	0	0	0	0	0	0
2004	0	0	0	0	0	0
2005	0	0	0	0	0	0
2006	0	0	0	0	0	0
2007	0	0	0	0	0	0
2008	0	0	0	0	0	0
2009	0	0	0	0	0	0
2010	0	0	0	0	16,864,454	8,011,593
2011	0	0	0	0	18,287,424	16,382,637
2012	0	0	0	0	19,322,790	17,268,487
2013	0	0	0	0	21,756,274	18,804,345
2014	0	0	0	0	22,470,547	20,111,473
2015	222	258	916	916	23,063,358	20,617,470
2016	2,120	4,335	14,589	14,592	23,753,615	21,439,660
2017	3,555	7,978	20,142	20,146	23,929,509	21,617,144
2018	1,898	2,444	3,502	3,502	21,790,732	5,283,170
Fluphenazine decanoate						
2000	0	0	0	0	0	0
2001	0	0	0	0	0	0
2002	0	0	0	0	0	0
2003	0	0	0	0	0	0
2004	0	0	0	0	0	0
2005	0	0	0	0	0	0
2006	0	0	0	0	0	0

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

Year	Number of Patients ¹	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members ²	Eligible Member-Years ²
2007	0	0	0	0	0	0
2008	0	0	0	0	0	0
2009	0	0	0	0	0	0
2010	15,631	33,529	50,285	50,285	16,864,454	8,011,593
2011	18,249	58,532	89,440	89,442	18,287,424	16,382,637
2012	15,371	52,187	83,751	83,753	19,322,790	17,268,487
2013	13,553	35,961	59,020	59,020	21,756,274	18,804,345
2014	10,846	33,134	60,541	60,541	22,470,547	20,111,473
2015	10,606	32,769	61,887	61,888	23,063,358	20,617,470
2016	10,299	32,459	61,973	61,976	23,753,615	21,439,660
2017	9,497	30,243	51,950	51,955	23,929,509	21,617,144
2018	5,227	7,241	9,227	9,227	21,790,732	5,283,170
Haloperidol decanoate						
2000	0	0	0	0	0	0
2001	0	0	0	0	0	0
2002	0	0	0	0	0	0
2003	0	0	0	0	0	0
2004	0	0	0	0	0	0
2005	0	0	0	0	0	0
2006	0	0	0	0	0	0
2007	0	0	0	0	0	0
2008	0	0	0	0	0	0
2009	0	0	0	0	0	0
2010	21,904	43,759	79,387	79,948	16,864,454	8,011,593
2011	29,358	94,106	205,819	207,521	18,287,424	16,382,637
2012	28,441	94,632	218,979	220,873	19,322,790	17,268,487
2013	29,172	95,190	237,486	238,907	21,756,274	18,804,345
2014	27,292	87,937	220,137	221,426	22,470,547	20,111,473
2015	25,338	78,693	215,704	217,036	23,063,358	20,617,470
2016	24,113	74,103	203,459	204,486	23,753,615	21,439,660
2017	22,549	68,689	163,186	163,823	23,929,509	21,617,144
2018	11,663	16,655	24,589	24,672	21,790,732	5,283,170
Olanzapine pamoate						
2000	0	0	0	0	0	0
2001	0	0	0	0	0	0
2002	0	0	0	0	0	0
2003	0	0	0	0	0	0
2004	0	0	0	0	0	0
2005	0	0	0	0	0	0
2006	0	0	0	0	0	0
2007	0	0	0	0	0	0
2008	0	0	0	0	0	0
2009	0	0	0	0	0	0
2010	189	339	1,287	1,288	16,864,454	8,011,593
2011	626	1,681	6,578	6,582	18,287,424	16,382,637
2012	647	1,942	6,790	6,792	19,322,790	17,268,487
2013	589	1,820	5,994	5,994	21,756,274	18,804,345
2014	464	1,411	5,657	5,657	22,470,547	20,111,473

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

Year	Number of Patients ¹	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members ²	Eligible Member-Years ²
2015	339	1,048	4,231	4,232	23,063,358	20,617,470
2016	325	959	3,858	3,859	23,753,615	21,439,660
2017	274	804	2,556	2,556	23,929,509	21,617,144
2018	138	219	358	358	21,790,732	5,283,170
Paliperidone palmitate (Sustenna, 4-week)						
2000	0	0	0	0	0	0
2001	0	0	0	0	0	0
2002	0	0	0	0	0	0
2003	0	0	0	0	0	0
2004	0	0	0	0	0	0
2005	0	0	0	0	0	0
2006	0	0	0	0	0	0
2007	0	0	0	0	0	0
2008	0	0	0	0	0	0
2009	0	0	0	0	0	0
2010	7,937	15,434	61,570	62,081	16,864,454	8,011,593
2011	16,227	44,148	172,691	174,266	18,287,424	16,382,637
2012	20,738	56,953	222,677	224,465	19,322,790	17,268,487
2013	25,077	68,050	261,320	263,045	21,756,274	18,804,345
2014	26,828	72,156	272,743	274,288	22,470,547	20,111,473
2015	28,940	76,222	270,494	272,133	23,063,358	20,617,470
2016	30,504	77,941	266,037	267,733	23,753,615	21,439,660
2017	31,338	79,731	219,248	220,885	23,929,509	21,617,144
2018	14,935	20,192	30,988	31,413	21,790,732	5,283,170
Paliperidone palmitate (Trinza, 12-week)						
2000	0	0	0	0	0	0
2001	0	0	0	0	0	0
2002	0	0	0	0	0	0
2003	0	0	0	0	0	0
2004	0	0	0	0	0	0
2005	0	0	0	0	0	0
2006	0	0	0	0	0	0
2007	0	0	0	0	0	0
2008	0	0	0	0	0	0
2009	0	0	0	0	0	0
2010	0	0	0	0	16,864,454	8,011,593
2011	0	0	0	0	18,287,424	16,382,637
2012	0	0	0	0	19,322,790	17,268,487
2013	0	0	0	0	21,756,274	18,804,345
2014	0	0	0	0	22,470,547	20,111,473
2015	2,732	3,275	8,703	8,716	23,063,358	20,617,470
2016	6,054	10,018	24,832	24,862	23,753,615	21,439,660
2017	6,452	10,338	19,104	19,105	23,929,509	21,617,144
2018	2,616	2,634	2,684	2,684	21,790,732	5,283,170
Risperidone microspheres						
2000	0	0	0	0	0	0
2001	0	0	0	0	0	0
2002	0	0	0	0	0	0

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

Year	Number of Patients ¹	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members ²	Eligible Member-Years ²
2003	0	0	0	0	0	0
2004	0	0	0	0	0	0
2005	0	0	0	0	0	0
2006	0	0	0	0	0	0
2007	0	0	0	0	0	0
2008	0	0	0	0	0	0
2009	0	0	0	0	0	0
2010	17,076	37,679	170,093	172,385	16,864,454	8,011,593
2011	23,046	73,211	307,988	311,848	18,287,424	16,382,637
2012	21,119	66,021	283,748	286,244	19,322,790	17,268,487
2013	20,182	61,902	255,547	257,531	21,756,274	18,804,345
2014	17,584	53,209	220,695	222,083	22,470,547	20,111,473
2015	14,465	43,612	178,163	179,112	23,063,358	20,617,470
2016	12,319	36,859	143,189	143,684	23,753,615	21,439,660
2017	10,688	31,430	102,008	102,263	23,929,509	21,617,144
2018	4,720	7,239	12,965	12,985	21,790,732	5,283,170
Any Prevalent Antipsychotics Use, NDCs only						
2000	0	0	0	0	0	0
2001	0	0	0	0	0	0
2002	0	0	0	0	0	0
2003	0	0	0	0	0	0
2004	0	0	0	0	0	0
2005	0	0	0	0	0	0
2006	0	0	0	0	0	0
2007	0	0	0	0	0	0
2008	0	0	0	0	0	0
2009	0	0	0	0	0	0
2010	59,973	127,811	363,552	366,971	16,864,454	8,011,593
2011	80,502	265,457	782,602	789,781	18,287,424	16,382,637
2012	81,085	266,201	819,205	825,273	19,322,790	17,268,487
2013	83,502	261,379	842,428	847,550	21,756,274	18,804,345
2014	83,331	255,690	834,186	838,445	22,470,547	20,111,473
2015	82,550	247,370	810,874	814,786	23,063,358	20,617,470
2016	84,261	247,447	779,805	783,053	23,753,615	21,439,660
2017	83,969	241,973	627,865	630,369	23,929,509	21,617,144
2018	43,479	60,475	91,545	92,044	21,790,732	5,283,170
Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS						
Aripiprazole extended release						
2000	0	0	0	0	0	0
2001	0	0	0	0	0	0
2002	0	0	0	0	0	0
2003	0	0	0	0	0	0
2004	0	0	0	0	0	0
2005	0	0	0	0	0	0
2006	0	0	0	0	0	0
2007	0	0	0	0	0	0
2008	0	0	0	0	0	0
2009	0	0	0	0	0	0

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

Year	Number of Patients ¹	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members ²	Eligible Member-Years ²
2010	0	0	0	0	16,864,454	8,011,593
2011	0	0	0	0	18,287,424	16,382,637
2012	0	0	0	0	19,322,790	17,268,487
2013	3,083	5,400	18,974	18,980	21,756,274	18,804,345
2014	6,864	15,023	41,638	41,641	22,470,547	20,111,473
2015	4,680	7,333	12,474	12,476	20,861,120	7,628,454
Aripiprazole lauroxil						
2000	0	0	0	0	0	0
2001	0	0	0	0	0	0
2002	0	0	0	0	0	0
2003	0	0	0	0	0	0
2004	0	0	0	0	0	0
2005	0	0	0	0	0	0
2006	0	0	0	0	0	0
2007	0	0	0	0	0	0
2008	0	0	0	0	0	0
2009	0	0	0	0	0	0
2010	0	0	0	0	16,864,454	8,011,593
2011	**	**	**	**	18,287,424	16,382,637
2012	0	0	0	0	19,322,790	17,268,487
2013	0	0	0	0	21,756,274	18,804,345
2014	0	0	0	0	22,470,547	20,111,473
2015	0	0	0	0	20,861,120	7,628,454
Fluphenazine decanoate						
2000	0	0	0	0	0	0
2001	0	0	0	0	0	0
2002	0	0	0	0	0	0
2003	0	0	0	0	0	0
2004	0	0	0	0	0	0
2005	0	0	0	0	0	0
2006	0	0	0	0	0	0
2007	0	0	0	0	0	0
2008	0	0	0	0	0	0
2009	0	0	0	0	0	0
2010	17,297	38,894	61,603	61,603	16,864,454	8,011,593
2011	20,084	68,271	108,568	108,570	18,287,424	16,382,637
2012	17,141	60,985	100,976	100,978	19,322,790	17,268,487
2013	15,268	43,278	71,079	71,079	21,756,274	18,804,345
2014	12,140	39,269	65,860	65,860	22,470,547	20,111,473
2015	8,180	14,642	19,677	19,678	20,861,120	7,628,454
Haloperidol decanoate						
2000	0	0	0	0	0	0
2001	0	0	0	0	0	0
2002	0	0	0	0	0	0
2003	0	0	0	0	0	0
2004	0	0	0	0	0	0
2005	0	0	0	0	0	0
2006	0	0	0	0	0	0

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

Year	Number of Patients ¹	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members ²	Eligible Member-Years ²
2007	0	0	0	0	0	0
2008	0	0	0	0	0	0
2009	0	0	0	0	0	0
2010	24,148	47,688	91,630	92,165	16,864,454	8,011,593
2011	32,055	101,739	228,541	230,150	18,287,424	16,382,637
2012	31,071	101,691	236,097	237,688	19,322,790	17,268,487
2013	31,913	102,350	247,051	248,118	21,756,274	18,804,345
2014	29,747	95,027	210,876	211,655	22,470,547	20,111,473
2015	18,910	33,251	52,926	53,055	20,861,120	7,628,454
Olanzapine pamoate						
2000	0	0	0	0	0	0
2001	0	0	0	0	0	0
2002	0	0	0	0	0	0
2003	0	0	0	0	0	0
2004	0	0	0	0	0	0
2005	0	0	0	0	0	0
2006	0	0	0	0	0	0
2007	0	0	0	0	0	0
2008	0	0	0	0	0	0
2009	0	0	0	0	0	0
2010	189	339	1,256	1,257	16,864,454	8,011,593
2011	1,057	2,150	7,024	7,028	18,287,424	16,382,637
2012	1,149	2,539	7,279	7,281	19,322,790	17,268,487
2013	1,185	2,525	6,511	6,511	21,756,274	18,804,345
2014	1,148	2,235	5,313	5,313	22,470,547	20,111,473
2015	490	745	1,211	1,212	20,861,120	7,628,454
Paliperidone palmitate (Sustenna, 4-week)						
2000	0	0	0	0	0	0
2001	0	0	0	0	0	0
2002	0	0	0	0	0	0
2003	0	0	0	0	0	0
2004	0	0	0	0	0	0
2005	0	0	0	0	0	0
2006	0	0	0	0	0	0
2007	0	0	0	0	0	0
2008	0	0	0	0	0	0
2009	0	0	0	0	0	0
2010	8,162	15,880	59,950	60,427	16,864,454	8,011,593
2011	16,913	46,427	169,823	171,328	18,287,424	16,382,637
2012	21,497	59,649	213,240	214,929	19,322,790	17,268,487
2013	25,970	71,125	239,232	240,831	21,756,274	18,804,345
2014	27,708	75,483	218,209	219,610	22,470,547	20,111,473
2015	17,493	29,672	51,962	52,533	20,861,120	7,628,454
Risperidone microspheres						
2000	0	0	0	0	0	0
2001	0	0	0	0	0	0
2002	0	0	0	0	0	0
2003	0	0	0	0	0	0

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

Year	Number of Patients ¹	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members ²	Eligible Member-Years ²
2004	0	0	0	0	0	0
2005	0	0	0	0	0	0
2006	0	0	0	0	0	0
2007	0	0	0	0	0	0
2008	0	0	0	0	0	0
2009	0	0	0	0	0	0
2010	18,900	44,179	177,766	179,689	16,864,454	8,011,593
2011	25,003	84,349	320,713	323,519	18,287,424	16,382,637
2012	22,664	74,627	284,350	286,225	19,322,790	17,268,487
2013	21,578	69,285	246,386	247,520	21,756,274	18,804,345
2014	18,677	59,324	185,930	186,426	22,470,547	20,111,473
2015	10,090	20,030	39,215	39,286	20,861,120	7,628,454
Any Prevalent Antipsychotics Use, NDCs or HCPCS						
2000	0	0	0	0	0	0
2001	0	0	0	0	0	0
2002	0	0	0	0	0	0
2003	0	0	0	0	0	0
2004	0	0	0	0	0	0
2005	0	0	0	0	0	0
2006	0	0	0	0	0	0
2007	0	0	0	0	0	0
2008	0	0	0	0	0	0
2009	0	0	0	0	0	0
2010	65,419	143,397	391,834	394,807	16,864,454	8,011,593
2011	86,950	295,289	832,143	838,084	18,287,424	16,382,637
2012	87,384	292,808	840,686	845,758	19,322,790	17,268,487
2013	89,772	285,716	823,867	827,639	21,756,274	18,804,345
2014	88,981	278,366	718,507	721,128	22,470,547	20,111,473
2015	57,358	102,725	174,182	174,911	20,861,120	7,628,454

¹Some 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.

²Eligible 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

	Number of Episodes	Reason(s) for Censoring ¹				
		Eligibility	Death	Data Partner Data End Date	Query End Date	Episode End
Prevalent Use (1/1/2000 - 3/31/2018), NDCs only						
<i>Any Prevalent Antipsychotics Use, NDCs only</i>						
2000	0	0	0	0	0	0
2001	0	0	0	0	0	0
2002	0	0	0	0	0	0
2003	0	0	0	0	0	0
2004	0	0	0	0	0	0
2005	0	0	0	0	0	0
2006	0	0	0	0	0	0
2007	0	0	0	0	0	0
2008	0	0	0	0	0	0
2009	0	0	0	0	0	0
2010	127,811	1,006	628	179	179	127,222
2011	265,457	2,415	1,296	474	474	264,230
2012	266,201	3,075	1,387	688	688	264,915
2013	261,379	4,153	1,390	1,120	1,120	260,072
2014	255,690	7,152	1,418	1,798	1,798	254,365
2015	247,370	7,456	1,500	3,358	3,358	245,961
2016	247,447	10,899	1,437	6,890	6,890	246,097
2017	241,973	25,041	1,261	21,263	21,263	240,793
2018	60,475	34,085	166	33,744	33,744	60,319
Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS						
<i>Any Prevalent Antipsychotics Use, NDCs or HCPCS</i>						
2000	0	0	0	0	0	0
2001	0	0	0	0	0	0
2002	0	0	0	0	0	0
2003	0	0	0	0	0	0
2004	0	0	0	0	0	0
2005	0	0	0	0	0	0
2006	0	0	0	0	0	0
2007	0	0	0	0	0	0
2008	0	0	0	0	0	0
2009	0	0	0	0	0	0
2010	143,397	888	630	0	410	142,298
2011	295,289	1,988	1,319	0	1,206	292,675
2012	292,808	2,369	1,367	0	2,194	289,190
2013	285,716	2,958	1,359	0	4,547	279,683
2014	278,366	4,972	1,230	0	14,276	262,745
2015	102,725	838	318	0	40,293	62,682

¹An 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 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
Prevalent Use (1/1/2000 - 3/31/2018), NDCs only									
<i>Any Prevalent Antipsychotics Use, NDCs only</i>									
2000	0	0	0	0	0	0	0	0	0
2001	0	0	0	0	0	0	0	0	0
2002	0	0	0	0	0	0	0	0	0
2003	0	0	0	0	0	0	0	0	0
2004	0	0	0	0	0	0	0	0	0
2005	0	0	0	0	0	0	0	0	0
2006	0	0	0	0	0	0	0	0	0
2007	0	0	0	0	0	0	0	0	0
2008	0	0	0	0	0	0	0	0	0
2009	0	0	0	0	0	0	0	0	0
2010	628	48	61	73	69	89	59	84	145
2011	1,296	91	150	124	148	198	104	164	317
2012	1,387	113	130	117	127	226	119	173	382
2013	1,390	117	136	130	145	214	125	183	340
2014	1,418	107	139	109	134	212	145	206	366
2015	1,500	96	135	138	136	223	141	230	401
2016	1,437	103	152	126	121	211	161	229	334
2017	1,261	98	131	149	160	236	167	218	102
2018	166	**	**	**	**	**	**	0	0
Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS									
<i>Any Prevalent Antipsychotics Use, NDCs or HCPCS</i>									
2000	0	0	0	0	0	0	0	0	0
2001	0	0	0	0	0	0	0	0	0
2002	0	0	0	0	0	0	0	0	0
2003	0	0	0	0	0	0	0	0	0
2004	0	0	0	0	0	0	0	0	0
2005	0	0	0	0	0	0	0	0	0
2006	0	0	0	0	0	0	0	0	0
2007	0	0	0	0	0	0	0	0	0
2008	0	0	0	0	0	0	0	0	0
2009	0	0	0	0	0	0	0	0	0
2010	630	52	65	76	68	92	61	86	130
2011	1,319	105	163	126	150	206	109	170	290
2012	1,367	126	137	127	131	226	120	181	319
2013	1,359	124	149	140	153	223	130	189	251
2014	1,230	119	148	112	138	218	147	209	139
2015	318	43	54	57	62	66	20	16	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 ¹	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members ²	Eligible Member-Years ²
Prevalent Use (1/1/2000 - 3/31/2018), NDCs only						
Female	11,876	44,191	132,996	133,049	20,656,373	87,826,654
Male	14,552	56,393	172,991	173,052	**	61,709,311
Other	0	0	0	0	**	14
Aripiprazole lauroxil						
Female	2,439	6,511	16,614	16,619	20,656,373	87,826,654
Male	3,075	8,504	22,535	22,537	**	61,709,311
Other	0	0	0	0	**	14
Fluphenazine decanoate						
Female	15,318	120,611	196,272	196,275	20,656,373	87,826,654
Male	21,859	195,444	331,802	331,812	**	61,709,311
Other	0	0	0	0	**	14
Haloperidol decanoate						
Female	30,705	243,673	567,717	571,069	20,656,373	87,826,654
Male	45,532	410,091	1,001,029	1,007,623	**	61,709,311
Other	0	0	0	0	**	14
Olanzapine pamoate						
Female	599	2,985	11,290	11,294	20,656,373	87,826,654
Male	1,227	7,238	26,019	26,024	**	61,709,311
Other	0	0	0	0	**	14
Paliperidone palmitate (Sustenna, 4-week)						
Female	36,078	190,689	646,896	651,569	20,656,373	87,826,654
Male	56,254	320,138	1,130,872	1,138,740	**	61,709,311
Other	0	0	0	0	**	14
Paliperidone palmitate (Trinza, 12-week)						
Female	4,079	8,980	18,548	18,553	20,656,373	87,826,654
Male	7,733	17,285	36,775	36,814	**	61,709,311
Other	0	0	0	0	**	14
Risperidone microspheres						
Female	28,423	174,114	685,503	690,339	20,656,373	87,826,654
Male	34,880	237,048	988,893	997,796	**	61,709,311
Other	0	0	0	0	**	14
Any Prevalent Antipsychotics Use, NDCs only						
Female	98,322	766,085	2,264,133	2,277,003	20,656,373	87,826,654
Male	134,812	1,207,718	3,687,929	3,711,269	**	61,709,311
Other	0	0	0	0	**	14
Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS						
Aripiprazole extended release						
Female	4,553	11,984	31,390	31,396	16,824,291	52,282,772
Male	5,922	15,772	41,696	41,701	**	**
Other	0	0	0	0	**	**
Aripiprazole lauroxil						
Female	0	0	0	0	16,824,291	52,282,772
Male	**	**	**	**	**	**
Other	0	0	0	0	**	**
Fluphenazine decanoate						
Female	14,107	101,621	159,405	159,406	16,824,291	52,282,772
Male	20,256	163,718	268,358	268,362	**	**
Other	0	0	0	0	**	**

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

Sex	Number of Patients ¹	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members ²	Eligible Member-Years ²
Haloperidol decanoate						
Female	25,835	180,269	391,292	393,156	16,824,291	52,282,772
Male	39,201	301,477	675,829	679,675	**	**
Other	0	0	0	0	**	**
Olanzapine pamoate						
Female	1,687	3,706	9,550	9,553	16,824,291	52,282,772
Male	2,168	6,827	19,044	19,049	**	**
Other	0	0	0	0	**	**
Paliperidone palmitate (Sustenna, 4-week)						
Female	22,907	111,722	349,966	352,706	16,824,291	52,282,772
Male	36,165	186,514	602,450	606,952	**	**
Other	0	0	0	0	**	**
Risperidone microspheres						
Female	24,640	146,710	509,908	512,757	16,824,291	52,282,772
Male	31,492	205,084	744,452	749,908	**	**
Other	0	0	0	0	**	**
Any Prevalent Antipsychotics Use, NDCs or HCPCS						
Female	76,169	542,332	1,444,061	1,451,485	16,824,291	52,282,772
Male	106,727	855,969	2,337,158	2,350,842	**	**
Other	0	0	0	0	**	**

¹Some 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.

²Eligible 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 3b. Summary of Reasons for Episode Censoring in the Sentinel Distributed Database (SDD), by Sex

	Number of Episodes	Reason(s) for Censoring ¹				
		Eligibility	Death	Data Partner		Episode End
				Data End Date	Query End Date	
Prevalent Use (1/1/2000 - 3/31/2018), NDCs only						
<i>Any Prevalent Antipsychotics Use, NDCs only</i>						
Female	766,085	36,376	5,021	25,972	25,972	761,391
Male	1,207,718	58,906	5,462	43,542	43,542	1,202,583
Other	0	0	0	0	0	0
Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS						
<i>Any Prevalent Antipsychotics Use, NDCs or HCPCS</i>						
Female	542,332	5,609	3,041	0	23,553	515,803
Male	855,969	8,404	3,182	0	39,373	813,470
Other	0	0	0	0	0	0

¹An 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 3c. Summary of Follow-up Time for Users Censored due to Death in the Sentinel Distributed Database (SDD), by 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
Prevalent Use (1/1/2000 - 3/31/2018), NDCs only									
<i>Any Prevalent Antipsychotics Use, NDCs only</i>									
Female	5,021	411	533	466	522	818	496	721	1,054
Male	5,462	387	538	538	546	824	530	766	1,333
Other	0	0	0	0	0	0	0	0	0
Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS									
<i>Any Prevalent Antipsychotics Use, NDCs or HCPCS</i>									
Female	3,041	307	352	293	351	519	279	427	513
Male	3,182	262	364	345	351	512	308	424	616
Other	0	0	0	0	0	0	0	0	0

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 ¹	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members ²	Eligible Member-Years ²
Prevalent Use (1/1/2000 - 3/31/2018), NDCs only						
0-17 years	0	0	0	0	3,910	8,813
18-49 years	17,253	65,191	196,617	196,696	3,384,759	12,817,485
50-64 years	7,684	28,360	88,793	88,815	5,518,391	18,505,053
65 years or older	2,118	7,033	20,577	20,590	29,373,691	118,204,627
Aripiprazole lauroxil						
0-17 years	0	0	0	0	3,910	8,813
18-49 years	3,484	9,459	24,221	24,224	3,384,759	12,817,485
50-64 years	1,679	4,492	12,327	12,329	5,518,391	18,505,053
65 years or older	416	1,064	2,601	2,603	29,373,691	118,204,627
Fluphenazine decanoate						
0-17 years	0	0	0	0	3,910	8,813
18-49 years	16,044	110,923	188,798	188,800	3,384,759	12,817,485
50-64 years	16,486	147,611	250,553	250,560	5,518,391	18,505,053
65 years or older	8,322	57,521	88,723	88,727	29,373,691	118,204,627
Haloperidol decanoate						
0-17 years	0	0	0	0	3,910	8,813
18-49 years	36,684	275,630	673,552	678,166	3,384,759	12,817,485
50-64 years	29,182	258,240	633,111	636,957	5,518,391	18,505,053
65 years or older	17,281	119,894	262,083	263,569	29,373,691	118,204,627
Olanzapine pamoate						
0-17 years	0	0	0	0	3,910	8,813
18-49 years	1,076	5,752	20,054	20,061	3,384,759	12,817,485
50-64 years	625	3,449	13,122	13,123	5,518,391	18,505,053
65 years or older	197	1,022	4,133	4,134	29,373,691	118,204,627
Paliperidone palmitate (Sustenna, 4-week)						
0-17 years	0	0	0	0	3,910	8,813
18-49 years	56,960	302,528	1,053,531	1,061,593	3,384,759	12,817,485
50-64 years	30,973	163,182	586,183	589,976	5,518,391	18,505,053
65 years or older	9,177	45,117	138,054	138,740	29,373,691	118,204,627
Paliperidone palmitate (Trinza, 12-week)						
0-17 years	0	0	0	0	3,910	8,813
18-49 years	7,143	15,536	33,069	33,091	3,384,759	12,817,485
50-64 years	4,056	8,978	18,953	18,969	5,518,391	18,505,053
65 years or older	804	1,751	3,301	3,307	29,373,691	118,204,627
Risperidone microspheres						
0-17 years	0	0	0	0	3,910	8,813
18-49 years	29,688	185,488	759,078	766,675	3,384,759	12,817,485
50-64 years	19,920	130,080	564,529	568,648	5,518,391	18,505,053
65 years or older	17,132	95,594	350,789	352,812	29,373,691	118,204,627
Any Prevalent Antipsychotics Use, NDCs only						
0-17 years	0	0	0	0	3,910	8,813
18-49 years	121,652	930,863	2,933,229	2,953,481	3,384,759	12,817,485
50-64 years	84,424	720,619	2,152,629	2,164,431	5,518,391	18,505,053
65 years or older	47,962	322,321	866,204	870,360	29,373,691	118,204,627
Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS						
Aripiprazole extended release						
0-17 years	0	0	0	0	3,122	5,948
18-49 years	6,902	18,270	47,695	47,702	2,903,263	8,402,338

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 ¹	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members ²	Eligible Member-Years ²
50-64 years	3,034	7,905	21,303	21,307	4,362,992	11,413,463
65 years or older	666	1,581	4,088	4,088	23,078,071	68,385,240
Aripiprazole lauroxil						
0-17 years	0	0	0	0	3,122	5,948
18-49 years	0	0	0	0	2,903,263	8,402,338
50-64 years	0	0	0	0	4,362,992	11,413,463
65 years or older	**	**	**	**	23,078,071	68,385,240
Fluphenazine decanoate						
0-17 years	0	0	0	0	3,122	5,948
18-49 years	14,724	97,233	159,850	159,851	2,903,263	8,402,338
50-64 years	15,172	122,914	201,526	201,530	4,362,992	11,413,463
65 years or older	7,212	45,192	66,387	66,387	23,078,071	68,385,240
Haloperidol decanoate						
0-17 years	0	0	0	0	3,122	5,948
18-49 years	31,454	209,692	472,863	475,536	2,903,263	8,402,338
50-64 years	25,025	189,928	427,656	429,864	4,362,992	11,413,463
65 years or older	13,243	82,126	166,602	167,431	23,078,071	68,385,240
Olanzapine pamoate						
0-17 years	0	0	0	0	3,122	5,948
18-49 years	1,915	5,561	15,111	15,118	2,903,263	8,402,338
50-64 years	1,128	3,434	9,873	9,874	4,362,992	11,413,463
65 years or older	868	1,538	3,610	3,610	23,078,071	68,385,240
Paliperidone palmitate (Sustenna, 4-week)						
0-17 years	0	0	0	0	3,122	5,948
18-49 years	37,249	182,284	583,860	588,595	2,903,263	8,402,338
50-64 years	19,194	93,331	304,872	307,043	4,362,992	11,413,463
65 years or older	4,947	22,621	63,684	64,020	23,078,071	68,385,240
Risperidone microspheres						
0-17 years	0	0	0	0	3,122	5,948
18-49 years	27,595	169,175	601,628	606,224	2,903,263	8,402,338
50-64 years	17,587	110,688	413,481	415,964	4,362,992	11,413,463
65 years or older	13,475	71,931	239,251	240,477	23,078,071	68,385,240
Any Prevalent Antipsychotics Use, NDCs or HCPCS						
0-17 years	0	0	0	0	3,122	5,948
18-49 years	93,799	661,661	1,869,410	1,881,331	2,903,263	8,402,338
50-64 years	66,045	515,245	1,370,179	1,377,024	4,362,992	11,413,463
65 years or older	36,024	221,395	541,630	543,972	23,078,071	68,385,240

¹Some 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.

²Eligible 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

	Number of Episodes	Reason(s) for Censoring ¹				
		Eligibility	Death	Data Partner Data End Date	Query End Date	Episode End
Prevalent Use (1/1/2000 - 3/31/2018), NDCs only						
<i>Any Prevalent Antipsychotics Use, NDCs only</i>						
0-17 years	0	0	0	0	0	0
18-49 years	930,863	48,583	1,675	35,097	35,097	929,281
50-64 years	720,619	34,027	3,418	24,952	24,952	717,399
65 years or older	322,321	12,672	5,390	9,465	9,465	317,294
Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS						
<i>Any Prevalent Antipsychotics Use, NDCs or HCPCS</i>						
0-17 years	0	0	0	0	0	0
18-49 years	661,661	7,350	960	0	31,309	629,288
50-64 years	515,245	4,954	1,936	0	23,325	489,975
65 years or older	221,395	1,709	3,327	0	8,292	210,010

¹An 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 4c. Summary of Follow-up Time for Users Censored due to Death in the Sentinel Distributed Database (SDD), by Age Group

	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
Prevalent Use (1/1/2000 - 3/31/2018), NDCs only									
<i>Any Prevalent Antipsychotics Use, NDCs only</i>									
0-17 years	0	0	0	0	0	0	0	0	0
18-49 years	1,675	114	130	124	150	234	163	252	508
50-64 years	3,418	222	310	311	332	493	297	488	965
65 years or older	5,390	462	631	569	586	915	566	747	914
Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS									
<i>Any Prevalent Antipsychotics Use, NDCs or HCPCS</i>									
0-17 years	0	0	0	0	0	0	0	0	0
18-49 years	960	80	87	84	92	152	88	142	235
50-64 years	1,936	159	202	178	222	315	169	259	432
65 years or older	3,327	330	427	376	388	564	330	450	462

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 ¹	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members ²	Eligible Member-Years ²
Prevalent Use (1/1/2000 - 3/31/2018), NDCs only						
Female						
0-17 years	0	0	0	0	1,693	3,757
18-49 years	7,100	26,166	78,196	78,227	1,613,216	6,086,685
50-64 years	3,776	13,666	42,296	42,305	2,847,428	9,591,220
65 years or older	1,312	4,359	12,504	12,517	17,380,681	72,144,992
Male						
0-17 years	0	0	0	0	2,217	5,057
18-49 years	10,153	39,025	118,421	118,469	1,771,541	6,730,794
50-64 years	3,908	14,694	46,497	46,510	2,670,963	8,913,833
65 years or older	806	2,674	8,073	8,073	11,993,006	46,059,628
Other						
0-17 years	0	0	0	0	0	0
18-49 years	0	0	0	0	**	**
50-64 years	0	0	0	0	0	0
65 years or older	0	0	0	0	**	**
Aripiprazole lauroxil						
Female						
0-17 years	0	0	0	0	1,693	3,757
18-49 years	1,435	3,781	9,556	9,558	1,613,216	6,086,685
50-64 years	804	2,146	5,660	5,662	2,847,428	9,591,220
65 years or older	234	584	1,398	1,399	17,380,681	72,144,992
Male						
0-17 years	0	0	0	0	2,217	5,057
18-49 years	2,049	5,678	14,665	14,666	1,771,541	6,730,794
50-64 years	875	2,346	6,667	6,667	2,670,963	8,913,833
65 years or older	182	480	1,203	1,204	11,993,006	46,059,628
Other						
0-17 years	0	0	0	0	0	0
18-49 years	0	0	0	0	**	**
50-64 years	0	0	0	0	0	0
65 years or older	0	0	0	0	**	**
Fluphenazine decanoate						
Female						
0-17 years	0	0	0	0	1,693	3,757
18-49 years	5,173	33,063	55,039	55,040	1,613,216	6,086,685
50-64 years	6,282	51,136	86,262	86,263	2,847,428	9,591,220
65 years or older	5,210	36,412	54,971	54,972	17,380,681	72,144,992
Male						
0-17 years	0	0	0	0	2,217	5,057
18-49 years	10,871	77,860	133,759	133,760	1,771,541	6,730,794
50-64 years	10,204	96,475	164,291	164,297	2,670,963	8,913,833
65 years or older	3,112	21,109	33,752	33,755	11,993,006	46,059,628
Other						
0-17 years	0	0	0	0	0	0
18-49 years	0	0	0	0	**	**
50-64 years	0	0	0	0	0	0
65 years or older	0	0	0	0	**	**

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 ¹	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members ²	Eligible Member-Years ²
Haloperidol decanoate						
Female						
0-17 years	0	0	0	0	1,693	3,757
18-49 years	11,582	78,493	189,344	190,623	1,613,216	6,086,685
50-64 years	11,117	91,382	219,267	220,566	2,847,428	9,591,220
65 years or older	10,515	73,798	159,106	159,880	17,380,681	72,144,992
Male						
0-17 years	0	0	0	0	2,217	5,057
18-49 years	25,102	197,137	484,208	487,543	1,771,541	6,730,794
50-64 years	18,065	166,858	413,844	416,391	2,670,963	8,913,833
65 years or older	6,766	46,096	102,977	103,689	11,993,006	46,059,628
Other						
0-17 years	0	0	0	0	0	0
18-49 years	0	0	0	0	**	**
50-64 years	0	0	0	0	0	0
65 years or older	0	0	0	0	**	**
Olanzapine pamoate						
Female						
0-17 years	0	0	0	0	1,693	3,757
18-49 years	267	1,156	4,269	4,271	1,613,216	6,086,685
50-64 years	226	1,208	4,533	4,534	2,847,428	9,591,220
65 years or older	128	621	2,488	2,489	17,380,681	72,144,992
Male						
0-17 years	0	0	0	0	2,217	5,057
18-49 years	809	4,596	15,785	15,790	1,771,541	6,730,794
50-64 years	399	2,241	8,589	8,589	2,670,963	8,913,833
65 years or older	69	401	1,645	1,645	11,993,006	46,059,628
Other						
0-17 years	0	0	0	0	0	0
18-49 years	0	0	0	0	**	**
50-64 years	0	0	0	0	0	0
65 years or older	0	0	0	0	**	**
Paliperidone palmitate (Sustenna, 4-week)						
Female						
0-17 years	0	0	0	0	1,693	3,757
18-49 years	18,846	92,292	313,635	316,319	1,613,216	6,086,685
50-64 years	13,473	69,661	245,792	247,404	2,847,428	9,591,220
65 years or older	5,762	28,736	87,469	87,846	17,380,681	72,144,992
Male						
0-17 years	0	0	0	0	2,217	5,057
18-49 years	38,114	210,236	739,896	745,274	1,771,541	6,730,794
50-64 years	17,500	93,521	340,391	342,572	2,670,963	8,913,833
65 years or older	3,415	16,381	50,585	50,894	11,993,006	46,059,628
Other						
0-17 years	0	0	0	0	0	0
18-49 years	0	0	0	0	**	**
50-64 years	0	0	0	0	0	0
65 years or older	0	0	0	0	**	**

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 ¹	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members ²	Eligible Member-Years ²
Paliperidone palmitate (Trinza, 12-week)						
Female						
0-17 years	0	0	0	0	1,693	3,757
18-49 years	1,968	4,133	8,688	8,691	1,613,216	6,086,685
50-64 years	1,722	3,811	7,883	7,883	2,847,428	9,591,220
65 years or older	472	1,036	1,977	1,979	17,380,681	72,144,992
Male						
0-17 years	0	0	0	0	2,217	5,057
18-49 years	5,175	11,403	24,381	24,400	1,771,541	6,730,794
50-64 years	2,334	5,167	11,070	11,086	2,670,963	8,913,833
65 years or older	332	715	1,324	1,328	11,993,006	46,059,628
Other						
0-17 years	0	0	0	0	0	0
18-49 years	0	0	0	0	**	**
50-64 years	0	0	0	0	0	0
65 years or older	0	0	0	0	**	**
Risperidone microspheres						
Female						
0-17 years	0	0	0	0	1,693	3,757
18-49 years	9,446	53,028	208,205	210,027	1,613,216	6,086,685
50-64 years	8,724	54,653	232,760	234,317	2,847,428	9,591,220
65 years or older	11,694	66,433	244,538	245,995	17,380,681	72,144,992
Male						
0-17 years	0	0	0	0	2,217	5,057
18-49 years	20,242	132,460	550,873	556,648	1,771,541	6,730,794
50-64 years	11,196	75,427	331,769	334,331	2,670,963	8,913,833
65 years or older	5,438	29,161	106,251	106,817	11,993,006	46,059,628
Other						
0-17 years	0	0	0	0	0	0
18-49 years	0	0	0	0	**	**
50-64 years	0	0	0	0	0	0
65 years or older	0	0	0	0	**	**
Any Prevalent Antipsychotics Use, NDCs only						
Female						
0-17 years	0	0	0	0	1,693	3,757
18-49 years	40,906	280,344	862,808	868,589	1,613,216	6,086,685
50-64 years	35,148	278,086	839,078	843,542	2,847,428	9,591,220
65 years or older	30,518	207,655	562,247	564,872	17,380,681	72,144,992
Male						
0-17 years	0	0	0	0	2,217	5,057
18-49 years	80,746	650,519	2,070,421	2,084,892	1,771,541	6,730,794
50-64 years	49,276	442,533	1,313,551	1,320,889	2,670,963	8,913,833
65 years or older	17,444	114,666	303,957	305,488	11,993,006	46,059,628
Other						
0-17 years	0	0	0	0	0	0
18-49 years	0	0	0	0	**	**
50-64 years	0	0	0	0	0	0
65 years or older	0	0	0	0	**	**

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 ¹	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members ²	Eligible Member-Years ²
Prevalent Use (1/1/2000 - 5/18/2015), NDCs or HCPCS						
Aripiprazole extended release						
Female						
0-17 years	0	0	0	0	1,378	2,553
18-49 years	2,755	7,173	18,778	18,783	1,382,831	3,983,905
50-64 years	1,438	3,800	10,087	10,088	2,258,089	5,929,806
65 years or older	423	1,011	2,525	2,525	13,917,219	42,366,508
Male						
0-17 years	0	0	0	0	1,744	3,395
18-49 years	4,147	11,097	28,917	28,919	1,520,431	4,418,431
50-64 years	1,596	4,105	11,216	11,219	2,104,903	5,483,657
65 years or older	243	570	1,563	1,563	9,160,849	26,018,729
Other						
0-17 years	0	0	0	0	0	0
18-49 years	0	0	0	0	**	**
50-64 years	0	0	0	0	0	0
65 years or older	0	0	0	0	**	**
Aripiprazole lauroxil						
Female						
0-17 years	0	0	0	0	1,378	2,553
18-49 years	0	0	0	0	1,382,831	3,983,905
50-64 years	0	0	0	0	2,258,089	5,929,806
65 years or older	0	0	0	0	13,917,219	42,366,508
Male						
0-17 years	0	0	0	0	1,744	3,395
18-49 years	0	0	0	0	1,520,431	4,418,431
50-64 years	0	0	0	0	2,104,903	5,483,657
65 years or older	**	**	**	**	9,160,849	26,018,729
Other						
0-17 years	0	0	0	0	0	0
18-49 years	0	0	0	0	**	**
50-64 years	0	0	0	0	0	0
65 years or older	0	0	0	0	**	**
Fluphenazine decanoate						
Female						
0-17 years	0	0	0	0	1,378	2,553
18-49 years	4,731	29,330	47,246	47,246	1,382,831	3,983,905
50-64 years	5,761	43,063	69,862	69,863	2,258,089	5,929,806
65 years or older	4,614	29,228	42,297	42,297	13,917,219	42,366,508
Male						
0-17 years	0	0	0	0	1,744	3,395
18-49 years	9,993	67,903	112,604	112,605	1,520,431	4,418,431
50-64 years	9,411	79,851	131,664	131,667	2,104,903	5,483,657
65 years or older	2,598	15,964	24,090	24,090	9,160,849	26,018,729
Other						
0-17 years	0	0	0	0	0	0
18-49 years	0	0	0	0	**	**
50-64 years	0	0	0	0	0	0
65 years or older	0	0	0	0	**	**

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 ¹	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members ²	Eligible Member-Years ²
Haloperidol decanoate						
Female						
0-17 years	0	0	0	0	1,378	2,553
18-49 years	9,848	60,495	136,241	136,915	1,382,831	3,983,905
50-64 years	9,488	68,155	151,553	152,278	2,258,089	5,929,806
65 years or older	8,225	51,619	103,498	103,963	13,917,219	42,366,508
Male						
0-17 years	0	0	0	0	1,744	3,395
18-49 years	21,606	149,197	336,622	338,621	1,520,431	4,418,431
50-64 years	15,537	121,773	276,103	277,586	2,104,903	5,483,657
65 years or older	5,018	30,507	63,104	63,468	9,160,849	26,018,729
Other						
0-17 years	0	0	0	0	0	0
18-49 years	0	0	0	0	**	**
50-64 years	0	0	0	0	0	0
65 years or older	0	0	0	0	**	**
Olanzapine pamoate						
Female						
0-17 years	0	0	0	0	1,378	2,553
18-49 years	695	1,494	3,740	3,742	1,382,831	3,983,905
50-64 years	475	1,260	3,557	3,558	2,258,089	5,929,806
65 years or older	535	952	2,253	2,253	13,917,219	42,366,508
Male						
0-17 years	0	0	0	0	1,744	3,395
18-49 years	1,220	4,067	11,371	11,376	1,520,431	4,418,431
50-64 years	653	2,174	6,316	6,316	2,104,903	5,483,657
65 years or older	333	586	1,357	1,357	9,160,849	26,018,729
Other						
0-17 years	0	0	0	0	0	0
18-49 years	0	0	0	0	**	**
50-64 years	0	0	0	0	0	0
65 years or older	0	0	0	0	**	**
Paliperidone palmitate (Sustenna, 4-week)						
Female						
0-17 years	0	0	0	0	1,378	2,553
18-49 years	12,341	56,750	178,808	180,437	1,382,831	3,983,905
50-64 years	8,306	40,176	129,356	130,279	2,258,089	5,929,806
65 years or older	3,220	14,796	41,802	41,990	13,917,219	42,366,508
Male						
0-17 years	0	0	0	0	1,744	3,395
18-49 years	24,908	125,534	405,052	408,158	1,520,431	4,418,431
50-64 years	10,888	53,155	175,516	176,764	2,104,903	5,483,657
65 years or older	1,727	7,825	21,882	22,030	9,160,849	26,018,729
Other						
0-17 years	0	0	0	0	0	0
18-49 years	0	0	0	0	**	**
50-64 years	0	0	0	0	0	0
65 years or older	0	0	0	0	**	**

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 ¹	Number of Episodes	Number of Adjusted Dispensings	Number of Raw Dispensings	Eligible Members ²	Eligible Member-Years ²
Risperidone microspheres						
Female						
0-17 years	0	0	0	0	1,378	2,553
18-49 years	8,728	48,764	167,607	168,619	1,382,831	3,983,905
50-64 years	7,682	47,331	173,325	174,263	2,258,089	5,929,806
65 years or older	9,296	50,615	168,976	169,875	13,917,219	42,366,508
Male						
0-17 years	0	0	0	0	1,744	3,395
18-49 years	18,867	120,411	434,021	437,605	1,520,431	4,418,431
50-64 years	9,905	63,357	240,156	241,701	2,104,903	5,483,657
65 years or older	4,179	21,316	70,275	70,602	9,160,849	26,018,729
Other						
0-17 years	0	0	0	0	0	0
18-49 years	0	0	0	0	**	**
50-64 years	0	0	0	0	0	0
65 years or older	0	0	0	0	**	**
Any Prevalent Antipsychotics Use, NDCs or HCPCS						
Female						
0-17 years	0	0	0	0	1,378	2,553
18-49 years	30,862	197,711	549,411	552,720	1,382,831	3,983,905
50-64 years	26,974	198,834	534,447	537,012	2,258,089	5,929,806
65 years or older	23,378	145,787	360,203	361,753	13,917,219	42,366,508
Male						
0-17 years	0	0	0	0	1,744	3,395
18-49 years	62,937	463,950	1,319,999	1,328,611	1,520,431	4,418,431
50-64 years	39,071	316,411	835,732	840,012	2,104,903	5,483,657
65 years or older	12,646	75,608	181,427	182,219	9,160,849	26,018,729
Other						
0-17 years	0	0	0	0	0	0
18-49 years	0	0	0	0	**	**
50-64 years	0	0	0	0	0	0
65 years or older	0	0	0	0	**	**

¹Some 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.

²Eligible 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 Available Data as of Request Distribution Date (June 26, 2019)

DP ID	DP Death Data		Actual Dates Used	
	Availability <i>Start</i> Date	Availability <i>End</i> Date	Query Period <i>Start</i> Date	Query Period <i>End</i> Date
Analyses Defining Prevalent LAIA Use by National Drug Codes (NDCs):				
DP01	01/01/2010	03/31/2018	01/01/2010	03/31/2018
Analyses Defining Prevalent LAIA Use by NDCs or Healthcare Common Procedure Coding System (HCPCS) procedure codes:				
DP01	01/01/2010	03/31/2018	01/01/2010	05/18/2015

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

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

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

Code	Description	Code Type
Aripiprazol Extended Release		
Aripiprazole Lauroxil		
C9470	Injection, aripiprazole lauroxil, 1 mg	HCPCS
J1942	Injection, aripiprazole lauroxil, 1 mg	HCPCS
Fluphenazine Decanoate		
J2680	Injection, fluphenazine decanoate, up to 25 mg	HCPCS
Haloperidol Decanoate		
J1631	Injection, haloperidol decanoate, per 50 mg	HCPCS
Olanzapine Pamoate		
J2358	Injection, olanzapine, long-acting, 1 mg	HCPCS
Paliperidone Palmitate (ALL)		
C9255	Injection, paliperidone palmitate, 1 mg	HCPCS
J2426	Injection, paliperidone palmitate extended release, 1 mg	HCPCS
Risperidone Microspheres		
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 Centers for Medicare and Medicaid Services (CMS), 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
Pre-index enrollment requirement: 183 days
Enrollment gap: 45 days
Age groups: 0 - 17 years, 18 - 49, 50 - 64, 65 or greater Age
Stratifications: group, Sex, Calendar year, Age group*Sex
Data Source: CMS

Scenario	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	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	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	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	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

Appendix D. Specifications for Type 2 Request [cder_mpl1r_wp152]														
Scenario	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
5	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
6	Start of DP Data-End of DP death data	183 days	Paliperidone palmitate, 4-week (Invega Sustenna), 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
7	Start of DP Data-End of DP death data	183 days	Paliperidone palmitate, 12-week (Invega Trinza), 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
8	Start of DP Data-End of DP death data	183 days	Risperidone microspheres (Risperdal Consta), 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
9	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

Appendix D. Specifications for Type 2 Request [cder_mpl1r_wp152]

Scenario	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
10	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	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	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	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	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	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	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	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	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

NDC codes are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."