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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.

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\_wp127

**Request ID:** cder\_mpl1r\_wp127

**Request Description:** In this report we evaluated utilization and coding patterns of long acting injectable antipsychotic (LAIA) drugs in the Sentinel Distributed Database (SDD).

**Sentinel Routine Querying Module:** Cohort Identification and Descriptive Analysis (CIDA) module, version 7.2.1.

**Data Source:** We distributed this request to eight Data Partners on March 15, 2019. The study period included data from July 31, 2009 to August 31, 2018. Please see appendix A for a list of dates available data for each Data Partner.

**Study Design:** We designed this request to examine utilization and coding patterns of eight LAIA drugs within the SDD. To examine LAIA coding patterns, we performed separate analyses that defined LAIA use with National Drug Codes (NDCs), Healthcare Common Procedure Coding System (HCPCS) procedure codes, or a combination of NDCs and HCPCS. Descriptive analyses examined cumulative duration of use across all patient exposure episodes, episode duration per distinct exposure episode, days supplied per dispensing, and length of gaps between treatment episodes.

**Exposures of Interest:** The exposures of interest were eight LAIA drugs: aripiprazole extended release, aripiprazole lauroxil, fluphenazine decanoate, haloperidol decanoate, olanzapine pamoate, paliperidone palmitate (4-week), paliperidone palmitate (12-week), and risperidone microspheres. Each of the LAIA drugs were assessed separately and as a combined, "all exposures" group. To explore specific coding patterns, we defined LAIA use with 1) NDCs only, 2) HCPCS codes only, or 3) a combination of NDCs or HCPCS codes. In analyses focused only on HCPCS codes, it was not possible to distinguish paliperidone palmitate (4-week) and paliperidone palmitate (12-week) as both drugs are defined with the same HCPCS codes. Thus, paliperidone palmitate use was defined by a single exposure group in analyses that used HCPCS codes [i.e., 1) HCPCS codes only or 2) a combination of NDCs and HCPCS codes]. 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 codes used to define exposures in this request.

**Cohort Eligibility Criteria:** We required members included in the cohort to be continuously enrolled in health plans with medical and drug coverage for at least 183 days prior to their first qualifying (index) exposure, during which gaps in coverage of up to 45 days were allowed. We defined index exposure as the date of LAIA dispensing for NDCs and the date of LAIA Injection for HCPCS codes. For NDC analyses, 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 HCPCS analyses, we bridged consecutive injections into a single exposure episode if they occurred on consecutive days.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Switch Gap Inclusion Indicator** - 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 1. Summary of Cumulative Exposure Episode Duration for Long-Acting Injectable Antipsychotic (LAIA) in the Sentinel Distributed Database (SDD) between July 31, 2009 and August 31, 2018, by Code Type**

Exposures	Exposure Episode Duration (days)											
	Total Exposed Patients		1-30		31-60		61-90		91-120		121-150	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
<b>National Drug Code (NDC) Only</b>												
Aripiprazole (Abilify Maintena)	20,886	100.0%	3,648	17.5%	2,320	11.1%	1,722	8.2%	1,340	6.4%	1,083	5.2%
Aripiprazole lauroxil	2,571	100.0%	584	22.7%	397	15.4%	308	12.0%	205	8.0%	192	7.5%
Fluphenazine decanoate	36,107	100.0%	5,137	14.2%	2,990	8.3%	2,796	7.7%	1,960	5.4%	1,754	4.9%
Haloperidol decanoate	72,358	100.0%	10,964	15.2%	5,655	7.8%	4,516	6.2%	3,223	4.5%	2,764	3.8%
Olanzapine pamoate	1,773	100.0%	323	18.2%	151	8.5%	125	7.1%	91	5.1%	86	4.9%
Paliperidone palmitate (Sustenna, 4-wk)	80,433	100.0%	9,431	11.7%	6,676	8.3%	5,083	6.3%	4,280	5.3%	3,530	4.4%
Paliperidone palmitate (Trinza - 12-wk)	7,421	100.0%	423	5.7%	415	5.6%	986	13.3%	412	5.6%	400	5.4%
Risperidone microspheres	62,345	100.0%	9,853	15.8%	5,170	8.3%	3,955	6.3%	3,044	4.9%	2,530	4.1%
All LAIA	216,134	100.0%	24,111	11.2%	14,479	6.7%	11,564	5.4%	8,998	4.2%	7,944	3.7%
<b>Procedure (Px) Code Only</b>												
Aripiprazole (Abilify Maintena)	938	100.0%	*****	*****	*****	*****	0	0.0%	0	0.0%	0	0.0%
Aripiprazole lauroxil	19	100.0%	19	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Fluphenazine decanoate	6,089	100.0%	5,468	89.8%	427	7.0%	126	2.1%	*****	*****	30	0.5%
Haloperidol decanoate	11,813	100.0%	10,656	90.2%	861	7.3%	237	2.0%	43	0.4%	*****	*****
Olanzapine pamoate	4,274	100.0%	*****	*****	*****	*****	*****	*****	0	0.0%	0	0.0%
Paliperidone palmitate	6,104	100.0%	5,654	92.6%	395	6.5%	*****	*****	*****	*****	0	0.0%
Risperidone microspheres	8,528	100.0%	7,546	88.5%	545	6.4%	256	3.0%	112	1.3%	51	0.6%
All LAIA	34,144	100.0%	30,776	90.1%	2,285	6.7%	741	2.2%	207	0.6%	97	0.3%
<b>NDC and Px Code</b>												
Aripiprazole (Abilify Maintena)	21,451	100.0%	4,170	19.4%	2,354	11.0%	1,728	8.1%	1,340	6.2%	1,083	5.0%
Aripiprazole lauroxil	2,589	100.0%	602	23.3%	397	15.3%	308	11.9%	205	7.9%	192	7.4%
Fluphenazine decanoate	38,836	100.0%	7,347	18.9%	3,271	8.4%	2,861	7.4%	2,017	5.2%	1,781	4.6%
Haloperidol decanoate	77,633	100.0%	15,227	19.6%	6,208	8.0%	4,730	6.1%	3,322	4.3%	2,817	3.6%
Olanzapine pamoate	5,980	100.0%	4,523	75.6%	156	2.6%	127	2.1%	91	1.5%	85	1.4%
Paliperidone palmitate	83,095	100.0%	11,234	13.5%	6,923	8.3%	5,033	6.1%	4,087	4.9%	3,364	4.0%
Risperidone microspheres	66,443	100.0%	13,262	20.0%	5,449	8.2%	4,130	6.2%	3,146	4.7%	2,585	3.9%
All LAIA	229,967	100.0%	35,408	15.4%	15,762	6.9%	12,082	5.3%	9,245	4.0%	8,098	3.5%

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

**Table 1. Summary of Cumulative Exposure Episode Duration for Long-Acting Injectable Antipsychotic (LAIA) in the Sentinel Distributed Database (SDD) between July 31, 2009 and August 31, 2018, by Code Type**

Exposures	Exposure Episode Duration (days)											
	Total Exposed Patients		151-183		184-365		366-547		548-730		730+	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
<b>National Drug Code (NDC) Only</b>												
Aripiprazole (Abilify Maintena)	20,886	100.0%	1,077	5.2%	4,004	19.2%	2,179	10.4%	1,452	7.0%	2,061	9.9%
Aripiprazole lauroxil	2,571	100.0%	189	7.4%	605	23.5%	78	3.0%	*****	*****	*****	*****
Fluphenazine decanoate	36,107	100.0%	1,756	4.9%	6,649	18.4%	3,768	10.4%	2,673	7.4%	6,624	18.3%
Haloperidol decanoate	72,358	100.0%	2,614	3.6%	10,557	14.6%	6,950	9.6%	5,188	7.2%	19,927	27.5%
Olanzapine pamoate	1,773	100.0%	84	4.7%	288	16.2%	167	9.4%	124	7.0%	334	18.8%
Paliperidone palmitate (Sustenna, 4-wk)	80,433	100.0%	3,318	4.1%	13,580	16.9%	8,250	10.3%	5,965	7.4%	20,320	25.3%
Paliperidone palmitate (Trinza - 12-wk)	7,421	100.0%	801	10.8%	2,528	34.1%	1,398	18.8%	35	0.5%	23	0.3%
Risperidone microspheres	62,345	100.0%	2,570	4.1%	9,166	14.7%	5,397	8.7%	3,985	6.4%	16,675	26.7%
All LAIA	216,134	100.0%	7,736	3.6%	31,933	14.8%	21,710	10.0%	16,881	7.8%	70,778	32.7%
<b>Procedure (Px) Code Only</b>												
Aripiprazole (Abilify Maintena)	938	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Aripiprazole lauroxil	19	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Fluphenazine decanoate	6,089	100.0%	*****	*****	*****	*****	0	0.0%	0	0.0%	0	0.0%
Haloperidol decanoate	11,813	100.0%	*****	*****	*****	*****	0	0.0%	0	0.0%	0	0.0%
Olanzapine pamoate	4,274	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Paliperidone palmitate	6,104	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Risperidone microspheres	8,528	100.0%	*****	*****	*****	*****	0	0.0%	0	0.0%	0	0.0%
All LAIA	34,144	100.0%	*****	*****	*****	*****	0	0.0%	0	0.0%	0	0.0%
<b>NDC and Px Code</b>												
Aripiprazole (Abilify Maintena)	21,451	100.0%	1,077	5.0%	4,006	18.7%	2,180	10.2%	1,451	6.8%	2,062	9.6%
Aripiprazole lauroxil	2,589	100.0%	189	7.3%	605	23.4%	78	3.0%	*****	*****	*****	*****
Fluphenazine decanoate	38,836	100.0%	1,783	4.6%	6,669	17.2%	3,794	9.8%	2,677	6.9%	6,636	17.1%
Haloperidol decanoate	77,633	100.0%	2,638	3.4%	10,556	13.6%	6,967	9.0%	5,201	6.7%	19,967	25.7%
Olanzapine pamoate	5,980	100.0%	85	1.4%	288	4.8%	166	2.8%	125	2.1%	334	5.6%
Paliperidone palmitate	83,095	100.0%	3,189	3.8%	13,403	16.1%	8,536	10.3%	6,105	7.3%	21,221	25.5%
Risperidone microspheres	66,443	100.0%	2,591	3.9%	9,196	13.8%	5,391	8.1%	4,002	6.0%	16,691	25.1%
All LAIA	229,967	100.0%	7,804	3.4%	32,021	13.9%	21,757	9.5%	16,916	7.4%	70,874	30.8%

**Table 2. Descriptive Statistics of Cumulative Exposure Episode Duration for Long-Acting Injectable Antipsychotic (LAIA) in the Sentinel Distributed Database (SDD) between July 31, 2009 and August 31, 2018, by Code Type, in Days**

Exposures	Total Exposed Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
<b>National Drug Code (NDC) Only</b>								
Aripiprazole (Abilify Maintena)	20,886	276.39	289.29	1	58	168	398	1,519
Aripiprazole lauroxil	2,571	130.85	110.78	1	41	90	196	787
Fluphenazine decanoate	36,107	391.28	429.43	1	76	224	564	2,802
Haloperidol decanoate	72,358	515.97	556.38	1	84	284	810	3,075
Olanzapine pamoate	1,773	397.24	473.29	1	57	196	560	2,288
Paliperidone palmitate (Sustenna, 4-wk)	80,433	495.3	533.15	1	88	280	737	2,779
Paliperidone palmitate (Trinza - 12-wk)	7,421	227.5	143.88	1	93	206	339	914
Risperidone microspheres	62,345	525.3	609.05	1	70	252	790	3,009
All LAIA	216,134	605.25	606.26	1	112	376	956	3,075
<b>Procedure (Px) Code Only</b>								
Aripiprazole (Abilify Maintena)	938	5.14	6.42	1	1	2	6	42
Aripiprazole lauroxil	19	2.26	2.33	1	1	1	3	9
Fluphenazine decanoate	6,089	11.05	19.98	1	1	3	12	279
Haloperidol decanoate	11,813	10.3	16.68	1	1	3	12	215
Olanzapine pamoate	4,274	1.33	2.65	1	1	1	1	70
Paliperidone palmitate	6,104	8.84	12.6	1	1	3	11	109
Risperidone microspheres	8,528	12.17	22.65	1	1	3	12	226
All LAIA	34,144	10.44	18.75	1	1	2	11	279
<b>NDC and Px Code</b>								
Aripiprazole (Abilify Maintena)	21,451	269.31	288.73	1	56	153	391	1,519
Aripiprazole lauroxil	2,589	129.95	110.91	1	39	90	195	787
Fluphenazine decanoate	38,836	365.43	425.41	1	59	195	528	2,802
Haloperidol decanoate	77,633	482.46	551.9	1	56	240	753	3,075
Olanzapine pamoate	5,980	118.72	314.87	1	1	1	30	2,288
Paliperidone palmitate	83,095	498.63	545.25	1	84	280	746	2,847
Risperidone microspheres	66,443	494.36	602.73	1	56	218	735	3,009
All LAIA	229,967	570.35	604.37	1	84	330	906	3,075



**Table 3. Summary of Exposure Episode Duration per Distinct Exposure Episode for Long-Acting Injectable Antipsychotic (LAIA) in the Sentinel Distributed Database (SDD) between July 31, 2009 and August 31, 2018, by Code Type**

Exposures	Exposure Episode Duration (days)											
	Total Episodes		1-30		31-60		61-90		91-120		121-150	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
<b>National Drug Code (NDC) Only</b>												
Aripiprazole (Abilify Maintena)	72,250	100.0%	38,883	53.8%	12,557	17.4%	6,397	8.9%	3,569	4.9%	2,400	3.3%
Aripiprazole lauroxil	5,449	100.0%	3,061	56.2%	958	17.6%	505	9.3%	254	4.7%	196	3.6%
Fluphenazine decanoate	290,160	100.0%	198,504	68.4%	44,222	15.2%	23,285	8.0%	7,293	2.5%	4,624	1.6%
Haloperidol decanoate	594,567	100.0%	373,994	62.9%	92,246	15.5%	49,575	8.3%	21,235	3.6%	13,512	2.3%
Olanzapine pamoate	9,567	100.0%	5,697	59.5%	1,451	15.2%	708	7.4%	411	4.3%	275	2.9%
Paliperidone palmitate (Sustenna, 4-wk)	430,611	100.0%	226,869	52.7%	73,201	17.0%	37,585	8.7%	21,174	4.9%	14,149	3.3%
Paliperidone palmitate (Trinza - 12-wk)	13,746	100.0%	2,351	17.1%	1,167	8.5%	5,465	39.8%	530	3.9%	428	3.1%
Risperidone microspheres	392,341	100.0%	227,915	58.1%	59,910	15.3%	29,619	7.5%	16,900	4.3%	11,328	2.9%
All LAIA	1,757,014	100.0%	1,044,145	59.4%	278,660	15.9%	146,506	8.3%	69,809	4.0%	45,821	2.6%
<b>Procedure (Px) Code Only</b>												
Aripiprazole (Abilify Maintena)	4,820	100.0%	4,820	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Aripiprazole lauroxil	43	100.0%	43	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Fluphenazine decanoate	67,251	100.0%	67,251	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Haloperidol decanoate	121,592	100.0%	121,592	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Olanzapine pamoate	5,666	100.0%	5,666	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Paliperidone palmitate	53,914	100.0%	53,914	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Risperidone microspheres	103,737	100.0%	103,737	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
All LAIA	356,268	100.0%	356,268	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
<b>NDC and Px Code</b>												
Aripiprazole (Abilify Maintena)	76,372	100.0%	43,000	56.3%	12,562	16.4%	6,397	8.4%	3,569	4.7%	2,400	3.1%
Aripiprazole lauroxil	5,489	100.0%	3,101	56.5%	958	17.5%	505	9.2%	254	4.6%	196	3.6%
Fluphenazine decanoate	351,062	100.0%	259,329	73.9%	44,280	12.6%	23,291	6.6%	7,300	2.1%	4,627	1.3%
Haloperidol decanoate	703,759	100.0%	483,054	68.6%	92,323	13.1%	49,588	7.0%	21,247	3.0%	13,520	1.9%
Olanzapine pamoate	15,138	100.0%	11,268	74.4%	1,451	9.6%	708	4.7%	411	2.7%	275	1.8%
Paliperidone palmitate	482,634	100.0%	273,714	56.7%	73,104	15.1%	39,351	8.2%	21,406	4.4%	14,263	3.0%
Risperidone microspheres	484,631	100.0%	320,170	66.1%	59,925	12.4%	29,627	6.1%	16,902	3.5%	11,331	2.3%
All LAIA	2,071,817	100.0%	1,358,590	65.6%	278,879	13.5%	146,546	7.1%	69,836	3.4%	45,847	2.2%

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

**Table 3. Summary of Exposure Episode Duration per Distinct Exposure Episode for Long-Acting Injectable Antipsychotic (LAIA) in the Sentinel Distributed Database (SDD) between July 31, 2009 and August 31, 2018, by Code Type**

Exposures	Exposure Episode Duration (days)											
	Total Episodes		151-183		184-365		366-547		548-730		730+	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
<b>National Drug Code (NDC) Only</b>												
Aripiprazole (Abilify Maintena)	72,250	100.0%	1,797	2.5%	4,429	6.1%	1,203	1.7%	531	0.7%	484	0.7%
Aripiprazole lauroxil	5,449	100.0%	140	2.6%	306	5.6%	*****	*****	*****	*****	0	0.0%
Fluphenazine decanoate	290,160	100.0%	3,647	1.3%	6,146	2.1%	1,458	0.5%	530	0.2%	451	0.2%
Haloperidol decanoate	594,567	100.0%	10,376	1.7%	21,837	3.7%	5,878	1.0%	2,677	0.5%	3,237	0.5%
Olanzapine pamoate	9,567	100.0%	225	2.4%	507	5.3%	144	1.5%	62	0.6%	87	0.9%
Paliperidone palmitate (Sustenna, 4-wk)	430,611	100.0%	10,467	2.4%	27,826	6.5%	8,797	2.0%	4,206	1.0%	6,337	1.5%
Paliperidone palmitate (Trinza - 12-wk)	13,746	100.0%	1,427	10.4%	1,766	12.8%	573	4.2%	24	0.2%	15	0.1%
Risperidone microspheres	392,341	100.0%	9,226	2.4%	21,545	5.5%	6,709	1.7%	3,474	0.9%	5,715	1.5%
All LAIA	1,757,014	100.0%	35,807	2.0%	82,570	4.7%	24,834	1.4%	11,787	0.7%	17,075	1.0%
<b>Procedure (Px) Code Only</b>												
Aripiprazole (Abilify Maintena)	4,820	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Aripiprazole lauroxil	43	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Fluphenazine decanoate	67,251	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Haloperidol decanoate	121,592	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Olanzapine pamoate	5,666	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Paliperidone palmitate	53,914	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Risperidone microspheres	103,737	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
All LAIA	356,268	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
<b>NDC and Px Code</b>												
Aripiprazole (Abilify Maintena)	76,372	100.0%	1,797	2.4%	4,429	5.8%	1,203	1.6%	531	0.7%	484	0.6%
Aripiprazole lauroxil	5,489	100.0%	140	2.6%	306	5.6%	*****	*****	*****	*****	0	0.0%
Fluphenazine decanoate	351,062	100.0%	3,648	1.0%	6,148	1.8%	1,458	0.4%	530	0.2%	451	0.1%
Haloperidol decanoate	703,759	100.0%	10,383	1.5%	21,848	3.1%	5,881	0.8%	2,678	0.4%	3,237	0.5%
Olanzapine pamoate	15,138	100.0%	225	1.5%	507	3.3%	144	1.0%	62	0.4%	87	0.6%
Paliperidone palmitate	482,634	100.0%	11,015	2.3%	29,054	6.0%	9,525	2.0%	4,472	0.9%	6,730	1.4%
Risperidone microspheres	484,631	100.0%	9,228	1.9%	21,547	4.4%	6,710	1.4%	3,476	0.7%	5,715	1.2%
All LAIA	2,071,817	100.0%	35,818	1.7%	82,590	4.0%	24,842	1.2%	11,793	0.6%	17,076	0.8%

**Table 4. Descriptive Statistics of Exposure Episode Duration per Distinct Exposure Episode for Long-Acting Injectable Antipsychotic (LAIA) in the Sentinel Distributed Database (SDD) between July 31, 2009 and August 31, 2018, by Code Type, in Days**

Exposures	Number of Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
<b>National Drug Code (NDC) Only</b>								
Aripiprazole (Abilify Maintena)	72,250	79.9	116.8	1	28	30	84	1,519
Aripiprazole lauroxil	5,449	61.74	65.13	1	28	30	72	728
Fluphenazine decanoate	290,160	48.69	68.6	1	28	30	56	2,347
Haloperidol decanoate	594,567	62.79	111.5	1	28	30	58	3,075
Olanzapine pamoate	9,567	73.62	137.37	1	21	28	63	2,232
Paliperidone palmitate (Sustenna, 4-wk)	430,611	92.52	167.08	1	28	30	84	2,578
Paliperidone palmitate (Trinza - 12-wk)	13,746	122.82	106.66	1	59	90	168	914
Risperidone microspheres	392,341	83.47	171.17	1	20	28	70	2,664
All LAIA	1,757,014	74.45	141.51	1	28	30	60	3,075
<b>Procedure (Px) Code Only</b>								
Aripiprazole (Abilify Maintena)	4,820	1	0.02	1	1	1	1	2
Aripiprazole lauroxil	43	1	0	1	1	1	1	1
Fluphenazine decanoate	67,251	1	0.02	1	1	1	1	2
Haloperidol decanoate	121,592	1	0.02	1	1	1	1	2
Olanzapine pamoate	5,666	1.01	0.09	1	1	1	1	3
Paliperidone palmitate	53,914	1	0.02	1	1	1	1	2
Risperidone microspheres	103,737	1	0.03	1	1	1	1	5
All LAIA	356,268	1	0.03	1	1	1	1	5
<b>NDC and Px Code</b>								
Aripiprazole (Abilify Maintena)	76,372	75.64	114.99	1	28	30	84	1,519
Aripiprazole lauroxil	5,489	61.3	65.1	1	28	30	70	728
Fluphenazine decanoate	351,062	40.43	64.93	1	14	28	34	2,347
Haloperidol decanoate	703,759	53.22	104.91	1	14	28	56	3,075
Olanzapine pamoate	15,138	46.9	114.68	1	1	14	42	2,232
Paliperidone palmitate	482,634	85.85	165.12	1	28	30	84	2,847
Risperidone microspheres	484,631	67.78	157.39	1	14	28	56	2,664
All LAIA	2,071,817	63.31	132.97	1	14	28	56	3,075

**Table 5. Summary of Days Supplied per Dispensing for Long-Acting Injectable Antipsychotic (LAIA) in the Sentinel Distributed Database (SDD) between July 31, 2009 and August 31, 2018, by Code Type**

Exposures	Days Supplied (days)															
	Total Dispensings		1		2		3		4		5		6		7	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
<b>National Drug Code (NDC) Only</b>																
Aripiprazole (Abilify Maintena)	207,637	100.0%	1,045	0.5%	438	0.2%	405	0.2%	364	0.2%	385	0.2%	262	0.1%	148	0.1%
Aripiprazole lauroxil	12,244	100.0%	73	0.6%	59	0.5%	84	0.7%	64	0.5%	68	0.6%	36	0.3%	*****	*****
Fluphenazine decanoate	475,840	100.0%	2,456	0.5%	858	0.2%	898	0.2%	518	0.1%	4,580	1.0%	860	0.2%	3,415	0.7%
Haloperidol decanoate	1,365,831	100.0%	18,708	1.4%	9,378	0.7%	4,501	0.3%	2,126	0.2%	4,827	0.4%	2,656	0.2%	6,239	0.5%
Olanzapine pamoate	33,139	100.0%	452	1.4%	109	0.3%	49	0.1%	22	0.1%	41	0.1%	14	0.0%	47	0.1%
Paliperidone palmitate (Sustenna, 4-wk)	1,451,174	100.0%	13,339	0.9%	4,837	0.3%	1,617	0.1%	1,563	0.1%	1,756	0.1%	1,179	0.1%	7,303	0.5%
Paliperidone palmitate (Trinza - 12-wk)	23,363	100.0%	121	0.5%	88	0.4%	133	0.6%	83	0.4%	102	0.4%	45	0.2%	50	0.2%
Risperidone microspheres	1,529,770	100.0%	6,293	0.4%	4,305	0.3%	2,567	0.2%	1,257	0.1%	1,931	0.1%	1,000	0.1%	7,891	0.5%
All LAIA	5,078,388	100.0%	42,408	0.8%	20,031	0.4%	10,231	0.2%	5,988	0.1%	13,652	0.3%	6,078	0.1%	25,027	0.5%
<b>Procedure (Px) Code Only</b>																
Aripiprazole (Abilify Maintena)	4,822	100.0%	4,822	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Aripiprazole lauroxil	43	100.0%	43	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Fluphenazine decanoate	67,283	100.0%	67,283	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Haloperidol decanoate	121,654	100.0%	121,654	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Olanzapine pamoate	5,707	100.0%	5,707	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Paliperidone palmitate	53,934	100.0%	53,934	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Risperidone microspheres	103,819	100.0%	103,819	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
All LAIA	357,468	100.0%	357,468	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
<b>NDC and Px Code</b>																
Aripiprazole (Abilify Maintena)	212,472	100.0%	5,875	2.8%	438	0.2%	405	0.2%	364	0.2%	385	0.2%	262	0.1%	148	0.1%
Aripiprazole lauroxil	12,284	100.0%	113	0.9%	59	0.5%	84	0.7%	64	0.5%	68	0.6%	36	0.3%	*****	*****
Fluphenazine decanoate	543,051	100.0%	69,577	12.8%	861	0.2%	898	0.2%	518	0.1%	4,580	0.8%	860	0.2%	3,415	0.6%
Haloperidol decanoate	1,487,682	100.0%	140,190	9.4%	9,378	0.6%	4,505	0.3%	2,126	0.1%	4,828	0.3%	2,657	0.2%	6,239	0.4%
Olanzapine pamoate	38,846	100.0%	6,159	15.9%	109	0.3%	49	0.1%	22	0.1%	41	0.1%	14	0.0%	47	0.1%
Paliperidone palmitate	1,525,982	100.0%	67,326	4.4%	4,910	0.3%	1,733	0.1%	1,633	0.1%	1,836	0.1%	1,242	0.1%	7,364	0.5%
Risperidone microspheres	1,632,455	100.0%	108,762	6.7%	4,305	0.3%	2,567	0.2%	1,257	0.1%	1,932	0.1%	1,000	0.1%	7,892	0.5%
All LAIA	5,434,916	100.0%	397,759	7.3%	20,039	0.4%	10,235	0.2%	5,988	0.1%	13,655	0.3%	6,080	0.1%	25,028	0.5%

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

**Table 5. Summary of Days Supplied per Dispensing for Long-Acting Injectable Antipsychotic (LAIA) in the Sentinel Distributed Database (SDD) between July 31, 2009 and August 31, 2018, by Code Type**

Exposures	Days Supplied (days)															
	Total Dispensings		8-15		16-30		31-45		46-60		61-75		75-90		91+	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
<b>National Drug Code (NDC) Only</b>																
Aripiprazole (Abilify Maintena)	207,637	100.0%	2,409	1.2%	201,025	96.8%	549	0.3%	330	0.2%	*****	*****	264	0.1%	*****	*****
Aripiprazole lauroxil	12,244	100.0%	357	2.9%	10,996	89.8%	451	3.7%	26	0.2%	*****	*****	16	0.1%	*****	*****
Fluphenazine decanoate	475,840	100.0%	59,998	12.6%	340,940	71.7%	23,801	5.0%	12,077	2.5%	10,199	2.1%	14,165	3.0%	1,075	0.2%
Haloperidol decanoate	1,365,831	100.0%	124,396	9.1%	1,121,461	82.1%	19,151	1.4%	20,933	1.5%	4,863	0.4%	25,925	1.9%	667	0.0%
Olanzapine pamoate	33,139	100.0%	13,893	41.9%	18,434	55.6%	56	0.2%	*****	*****	0	0.0%	*****	*****	0	0.0%
Paliperidone palmitate (Sustenna, 4-wk)	1,451,174	100.0%	21,077	1.5%	1,382,885	95.3%	5,585	0.4%	7,467	0.5%	190	0.0%	2,320	0.2%	56	0.0%
Paliperidone palmitate (Trinza - 12-wk)	23,363	100.0%	482	2.1%	2,642	11.3%	1,180	5.1%	1,028	4.4%	926	4.0%	16,381	70.1%	102	0.4%
Risperidone microspheres	1,529,770	100.0%	701,664	45.9%	789,837	51.6%	3,397	0.2%	6,752	0.4%	259	0.0%	2,575	0.2%	42	0.0%
All LAIA	5,078,388	100.0%	922,885	18.2%	3,851,054	75.8%	53,992	1.1%	48,424	1.0%	16,316	0.3%	60,310	1.2%	1,992	0.0%
<b>Procedure (Px) Code Only</b>																
Aripiprazole (Abilify Maintena)	4,822	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Aripiprazole lauroxil	43	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Fluphenazine decanoate	67,283	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Haloperidol decanoate	121,654	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Olanzapine pamoate	5,707	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Paliperidone palmitate	53,934	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Risperidone microspheres	103,819	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
All LAIA	357,468	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
<b>NDC and Px Code</b>																
Aripiprazole (Abilify Maintena)	212,472	100.0%	2,409	1.1%	201,030	94.6%	549	0.3%	330	0.2%	*****	*****	264	0.1%	*****	*****
Aripiprazole lauroxil	12,284	100.0%	357	2.9%	10,996	89.5%	451	3.7%	26	0.2%	*****	*****	16	0.1%	*****	*****
Fluphenazine decanoate	543,051	100.0%	60,003	11.0%	341,013	62.8%	23,805	4.4%	12,077	2.2%	10,201	1.9%	14,167	2.6%	1,076	0.2%
Haloperidol decanoate	1,487,682	100.0%	124,426	8.4%	1,121,782	75.4%	19,151	1.3%	20,941	1.4%	4,865	0.3%	25,927	1.7%	667	0.0%
Olanzapine pamoate	38,846	100.0%	13,893	35.8%	18,434	47.5%	56	0.1%	*****	*****	0	0.0%	*****	*****	0	0.0%
Paliperidone palmitate	1,525,982	100.0%	21,544	1.4%	1,384,471	90.7%	6,758	0.4%	8,462	0.6%	1,030	0.1%	17,470	1.1%	203	0.0%
Risperidone microspheres	1,632,455	100.0%	701,779	43.0%	789,936	48.4%	3,397	0.2%	6,752	0.4%	259	0.0%	2,575	0.2%	42	0.0%
All LAIA	5,434,916	100.0%	923,067	17.0%	3,852,001	70.9%	53,999	1.0%	48,437	0.9%	16,321	0.3%	60,313	1.1%	1,994	0.0%

**Table 6. Descriptive Statistics of Days Supplied per Dispensing for Long-Acting Injectable Antipsychotic (LAIA) in the Sentinel Distributed Database (SDD) between July 31, 2009 and August 31, 2018, by Code Type, in Days**

Exposures	Number of Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
<b>National Drug Code (NDC) Only</b>								
Aripiprazole (Abilify Maintena)	207,637	27.8	4.7	1	28	28	30	293
Aripiprazole lauroxil	12,244	27.48	6.72	1	28	28	30	112
Fluphenazine decanoate	475,840	29.69	15.59	1	28	28	30	692
Haloperidol decanoate	1,365,831	27.33	11.85	1	28	28	29	750
Olanzapine pamoate	33,139	21.25	7.59	1	14	21	28	90
Paliperidone palmitate (Sustenna, 4-wk)	1,451,174	27.45	5.67	1	28	28	28	390
Paliperidone palmitate (Trinza - 12-wk)	23,363	72.26	26.73	1	59	84	90	291
Risperidone microspheres	1,529,770	21.41	8.26	1	14	28	28	180
All LAIA	5,078,388	25.98	10.61	1	21	28	28	750
<b>Procedure (Px) Code Only</b>								
Aripiprazole (Abilify Maintena)	4,822	1	0	1	1	1	1	1
Aripiprazole lauroxil	43	1	0	1	1	1	1	1
Fluphenazine decanoate	67,283	1	0	1	1	1	1	1
Haloperidol decanoate	121,654	1	0	1	1	1	1	1
Olanzapine pamoate	5,707	1	0	1	1	1	1	1
Paliperidone palmitate	53,934	1	0	1	1	1	1	1
Risperidone microspheres	103,819	1	0	1	1	1	1	1
All LAIA	357,468	1	0	1	1	1	1	1
<b>NDC and Px Code</b>								
Aripiprazole (Abilify Maintena)	212,472	27.19	6.13	1	28	28	30	293
Aripiprazole lauroxil	12,284	27.39	6.88	1	28	28	30	112
Fluphenazine decanoate	543,051	26.14	17.38	1	14	28	30	692
Haloperidol decanoate	1,487,682	25.18	13.45	1	21	28	28	750
Olanzapine pamoate	38,846	18.28	10.03	1	14	14	28	90
Paliperidone palmitate	1,525,982	27.16	9.69	1	28	28	28	390
Risperidone microspheres	1,632,455	20.13	9.41	1	14	15	28	180
All LAIA	5,434,916	24.34	11.98	1	14	28	28	750

**Table 7. Descriptive Statistics of Episode Gaps for Long-Acting Injectable Antipsychotic (LAIA) in the Sentinel Distributed Database (SDD) between July 31, 2009 and August 31, 2018, by Code Type<sup>1</sup>, in Days**

Exposures	Number of Gaps	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
<b>National Drug Code (NDC) Only</b>								
Aripiprazole (Abilify Maintena)	51,364	23.22	64.17	1	3	7	20	1,220
Aripiprazole lauroxil	2,878	16.55	28.98	1	3	8	20	599
Fluphenazine decanoate	254,053	52.50	114.87	1	10	24	52	2,561
Haloperidol decanoate	522,209	41.10	108.41	1	5	15	35	2,930
Olanzapine pamoate	7,794	19.50	77.39	1	2	6	14	2,401
Paliperidone palmitate (Sustenna, 4-wk)	350,178	32.56	117.52	1	3	7	21	2,700
Paliperidone palmitate (Trinza - 12-wk)	6,325	26.52	33.48	1	4	12	47	454
Risperidone microspheres	329,996	23.73	92.52	1	2	7	15	2,709
All LAIA	1,540,880	39.97	118.20	1	4	12	30	2,930
<b>Procedure (Px) Code Only</b>								
Aripiprazole (Abilify Maintena)	3,882	37.08	37.67	2	27	27	33	850
Aripiprazole lauroxil	24	28.25	7.00	7	27	28	32	47
Fluphenazine decanoate	61,162	38.03	95.81	1	13	20	29	2,369
Haloperidol decanoate	109,779	46.02	105.13	1	25	27	34	2,775
Olanzapine pamoate	1,392	119.03	244.51	1	20	28	80	1,887
Paliperidone palmitate	47,810	41.83	76.35	1	27	27	33	2,686
Risperidone microspheres	95,209	28.12	74.16	1	13	13	27	2,288
All LAIA	322,124	40.53	100.99	1	13	27	30	2,686
<b>NDC and Px Code</b>								
Aripiprazole (Abilify Maintena)	54,921	24.08	62.71	1	3	7	25	1,220
Aripiprazole lauroxil	2,900	16.64	28.89	1	3	8	20	599
Fluphenazine decanoate	312,226	49.40	110.54	1	12	23	46	2,561
Haloperidol decanoate	626,126	41.56	107.50	1	6	20	34	2,930
Olanzapine pamoate	9,158	34.90	127.06	1	3	7	21	2,401
Paliperidone palmitate	399,539	32.98	112.42	1	3	8	27	2,700
Risperidone microspheres	418,188	24.23	87.47	1	3	10	17	2,709
All LAIA	1,841,850	39.60	114.15	1	5	14	30	2,930

<sup>1</sup> Gaps described in this table represent gaps between valid treatment episodes. Information on the time from the final treatment episode until censoring is not present.

**Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (March 15, 2019)**

<b>DP ID</b>	<b>DP Start Date*</b>	<b>DP End Date*</b>
DP01	01/01/2010	12/31/2016
DP02	01/01/2000	06/30/2018
DP03	01/01/2000	03/31/2018
DP04	01/01/2000	07/31/2017
DP05	01/01/2000	12/31/2017
DP06	01/01/2000	06/30/2018
DP07	01/01/2004	08/31/2018
DP08	01/01/2000	12/31/2017

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



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

Generic Name	Brand Name
Aripiprazole	Abilify Maintena
Aripiprazole lauroxil	Aristada
Fluphenazine decanoate	Fluphenazine Decanoate
Haloperidol decanoate	Haldol Decanoate
Haloperidol decanoate	Haloperidol Decanoate
Olanzapine pamoate	Zyprexa Relprevv
Paliperidone palmitate	Invega Sustenna
Paliperidone palmitate	Invega Trinza
Risperidone microspheres	Risperdal Consta

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

<b>Code</b>	<b>Description</b>	<b>Code Category</b>	<b>Code Type</b>
J0401	Injection, aripiprazole, extended release, 1 mg	Procedure	HCPCS
C9470	Injection, aripiprazole lauroxil, 1 mg	Procedure	HCPCS
J1942	Injection, aripiprazole lauroxil, 1 mg	Procedure	HCPCS
J2680	Injection, fluphenazine decanoate, up to 25 mg	Procedure	HCPCS
J1631	Injection, haloperidol decanoate, per 50 mg	Procedure	HCPCS
J2358	Injection, olanzapine, long-acting, 1 mg	Procedure	HCPCS
C9255	Injection, paliperidone palmitate, 1 mg	Procedure	HCPCS
J2426	Injection, paliperidone palmitate extended release, 1 mg	Procedure	HCPCS
J2794	Injection, risperidone, long acting, 0.5 mg	Procedure	HCPCS
C9125	Injection, risperidone, per 12.5 mg	Procedure	HCPCS
S0163	Injection, risperidone, long acting, 12.5 mg	Procedure	HCPCS

**Appendix D. Specifications Defining Parameters in this Request**

This request utilized the Cohort Identification and Descriptive Analysis (CIDA) module, version 7.2.1 to assess utilization and coding patterns of long-acting injectable antipsychotics in the Sentinel Distributed Database (SDD).

**Query Period:** July 31, 2009 to August 31, 2018  
**Enrollment Gap:** 45 days  
**Age Groups:** 0-17, 18-49, 50-64, 65+ years  
**Enrollment Requirement:** 183 days  
**Coverage Requirement:** Medical and Drug Coverage

**Exposure**

Scenario	Index Exposure	Code Type	Cohort Definition	Care Setting	Washout Period (days)	Incident with Respect to:	Episode Gap (days)	Censor Episode at Evidence of:
1	Aripiprazole extended release (Abilify Maintena)	National Drug Code (NDC)	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
2	Aripiprazole lauroxil (Aristada)	NDC	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
3	Fluphenazine decanoate	NDC	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
4	Haloperidol decanoate	NDC	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
5	Olanzapine pamoate (Zyprexa Relprevv)	NDC	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
6	Paliperidone palmitate, 4-week (Invega Sustenna)	NDC	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date

**Appendix D. Specifications Defining Parameters in this Request**

Exposure								
Scenario	Index Exposure	Code Type	Cohort Definition	Care Setting	Washout Period (days)	Incident with Respect to:	Episode Gap (days)	Censor Episode at Evidence of:
7	Paliperidone palmitate, 12-week (Invega Trinza)	NDC	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
8	Risperidone microspheres (Risperdal Consta)	NDC	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
9	All Injectable Antipsychotics	NDC	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
10	Aripiprazole, extended release, 1 mg	Healthcare Common Procedure Coding System (HCPCS)	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
11	Aripiprazole lauroxil, 1 mg	HCPCS	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
12	Fluphenazine decanoate, up to 25 mg	HCPCS	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
13	Haloperidol decanoate, per 50 mg	HCPCS	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
14	Olanzapine, long-acting, 1 mg	HCPCS	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date

**Appendix D. Specifications Defining Parameters in this Request**

Exposure								
Scenario	Index Exposure	Code Type	Cohort Definition	Care Setting	Washout Period (days)	Incident with Respect to:	Episode Gap (days)	Censor Episode at Evidence of:
15	Paliperidone palmitate, 1 mg, or paliperidone palmitate extended release, 1 mg	HCPCS	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
16	Risperidone	HCPCS	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
17	All Injectable Antipsychotics	HCPCS	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
18	Aripiprazole extended release	NDC and HCPCS	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
19	Aripiprazole lauroxil	NDC and HCPCS	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
20	Fluphenazine decanoate	NDC and HCPCS	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
21	Haloperidol decanoate	NDC and HCPCS	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
22	Olanzapine pamoate	NDC and HCPCS	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date

**Appendix D. Specifications Defining Parameters in this Request**

Exposure								
Scenario	Index Exposure	Code Type	Cohort Definition	Care Setting	Washout Period (days)	Incident with Respect to:	Episode Gap (days)	Censor Episode at Evidence of:
23	Paliperidone palmitate	NDC and HCPCS	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
24	Risperidone microspheres	NDC and HCPCS	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date
25	All Injectable Antipsychotics	NDC and HCPCS	All valid exposure episodes during query period	Any	0	N/A	0	Death; Data Partner End Date

HCPCS codes are provided by Optum360.

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