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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 to16_cap_mpl1r_wp035_nsdp_v01

Request ID: to16_cap_mpl1r_wp035_nsdp_v01

Report Description: FDA has requested execution of the Cohort Identification and Descriptive Analysis (CIDA) Tool, version 2.0.8, to investigate the estimated numbers of extended-release and long-acting (ER/LA) opioid analgesics users.

Data Source: Data from January 1, 2009 to December 31, 2013, from 15 Data Partners contributing to the Mini-Sentinel Distributed Database (MSDD), were included in this report.

Study Design: This request was designed to calculate background rates. The number of qualifying users with the exposure, number of eligible members, and member days were calculated overall and were stratified by age group, sex, and year.

Exposure of Interest: The exposures of interest were ER/LA opioid analgesics, including Butrans, Duragesic, generic fentanyl patch, Hysingla ER, Zohydro ER, Exalgo ER, generic ER/LA hydromorphone, Palladone, Avinza, Kadian, generic ER/LA morphine, MS Contin, Oramorph SR, Embeda, generic ER/LA oxycodone, OxyContin, Opana ER, generic ER/LA oxymorphone, Nucynta ER, Dolophine, generic methadone (5-10 mg tablets), generic methadone (40 mg soluble tablets), and generic methadone (liquid formulations). All ER/LA opioid analgesics were defined using National Drug Codes (NDCs).

Cohort Eligibility Criteria: Those included in the cohort were required to be continuously enrolled in plans with both medical and drug coverage for at least six months (183 days) before their dispensing date, during which gaps in coverage of up to 45 days were allowed. Individuals were also required to have no evidence of any ER/LA opioid in the six months (183 days) prior to the dispensing of the drug of interest.

A sensitivity analysis was run to examine a less strict definition of cohort eligibility, in which individuals were required to be continuously enrolled in plans with both medical and drug coverage for at least three months (90 days) before their dispensing date, during which gaps in coverage of up to 45 days were allowed. Individuals were also required to have no evidence of any ER/LA opioid in the three months (90 days) prior to the dispensing of the drug of interest.

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

Limitations: Algorithms to define exposures are imperfect and, therefore, may be misclassified.

Notes: Please contact the Sentinel Operations Center Query Fulfillment Team (qf@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. This is equivalent to the

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). Along with the Principal Diagnosis Indicator, forms the Care Setting/PDX

Cohort Definition (drug/exposure) - indicates how the cohort will be defined: (1) Cohort includes only the first valid incident treatment episode during the query period; (2) Cohort includes all valid incident treatment episodes during the query period; (3) Cohort includes all valid incident treatment episodes during the query period until an event occurs.

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

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

Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered

Episodes - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings

Event Deduplication - specifies how events are counted by the MP algorithm: (0) Counts all occurrences of an 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

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

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.

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

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

Treatment Episode Truncation Indicator - indicates whether observation of the incident query code during follow-up requires truncation of valid treatment episodes. A value of Y indicates that the treatment episodes should be truncated at the first occurrence of an incident query code. A value of N indicates that the treatment episodes should not be truncated at the occurrence of the incident query code.

Users - number of members with exposure during the query period. Member must have no evidence of exposure(s) of interest (defined by incidence criteria) in the prior washout period. A user may only be counted once in a query period.

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

**incident treatment episodes must be incident to both the exposure and the event

Table 1: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure and Washout/Enrollment Requirement

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
Butrans								
<i>183-Day Washout/Enrollment Requirement</i>	17,095	17,362	477,334	68,619	74,713,198	152,256,262.3	22.88	27.49
<i>90-Day Washout/Enrollment Requirement</i>	19,474	20,211	556,035	79,941	81,057,299	164,986,575.7	24.02	27.51
Duragesic								
<i>183-Day Washout/Enrollment Requirement</i>	1,591	1,612	41,910	15,003	74,713,198	152,256,262.3	2.13	26.00
<i>90-Day Washout/Enrollment Requirement</i>	1,987	2,058	54,427	19,838	81,057,299	164,986,575.7	2.45	26.45
Generic fentanyl patch								
<i>183-Day Washout/Enrollment Requirement</i>	81,174	84,107	2,122,498	737,128	74,713,198	152,256,262.3	108.65	25.24
<i>90-Day Washout/Enrollment Requirement</i>	93,417	100,334	2,561,903	896,011	81,057,299	164,986,575.7	115.25	25.53
Hysingla ER								
<i>183-Day Washout/Enrollment Requirement</i>	0	0	0	0	74,713,198	152,256,262.3	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>	0	0	0	0	81,057,299	164,986,575.7	0.00	---
Zohydro ER								
<i>183-Day Washout/Enrollment Requirement</i>	0	0	0	0	74,713,198	152,256,262.3	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>	0	0	0	0	81,057,299	164,986,575.7	0.00	---
Exalgo ER								
<i>183-Day Washout/Enrollment Requirement</i>	2,695	2,732	73,143	87,373	74,713,198	152,256,262.3	3.61	26.77
<i>90-Day Washout/Enrollment Requirement</i>	3,376	3,479	93,174	111,897	81,057,299	164,986,575.7	4.16	26.78
Generic ER/LA hydromorphone								
<i>183-Day Washout/Enrollment Requirement</i>	0	0	0	0	74,713,198	152,256,262.3	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>	0	0	0	0	81,057,299	164,986,575.7	0.00	---
Palladone								
<i>183-Day Washout/Enrollment Requirement</i>	0	0	0	0	74,713,198	152,256,262.3	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>	0	0	0	0	81,057,299	164,986,575.7	0.00	---
Avinza								
<i>183-Day Washout/Enrollment Requirement</i>	3,458	3,548	96,368	109,304	74,713,198	152,256,262.3	4.63	27.16
<i>90-Day Washout/Enrollment Requirement</i>	4,251	4,534	125,008	145,285	81,057,299	164,986,575.7	5.24	27.57
Kadian								
<i>183-Day Washout/Enrollment Requirement</i>	5,693	5,816	149,988	255,916	74,713,198	152,256,262.3	7.62	25.79
<i>90-Day Washout/Enrollment Requirement</i>	6,832	7,195	188,013	324,785	81,057,299	164,986,575.7	8.43	26.13
Generic ER/LA morphine								
<i>183-Day Washout/Enrollment Requirement</i>	126,969	133,461	3,171,111	6,903,068	74,713,198	152,256,262.3	169.94	23.76
<i>90-Day Washout/Enrollment Requirement</i>	144,634	159,266	3,856,113	8,532,360	81,057,299	164,986,575.7	178.43	24.21
MS Contin								
<i>183-Day Washout/Enrollment Requirement</i>	168	173	4,165	9,999	74,713,198	152,256,262.3	0.22	24.08
<i>90-Day Washout/Enrollment Requirement</i>	199	216	5,395	13,547	81,057,299	164,986,575.7	0.25	24.98
Oramorph SR								
<i>183-Day Washout/Enrollment Requirement</i>	203	203	2,929	6,621	74,713,198	152,256,262.3	0.27	14.43
<i>90-Day Washout/Enrollment Requirement</i>	242	244	3,888	8,905	81,057,299	164,986,575.7	0.30	15.93
Embeda								
<i>183-Day Washout/Enrollment Requirement</i>	2,202	2,209	57,999	98,637	74,713,198	152,256,262.3	2.95	26.26
<i>90-Day Washout/Enrollment Requirement</i>	2,568	2,590	68,106	115,761	81,057,299	164,986,575.7	3.17	26.30
Generic ER/LA Oxycodone								
<i>183-Day Washout/Enrollment Requirement</i>	26,073	26,280	454,299	994,491	74,713,198	152,256,262.3	34.90	17.29
<i>90-Day Washout/Enrollment Requirement</i>	30,036	30,667	548,209	1,210,307	81,057,299	164,986,575.7	37.06	17.88
OxyContin								
<i>183-Day Washout/Enrollment Requirement</i>	175,993	183,898	3,233,057	7,024,033	74,713,198	152,256,262.3	235.56	17.58
<i>90-Day Washout/Enrollment Requirement</i>	196,507	212,088	3,840,304	8,410,298	81,057,299	164,986,575.7	242.43	18.11

Table 1: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure and Washout/Enrollment Requirement

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
Opana ER								
<i>183-Day Washout/Enrollment Requirement</i>	21,652	22,367	577,650	1,170,865	74,713,198	152,256,262.3	28.98	25.83
<i>90-Day Washout/Enrollment Requirement</i>	25,867	27,664	720,415	1,471,546	81,057,299	164,986,575.7	31.91	26.04
Generic ER/LA Oxymorphone								
<i>183-Day Washout/Enrollment Requirement</i>	661	663	17,944	37,279	74,713,198	152,256,262.3	0.88	27.06
<i>90-Day Washout/Enrollment Requirement</i>	864	873	23,689	49,643	81,057,299	164,986,575.7	1.07	27.14
Nucynta ER								
<i>183-Day Washout/Enrollment Requirement</i>	6,477	6,588	168,490	332,963	74,713,198	152,256,262.3	8.67	25.58
<i>90-Day Washout/Enrollment Requirement</i>	7,394	7,705	198,036	391,811	81,057,299	164,986,575.7	9.12	25.70
Dolophine								
<i>183-Day Washout/Enrollment Requirement</i>	0	0	0	0	74,713,198	152,256,262.3	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>	1	1	30	270	81,057,299	164,986,575.7	0.00	30.00
Generic Methadone (5-10 mg tablets)								
<i>183-Day Washout/Enrollment Requirement</i>	26,636	27,935	710,504	2,209,679	74,713,198	152,256,262.3	35.65	25.43
<i>90-Day Washout/Enrollment Requirement</i>	34,313	38,712	1,017,308	3,409,748	81,057,299	164,986,575.7	42.33	26.28
Generic Methadone (40 mg soluble tablets)								
<i>183-Day Washout/Enrollment Requirement</i>	28	28	596	2,561	74,713,198	152,256,262.3	0.04	21.29
<i>90-Day Washout/Enrollment Requirement</i>	33	34	745	2,997	81,057,299	164,986,575.7	0.04	21.91
Generic Methadone (liquid formulations)								
<i>183-Day Washout/Enrollment Requirement</i>	1,291	1,319	23,788	212,515	74,713,198	152,256,262.3	1.73	18.03
<i>90-Day Washout/Enrollment Requirement</i>	1,619	1,693	30,669	258,000	81,057,299	164,986,575.7	2.00	18.12

Table 2: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Age Group

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
Butrans								
<i>183-Day Washout/Enrollment Requirement</i>								
00-11 Years	1	1	28	4	13,243,618	23,653,754.0	0.01	28.00
12-17 Years	35	36	991	145	8,633,823	13,935,646.3	0.41	27.53
18-24 Years	574	581	15,649	2,260	10,899,829	15,585,775.5	5.27	26.93
25-34 Years	2,335	2,356	64,091	9,199	15,396,777	22,357,997.7	15.17	27.20
35-44 Years	4,003	4,047	111,476	16,012	14,962,986	25,375,108.5	26.75	27.55
45-54 Years	5,604	5,691	156,547	22,492	15,343,471	28,416,164.8	36.52	27.51
55-64 Years	4,567	4,650	128,552	18,507	11,560,076	22,931,815.6	39.51	27.65
<i>90-Day Washout/Enrollment Requirement</i>								
00-11 Years	1	1	28	4	14,544,740	25,993,984.2	0.01	28.00
12-17 Years	37	39	1,077	157	9,218,653	14,903,602.1	0.40	27.62
18-24 Years	665	681	18,315	2,646	12,220,104	17,230,343.5	5.44	26.89
25-34 Years	2,746	2,823	76,934	11,051	17,149,837	24,891,976.4	16.01	27.25
35-44 Years	4,635	4,775	131,548	18,887	16,167,837	27,444,834.0	28.67	27.55
45-54 Years	6,396	6,623	182,497	26,209	16,302,066	30,336,625.6	39.23	27.56
55-64 Years	5,041	5,269	145,636	20,986	12,075,572	24,185,210.0	41.75	27.64
Duragesic								
<i>183-Day Washout/Enrollment Requirement</i>								
00-11 Years	5	5	138	46	13,243,618	23,653,754.0	0.04	27.60
12-17 Years	9	9	131	44	8,633,823	13,935,646.3	0.10	14.56
18-24 Years	26	26	621	210	10,899,829	15,585,775.5	0.24	23.88
25-34 Years	128	129	3,306	1,165	15,396,777	22,357,997.7	0.83	25.63
35-44 Years	280	281	7,138	2,558	14,962,986	25,375,108.5	1.87	25.40
45-54 Years	592	603	15,733	5,654	15,343,471	28,416,164.8	3.86	26.09
55-64 Years	552	559	14,843	5,325	11,560,076	22,931,815.6	4.78	26.55
<i>90-Day Washout/Enrollment Requirement</i>								
00-11 Years	6	6	168	106	14,544,740	25,993,984.2	0.04	28.00
12-17 Years	11	11	191	64	9,218,653	14,903,602.1	0.12	17.36
18-24 Years	33	33	785	265	12,220,104	17,230,343.5	0.27	23.79
25-34 Years	163	164	4,214	1,492	17,149,837	24,891,976.4	0.95	25.70
35-44 Years	369	376	9,639	3,510	16,167,837	27,444,834.0	2.28	25.64
45-54 Years	732	760	20,193	7,361	16,302,066	30,336,625.6	4.49	26.57
55-64 Years	675	708	19,237	7,039	12,075,572	24,185,210.0	5.59	27.17
Generic fentanyl patch								
<i>183-Day Washout/Enrollment Requirement</i>								
00-11 Years	139	141	3,086	1,079	13,243,618	23,653,754.0	1.05	21.89
12-17 Years	359	361	7,471	2,664	8,633,823	13,935,646.3	4.16	20.70
18-24 Years	1,847	1,899	43,354	15,249	10,899,829	15,585,775.5	16.95	22.83
25-34 Years	6,109	6,267	150,850	52,718	15,396,777	22,357,997.7	39.68	24.07
35-44 Years	13,112	13,488	334,619	117,038	14,962,986	25,375,108.5	87.63	24.81
45-54 Years	26,049	26,900	685,212	238,150	15,343,471	28,416,164.8	169.77	25.47
55-64 Years	33,931	35,051	897,906	310,230	11,560,076	22,931,815.6	293.52	25.62

Table 2: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Age Group

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
90-Day Washout/Enrollment Requirement								
00-11 Years	151	158	3,501	1,246	14,544,740	25,993,984.2	1.04	22.16
12-17 Years	394	402	8,525	3,073	9,218,653	14,903,602.1	4.27	21.21
18-24 Years	2,142	2,252	51,637	18,237	12,220,104	17,230,343.5	17.53	22.93
25-34 Years	7,340	7,706	186,347	65,488	17,149,837	24,891,976.4	42.80	24.18
35-44 Years	15,424	16,391	410,782	144,553	16,167,837	27,444,834.0	95.40	25.06
45-54 Years	30,251	32,393	835,166	292,681	16,302,066	30,336,625.6	185.57	25.78
55-64 Years	38,337	41,032	1,065,945	370,732	12,075,572	24,185,210.0	317.48	25.98
Hysingla ER								
183-Day Washout/Enrollment Requirement								
00-11 Years	0	0	0	0	13,243,618	23,653,754.0	0.00	---
12-17 Years	0	0	0	0	8,633,823	13,935,646.3	0.00	---
18-24 Years	0	0	0	0	10,899,829	15,585,775.5	0.00	---
25-34 Years	0	0	0	0	15,396,777	22,357,997.7	0.00	---
35-44 Years	0	0	0	0	14,962,986	25,375,108.5	0.00	---
45-54 Years	0	0	0	0	15,343,471	28,416,164.8	0.00	---
55-64 Years	0	0	0	0	11,560,076	22,931,815.6	0.00	---
90-Day Washout/Enrollment Requirement								
00-11 Years	0	0	0	0	14,544,740	25,993,984.2	0.00	---
12-17 Years	0	0	0	0	9,218,653	14,903,602.1	0.00	---
18-24 Years	0	0	0	0	12,220,104	17,230,343.5	0.00	---
25-34 Years	0	0	0	0	17,149,837	24,891,976.4	0.00	---
35-44 Years	0	0	0	0	16,167,837	27,444,834.0	0.00	---
45-54 Years	0	0	0	0	16,302,066	30,336,625.6	0.00	---
55-64 Years	0	0	0	0	12,075,572	24,185,210.0	0.00	---
Zohydro ER								
183-Day Washout/Enrollment Requirement								
00-11 Years	0	0	0	0	13,243,618	23,653,754.0	0.00	---
12-17 Years	0	0	0	0	8,633,823	13,935,646.3	0.00	---
18-24 Years	0	0	0	0	10,899,829	15,585,775.5	0.00	---
25-34 Years	0	0	0	0	15,396,777	22,357,997.7	0.00	---
35-44 Years	0	0	0	0	14,962,986	25,375,108.5	0.00	---
45-54 Years	0	0	0	0	15,343,471	28,416,164.8	0.00	---
55-64 Years	0	0	0	0	11,560,076	22,931,815.6	0.00	---
90-Day Washout/Enrollment Requirement								
00-11 Years	0	0	0	0	14,544,740	25,993,984.2	0.00	---
12-17 Years	0	0	0	0	9,218,653	14,903,602.1	0.00	---
18-24 Years	0	0	0	0	12,220,104	17,230,343.5	0.00	---
25-34 Years	0	0	0	0	17,149,837	24,891,976.4	0.00	---
35-44 Years	0	0	0	0	16,167,837	27,444,834.0	0.00	---
45-54 Years	0	0	0	0	16,302,066	30,336,625.6	0.00	---
55-64 Years	0	0	0	0	12,075,572	24,185,210.0	0.00	---

Table 2: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Age Group

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
Exalgo ER								
183-Day Washout/Enrollment Requirement								
00-11 Years	1	1	30	30	13,243,618	23,653,754.0	0.01	30.00
12-17 Years	5	5	150	180	8,633,823	13,935,646.3	0.06	30.00
18-24 Years	57	58	1,507	1,941	10,899,829	15,585,775.5	0.52	25.98
25-34 Years	307	308	7,985	9,645	15,396,777	22,357,997.7	1.99	25.93
35-44 Years	625	630	16,696	19,605	14,962,986	25,375,108.5	4.18	26.50
45-54 Years	938	950	25,363	30,572	15,343,471	28,416,164.8	6.11	26.70
55-64 Years	767	780	21,412	25,400	11,560,076	22,931,815.6	6.63	27.45
90-Day Washout/Enrollment Requirement								
00-11 Years	1	1	30	30	14,544,740	25,993,984.2	0.01	30.00
12-17 Years	5	5	150	180	9,218,653	14,903,602.1	0.05	30.00
18-24 Years	79	84	2,203	2,757	12,220,104	17,230,343.5	0.65	26.23
25-34 Years	412	418	10,928	12,937	17,149,837	24,891,976.4	2.40	26.14
35-44 Years	777	793	20,917	24,570	16,167,837	27,444,834.0	4.81	26.38
45-54 Years	1,168	1,207	32,425	39,682	16,302,066	30,336,625.6	7.16	26.86
55-64 Years	944	971	26,521	31,741	12,075,572	24,185,210.0	7.82	27.31
Generic ER/LA hydromorphone								
183-Day Washout/Enrollment Requirement								
00-11 Years	0	0	0	0	13,243,618	23,653,754.0	0.00	---
12-17 Years	0	0	0	0	8,633,823	13,935,646.3	0.00	---
18-24 Years	0	0	0	0	10,899,829	15,585,775.5	0.00	---
25-34 Years	0	0	0	0	15,396,777	22,357,997.7	0.00	---
35-44 Years	0	0	0	0	14,962,986	25,375,108.5	0.00	---
45-54 Years	0	0	0	0	15,343,471	28,416,164.8	0.00	---
55-64 Years	0	0	0	0	11,560,076	22,931,815.6	0.00	---
90-Day Washout/Enrollment Requirement								
00-11 Years	0	0	0	0	14,544,740	25,993,984.2	0.00	---
12-17 Years	0	0	0	0	9,218,653	14,903,602.1	0.00	---
18-24 Years	0	0	0	0	12,220,104	17,230,343.5	0.00	---
25-34 Years	0	0	0	0	17,149,837	24,891,976.4	0.00	---
35-44 Years	0	0	0	0	16,167,837	27,444,834.0	0.00	---
45-54 Years	0	0	0	0	16,302,066	30,336,625.6	0.00	---
55-64 Years	0	0	0	0	12,075,572	24,185,210.0	0.00	---
Palladone								
183-Day Washout/Enrollment Requirement								
00-11 Years	0	0	0	0	13,243,618	23,653,754.0	0.00	---
12-17 Years	0	0	0	0	8,633,823	13,935,646.3	0.00	---
18-24 Years	0	0	0	0	10,899,829	15,585,775.5	0.00	---
25-34 Years	0	0	0	0	15,396,777	22,357,997.7	0.00	---
35-44 Years	0	0	0	0	14,962,986	25,375,108.5	0.00	---
45-54 Years	0	0	0	0	15,343,471	28,416,164.8	0.00	---
55-64 Years	0	0	0	0	11,560,076	22,931,815.6	0.00	---

Table 2: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Age Group

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
90-Day Washout/Enrollment Requirement								
00-11 Years	0	0	0	0	14,544,740	25,993,984.2	0.00	---
12-17 Years	0	0	0	0	9,218,653	14,903,602.1	0.00	---
18-24 Years	0	0	0	0	12,220,104	17,230,343.5	0.00	---
25-34 Years	0	0	0	0	17,149,837	24,891,976.4	0.00	---
35-44 Years	0	0	0	0	16,167,837	27,444,834.0	0.00	---
45-54 Years	0	0	0	0	16,302,066	30,336,625.6	0.00	---
55-64 Years	0	0	0	0	12,075,572	24,185,210.0	0.00	---
Avinza								
183-Day Washout/Enrollment Requirement								
00-11 Years	1	1	30	30	13,243,618	23,653,754.0	0.01	30.00
12-17 Years	10	10	209	279	8,633,823	13,935,646.3	0.12	20.90
18-24 Years	86	87	2,273	2,646	10,899,829	15,585,775.5	0.79	26.13
25-34 Years	394	396	10,426	11,591	15,396,777	22,357,997.7	2.56	26.33
35-44 Years	816	837	22,368	24,932	14,962,986	25,375,108.5	5.45	26.72
45-54 Years	1,236	1,258	34,490	39,529	15,343,471	28,416,164.8	8.06	27.42
55-64 Years	930	959	26,572	30,297	11,560,076	22,931,815.6	8.04	27.71
90-Day Washout/Enrollment Requirement								
00-11 Years	1	1	30	30	14,544,740	25,993,984.2	0.01	30.00
12-17 Years	12	12	217	287	9,218,653	14,903,602.1	0.13	18.08
18-24 Years	102	104	2,706	3,184	12,220,104	17,230,343.5	0.83	26.02
25-34 Years	475	481	12,700	14,191	17,149,837	24,891,976.4	2.77	26.40
35-44 Years	1,013	1,071	29,227	32,973	16,167,837	27,444,834.0	6.27	27.29
45-54 Years	1,511	1,619	44,892	53,419	16,302,066	30,336,625.6	9.27	27.73
55-64 Years	1,169	1,246	35,236	41,202	12,075,572	24,185,210.0	9.68	28.28
Kadian								
183-Day Washout/Enrollment Requirement								
00-11 Years	15	15	130	228	13,243,618	23,653,754.0	0.11	8.67
12-17 Years	57	63	832	1,395	8,633,823	13,935,646.3	0.66	13.21
18-24 Years	171	173	4,165	6,979	10,899,829	15,585,775.5	1.57	24.08
25-34 Years	825	840	21,539	36,330	15,396,777	22,357,997.7	5.36	25.64
35-44 Years	1,358	1,380	35,904	62,008	14,962,986	25,375,108.5	9.08	26.02
45-54 Years	1,815	1,846	48,130	82,620	15,343,471	28,416,164.8	11.83	26.07
55-64 Years	1,465	1,499	39,288	66,356	11,560,076	22,931,815.6	12.67	26.21
90-Day Washout/Enrollment Requirement								
00-11 Years	16	20	196	360	14,544,740	25,993,984.2	0.11	9.80
12-17 Years	63	71	950	1,631	9,218,653	14,903,602.1	0.68	13.38
18-24 Years	197	201	4,821	8,252	12,220,104	17,230,343.5	1.61	23.99
25-34 Years	990	1,025	26,388	44,781	17,149,837	24,891,976.4	5.77	25.74
35-44 Years	1,614	1,673	43,883	75,967	16,167,837	27,444,834.0	9.98	26.23
45-54 Years	2,234	2,348	62,393	109,252	16,302,066	30,336,625.6	13.70	26.57
55-64 Years	1,748	1,857	49,382	84,542	12,075,572	24,185,210.0	14.48	26.59

Table 2: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Age Group

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
Generic ER/LA morphine								
183-Day Washout/Enrollment Requirement								
00-11 Years	141	156	2,221	4,924	13,243,618	23,653,754.0	1.06	14.24
12-17 Years	1,089	1,160	13,928	32,422	8,633,823	13,935,646.3	12.61	12.01
18-24 Years	4,311	4,447	80,607	180,595	10,899,829	15,585,775.5	39.55	18.13
25-34 Years	13,289	13,727	308,888	657,035	15,396,777	22,357,997.7	86.31	22.50
35-44 Years	23,266	24,160	570,653	1,227,002	14,962,986	25,375,108.5	155.49	23.62
45-54 Years	40,292	42,106	1,022,401	2,235,624	15,343,471	28,416,164.8	262.60	24.28
55-64 Years	45,460	47,705	1,172,413	2,565,466	11,560,076	22,931,815.6	393.25	24.58
90-Day Washout/Enrollment Requirement								
00-11 Years	147	167	2,370	5,383	14,544,740	25,993,984.2	1.01	14.19
12-17 Years	1,164	1,304	15,803	36,983	9,218,653	14,903,602.1	12.63	12.12
18-24 Years	4,843	5,127	94,507	212,519	12,220,104	17,230,343.5	39.63	18.43
25-34 Years	15,451	16,453	373,284	800,916	17,149,837	24,891,976.4	90.09	22.69
35-44 Years	27,028	29,104	695,161	1,511,971	16,167,837	27,444,834.0	167.17	23.89
45-54 Years	46,232	50,575	1,249,430	2,780,455	16,302,066	30,336,625.6	283.60	24.70
55-64 Years	51,209	56,536	1,425,558	3,184,133	12,075,572	24,185,210.0	424.07	25.22
MS Contin								
183-Day Washout/Enrollment Requirement								
00-11 Years	0	0	0	0	13,243,618	23,653,754.0	0.00	---
12-17 Years	4	4	31	67	8,633,823	13,935,646.3	0.05	7.75
18-24 Years	5	5	110	220	10,899,829	15,585,775.5	0.05	22.00
25-34 Years	15	15	265	723	15,396,777	22,357,997.7	0.10	17.67
35-44 Years	23	23	535	1,090	14,962,986	25,375,108.5	0.15	23.26
45-54 Years	69	72	1,759	4,391	15,343,471	28,416,164.8	0.45	24.43
55-64 Years	52	54	1,465	3,508	11,560,076	22,931,815.6	0.45	27.13
90-Day Washout/Enrollment Requirement								
00-11 Years	0	0	0	0	14,544,740	25,993,984.2	0.00	---
12-17 Years	4	4	31	67	9,218,653	14,903,602.1	0.04	7.75
18-24 Years	5	6	140	235	12,220,104	17,230,343.5	0.04	23.33
25-34 Years	19	19	376	1,095	17,149,837	24,891,976.4	0.11	19.79
35-44 Years	24	24	565	1,150	16,167,837	27,444,834.0	0.15	23.54
45-54 Years	83	93	2,308	6,262	16,302,066	30,336,625.6	0.51	24.82
55-64 Years	64	70	1,975	4,738	12,075,572	24,185,210.0	0.53	28.21
Oramorph SR								
183-Day Washout/Enrollment Requirement								
00-11 Years	1	1	3	6	13,243,618	23,653,754.0	0.01	3.00
12-17 Years	11	11	72	190	8,633,823	13,935,646.3	0.13	6.55
18-24 Years	8	8	77	198	10,899,829	15,585,775.5	0.07	9.63
25-34 Years	20	20	266	545	15,396,777	22,357,997.7	0.13	13.30
35-44 Years	57	57	751	1,708	14,962,986	25,375,108.5	0.38	13.18
45-54 Years	59	59	938	2,091	15,343,471	28,416,164.8	0.38	15.90
55-64 Years	47	47	822	1,883	11,560,076	22,931,815.6	0.41	17.49

Table 2: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Age Group

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
90-Day Washout/Enrollment Requirement								
00-11 Years	1	1	3	6	14,544,740	25,993,984.2	0.01	3.00
12-17 Years	11	11	72	190	9,218,653	14,903,602.1	0.12	6.55
18-24 Years	10	11	142	398	12,220,104	17,230,343.5	0.08	12.91
25-34 Years	23	23	309	701	17,149,837	24,891,976.4	0.13	13.43
35-44 Years	66	66	964	2,164	16,167,837	27,444,834.0	0.41	14.61
45-54 Years	72	73	1,287	3,043	16,302,066	30,336,625.6	0.44	17.63
55-64 Years	59	59	1,111	2,403	12,075,572	24,185,210.0	0.49	18.83
Embeda								
183-Day Washout/Enrollment Requirement								
00-11 Years	0	0	0	0	13,243,618	23,653,754.0	0.00	---
12-17 Years	3	3	67	141	8,633,823	13,935,646.3	0.03	22.33
18-24 Years	64	64	1,588	2,629	10,899,829	15,585,775.5	0.59	24.81
25-34 Years	330	333	8,467	14,468	15,396,777	22,357,997.7	2.14	25.43
35-44 Years	549	551	14,125	24,144	14,962,986	25,375,108.5	3.67	25.64
45-54 Years	800	801	21,362	36,406	15,343,471	28,416,164.8	5.21	26.67
55-64 Years	456	457	12,390	20,849	11,560,076	22,931,815.6	3.94	27.11
90-Day Washout/Enrollment Requirement								
00-11 Years	0	0	0	0	14,544,740	25,993,984.2	0.00	---
12-17 Years	3	3	67	141	9,218,653	14,903,602.1	0.03	22.33
18-24 Years	76	76	1,878	3,089	12,220,104	17,230,343.5	0.62	24.71
25-34 Years	397	401	10,120	17,209	17,149,837	24,891,976.4	2.31	25.24
35-44 Years	653	656	17,034	28,986	16,167,837	27,444,834.0	4.04	25.97
45-54 Years	927	935	24,865	42,316	16,302,066	30,336,625.6	5.69	26.59
55-64 Years	512	519	14,142	24,020	12,075,572	24,185,210.0	4.24	27.25
Generic ER/LA Oxycodone								
183-Day Washout/Enrollment Requirement								
00-11 Years	23	23	366	777	13,243,618	23,653,754.0	0.17	15.91
12-17 Years	493	495	4,755	10,320	8,633,823	13,935,646.3	5.71	9.61
18-24 Years	1,230	1,235	16,967	38,056	10,899,829	15,585,775.5	11.28	13.74
25-34 Years	2,846	2,864	47,441	106,347	15,396,777	22,357,997.7	18.48	16.56
35-44 Years	4,911	4,939	84,982	188,318	14,962,986	25,375,108.5	32.82	17.21
45-54 Years	8,251	8,306	148,558	324,678	15,343,471	28,416,164.8	53.78	17.89
55-64 Years	8,341	8,418	151,230	325,994	11,560,076	22,931,815.6	72.15	17.97
90-Day Washout/Enrollment Requirement								
00-11 Years	25	26	407	853	14,544,740	25,993,984.2	0.17	15.65
12-17 Years	538	543	5,213	11,314	9,218,653	14,903,602.1	5.84	9.60
18-24 Years	1,431	1,444	20,069	45,293	12,220,104	17,230,343.5	11.71	13.90
25-34 Years	3,407	3,457	59,090	133,057	17,149,837	24,891,976.4	19.87	17.09
35-44 Years	5,760	5,842	103,866	231,589	16,167,837	27,444,834.0	35.63	17.78
45-54 Years	9,484	9,689	179,316	397,246	16,302,066	30,336,625.6	58.18	18.51
55-64 Years	9,440	9,666	180,248	390,954	12,075,572	24,185,210.0	78.17	18.65

Table 2: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Age Group

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
OxyContin								
<i>183-Day Washout/Enrollment Requirement</i>								
00-11 Years	139	144	2,245	5,010	13,243,618	23,653,754.0	1.05	15.59
12-17 Years	3,657	3,749	38,710	84,912	8,633,823	13,935,646.3	42.36	10.33
18-24 Years	9,578	9,869	133,519	300,172	10,899,829	15,585,775.5	87.87	13.53
25-34 Years	19,349	19,870	337,911	750,520	15,396,777	22,357,997.7	125.67	17.01
35-44 Years	31,071	32,142	571,716	1,251,069	14,962,986	25,375,108.5	207.65	17.79
45-54 Years	53,699	55,903	1,018,969	2,212,625	15,343,471	28,416,164.8	349.98	18.23
55-64 Years	59,491	62,221	1,129,987	2,419,725	11,560,076	22,931,815.6	514.62	18.16
<i>90-Day Washout/Enrollment Requirement</i>								
00-11 Years	149	155	2,387	5,342	14,544,740	25,993,984.2	1.02	15.40
12-17 Years	3,926	4,091	42,348	93,521	9,218,653	14,903,602.1	42.59	10.35
18-24 Years	10,785	11,285	156,557	352,979	12,220,104	17,230,343.5	88.26	13.87
25-34 Years	22,571	23,731	413,624	923,521	17,149,837	24,891,976.4	131.61	17.43
35-44 Years	35,318	37,633	690,337	1,520,378	16,167,837	27,444,834.0	218.45	18.34
45-54 Years	60,216	64,814	1,219,692	2,669,328	16,302,066	30,336,625.6	369.38	18.82
55-64 Years	65,016	70,379	1,315,359	2,845,228	12,075,572	24,185,210.0	538.41	18.69
Opana ER								
<i>183-Day Washout/Enrollment Requirement</i>								
00-11 Years	4	4	104	208	13,243,618	23,653,754.0	0.03	26.00
12-17 Years	55	57	973	1,917	8,633,823	13,935,646.3	0.64	17.07
18-24 Years	787	801	19,445	39,812	10,899,829	15,585,775.5	7.22	24.28
25-34 Years	3,295	3,370	87,286	175,913	15,396,777	22,357,997.7	21.40	25.90
35-44 Years	5,229	5,356	140,484	281,093	14,962,986	25,375,108.5	34.95	26.23
45-54 Years	7,037	7,251	189,018	385,549	15,343,471	28,416,164.8	45.86	26.07
55-64 Years	5,322	5,528	140,340	286,373	11,560,076	22,931,815.6	46.04	25.39
<i>90-Day Washout/Enrollment Requirement</i>								
00-11 Years	4	4	104	208	14,544,740	25,993,984.2	0.03	26.00
12-17 Years	62	65	1,143	2,287	9,218,653	14,903,602.1	0.67	17.58
18-24 Years	934	983	23,893	48,794	12,220,104	17,230,343.5	7.64	24.31
25-34 Years	4,050	4,242	109,931	221,854	17,149,837	24,891,976.4	23.62	25.91
35-44 Years	6,324	6,675	175,393	355,199	16,167,837	27,444,834.0	39.11	26.28
45-54 Years	8,385	8,942	235,613	484,062	16,302,066	30,336,625.6	51.44	26.35
55-64 Years	6,270	6,753	174,338	359,142	12,075,572	24,185,210.0	51.92	25.82
Generic ER/LA Oxycodone								
<i>183-Day Washout/Enrollment Requirement</i>								
00-11 Years	0	0	0	0	13,243,618	23,653,754.0	0.00	---
12-17 Years	0	0	0	0	8,633,823	13,935,646.3	0.00	---
18-24 Years	26	26	650	1,338	10,899,829	15,585,775.5	0.24	25.00
25-34 Years	112	112	2,941	5,897	15,396,777	22,357,997.7	0.73	26.26
35-44 Years	155	155	4,061	8,365	14,962,986	25,375,108.5	1.04	26.20
45-54 Years	207	207	5,809	12,161	15,343,471	28,416,164.8	1.35	28.06
55-64 Years	161	163	4,483	9,518	11,560,076	22,931,815.6	1.39	27.50

Table 2: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Age Group

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
90-Day Washout/Enrollment Requirement								
00-11 Years	0	0	0	0	14,544,740	25,993,984.2	0.00	---
12-17 Years	0	0	0	0	9,218,653	14,903,602.1	0.00	---
18-24 Years	30	30	768	1,634	12,220,104	17,230,343.5	0.25	25.60
25-34 Years	149	151	4,000	8,236	17,149,837	24,891,976.4	0.87	26.49
35-44 Years	207	207	5,482	11,300	16,167,837	27,444,834.0	1.28	26.48
45-54 Years	276	278	7,828	16,517	16,302,066	30,336,625.6	1.69	28.16
55-64 Years	205	207	5,611	11,956	12,075,572	24,185,210.0	1.70	27.11
Nucynta ER								
183-Day Washout/Enrollment Requirement								
00-11 Years	1	1	15	30	13,243,618	23,653,754.0	0.01	15.00
12-17 Years	26	27	553	1,133	8,633,823	13,935,646.3	0.30	20.48
18-24 Years	197	201	4,844	9,599	10,899,829	15,585,775.5	1.81	24.10
25-34 Years	813	821	20,922	40,895	15,396,777	22,357,997.7	5.28	25.48
35-44 Years	1,521	1,545	39,158	77,640	14,962,986	25,375,108.5	10.17	25.34
45-54 Years	2,205	2,243	57,668	113,868	15,343,471	28,416,164.8	14.37	25.71
55-64 Years	1,723	1,750	45,330	89,798	11,560,076	22,931,815.6	14.90	25.90
90-Day Washout/Enrollment Requirement								
00-11 Years	1	1	15	30	14,544,740	25,993,984.2	0.01	15.00
12-17 Years	28	29	568	1,183	9,218,653	14,903,602.1	0.30	19.59
18-24 Years	222	229	5,542	11,015	12,220,104	17,230,343.5	1.82	24.20
25-34 Years	956	981	24,925	49,004	17,149,837	24,891,976.4	5.57	25.41
35-44 Years	1,772	1,836	46,768	92,967	16,167,837	27,444,834.0	10.96	25.47
45-54 Years	2,502	2,614	67,642	133,381	16,302,066	30,336,625.6	15.35	25.88
55-64 Years	1,933	2,015	52,576	104,231	12,075,572	24,185,210.0	16.01	26.09
Dolophine								
183-Day Washout/Enrollment Requirement								
00-11 Years	0	0	0	0	13,243,618	23,653,754.0	0.00	---
12-17 Years	0	0	0	0	8,633,823	13,935,646.3	0.00	---
18-24 Years	0	0	0	0	10,899,829	15,585,775.5	0.00	---
25-34 Years	0	0	0	0	15,396,777	22,357,997.7	0.00	---
35-44 Years	0	0	0	0	14,962,986	25,375,108.5	0.00	---
45-54 Years	0	0	0	0	15,343,471	28,416,164.8	0.00	---
55-64 Years	0	0	0	0	11,560,076	22,931,815.6	0.00	---
90-Day Washout/Enrollment Requirement								
00-11 Years	0	0	0	0	14,544,740	25,993,984.2	0.00	---
12-17 Years	0	0	0	0	9,218,653	14,903,602.1	0.00	---
18-24 Years	0	0	0	0	12,220,104	17,230,343.5	0.00	---
25-34 Years	0	0	0	0	17,149,837	24,891,976.4	0.00	---
35-44 Years	1	1	30	270	16,167,837	27,444,834.0	0.01	30.00
45-54 Years	0	0	0	0	16,302,066	30,336,625.6	0.00	---
55-64 Years	0	0	0	0	12,075,572	24,185,210.0	0.00	---

Table 2: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Age Group

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
Generic Methadone (5-10 mg tablets)								
<i>183-Day Washout/Enrollment Requirement</i>								
00-11 Years	72	74	1,759	3,904	13,243,618	23,653,754.0	0.54	23.77
12-17 Years	281	284	5,716	14,272	8,633,823	13,935,646.3	3.25	20.13
18-24 Years	1,390	1,424	28,461	95,786	10,899,829	15,585,775.5	12.75	19.99
25-34 Years	3,674	3,784	87,071	285,344	15,396,777	22,357,997.7	23.86	23.01
35-44 Years	5,353	5,542	138,903	439,815	14,962,986	25,375,108.5	35.77	25.06
45-54 Years	8,451	8,835	233,212	726,662	15,343,471	28,416,164.8	55.08	26.40
55-64 Years	7,591	7,992	215,382	643,895	11,560,076	22,931,815.6	65.67	26.95
<i>90-Day Washout/Enrollment Requirement</i>								
00-11 Years	83	94	2,264	5,123	14,544,740	25,993,984.2	0.57	24.09
12-17 Years	316	334	6,761	17,670	9,218,653	14,903,602.1	3.43	20.24
18-24 Years	1,663	1,774	36,077	125,037	12,220,104	17,230,343.5	13.61	20.34
25-34 Years	4,740	5,110	119,122	411,445	17,149,837	24,891,976.4	27.64	23.31
35-44 Years	7,036	7,670	196,063	661,636	16,167,837	27,444,834.0	43.52	25.56
45-54 Years	10,978	12,333	335,522	1,129,258	16,302,066	30,336,625.6	67.34	27.21
55-64 Years	9,878	11,397	321,499	1,059,579	12,075,572	24,185,210.0	81.80	28.21
Generic Methadone (40 mg soluble tablets)								
<i>183-Day Washout/Enrollment Requirement</i>								
00-11 Years	0	0	0	0	13,243,618	23,653,754.0	0.00	---
12-17 Years	0	0	0	0	8,633,823	13,935,646.3	0.00	---
18-24 Years	4	4	16	24	10,899,829	15,585,775.5	0.04	4.00
25-34 Years	4	4	72	184	15,396,777	22,357,997.7	0.03	18.00
35-44 Years	9	9	312	1,978	14,962,986	25,375,108.5	0.06	34.67
45-54 Years	5	5	82	145	15,343,471	28,416,164.8	0.03	16.40
55-64 Years	6	6	114	230	11,560,076	22,931,815.6	0.05	19.00
<i>90-Day Washout/Enrollment Requirement</i>								
00-11 Years	0	0	0	0	14,544,740	25,993,984.2	0.00	---
12-17 Years	0	0	0	0	9,218,653	14,903,602.1	0.00	---
18-24 Years	4	4	16	24	12,220,104	17,230,343.5	0.03	4.00
25-34 Years	4	4	72	184	17,149,837	24,891,976.4	0.02	18.00
35-44 Years	11	12	426	2,303	16,167,837	27,444,834.0	0.07	35.50
45-54 Years	7	7	101	206	16,302,066	30,336,625.6	0.04	14.43
55-64 Years	7	7	130	280	12,075,572	24,185,210.0	0.06	18.57
Generic Methadone (liquid formulations)								
<i>183-Day Washout/Enrollment Requirement</i>								
00-11 Years	606	617	9,307	36,115	13,243,618	23,653,754.0	4.58	15.08
12-17 Years	141	143	2,127	14,863	8,633,823	13,935,646.3	1.63	14.87
18-24 Years	54	57	1,031	17,274	10,899,829	15,585,775.5	0.50	18.09
25-34 Years	93	94	1,781	53,487	15,396,777	22,357,997.7	0.60	18.95
35-44 Years	69	71	1,463	21,201	14,962,986	25,375,108.5	0.46	20.61
45-54 Years	137	139	3,251	31,264	15,343,471	28,416,164.8	0.89	23.39
55-64 Years	193	198	4,828	38,311	11,560,076	22,931,815.6	1.67	24.38

Table 2: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Age Group

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
<i>90-Day Washout/Enrollment Requirement</i>								
00-11 Years	808	835	12,303	43,328	14,544,740	25,993,984.2	5.56	14.73
12-17 Years	146	151	2,326	16,698	9,218,653	14,903,602.1	1.58	15.40
18-24 Years	68	72	1,286	19,792	12,220,104	17,230,343.5	0.56	17.86
25-34 Years	116	118	2,287	59,934	17,149,837	24,891,976.4	0.68	19.38
35-44 Years	87	93	2,000	25,842	16,167,837	27,444,834.0	0.54	21.51
45-54 Years	171	181	4,686	39,911	16,302,066	30,336,625.6	1.05	25.89
55-64 Years	228	243	5,781	52,494	12,075,572	24,185,210.0	1.89	23.79

Table 3: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Sex

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
Butrans								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	10,843	11,021	303,639	43,685	37,698,806	77,381,205.3	28.76	27.55
Male	6,248	6,337	173,583	24,918	37,011,226	74,869,411.5	16.88	27.39
Unknown	4	4	112	16	3,166	5,645.5	126.34	28.00
<i>90-Day Washout/Enrollment Requirement</i>								
Female	12,325	12,816	353,506	50,865	40,827,691	83,763,342.8	30.19	27.58
Male	7,145	7,390	202,389	29,052	40,225,959	81,217,041.1	17.76	27.39
Unknown	4	5	140	24	3,649	6,191.8	109.62	28.00
Duragesic								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	918	933	24,308	8,704	37,698,806	77,381,205.3	2.44	26.05
Male	673	679	17,602	6,299	37,011,226	74,869,411.5	1.82	25.92
Unknown	0	0	0	0	3,166	5,645.5	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>								
Female	1,162	1,213	32,359	11,818	40,827,691	83,763,342.8	2.85	26.68
Male	825	845	22,068	8,019	40,225,959	81,217,041.1	2.05	26.12
Unknown	0	0	0	0	3,649	6,191.8	0.00	---
Generic fentanyl patch								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	47,314	49,216	1,245,854	432,539	37,698,806	77,381,205.3	125.51	25.31
Male	33,856	34,887	876,575	304,566	37,011,226	74,869,411.5	91.47	25.13
Unknown	4	4	69	23	3,166	5,645.5	126.34	17.25
<i>90-Day Washout/Enrollment Requirement</i>								
Female	54,634	59,127	1,515,698	530,245	40,827,691	83,763,342.8	133.82	25.63
Male	38,779	41,203	1,046,136	365,743	40,225,959	81,217,041.1	96.40	25.39
Unknown	4	4	69	23	3,649	6,191.8	109.62	17.25
Hysingla ER								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	0	0	0	0	37,698,806	77,381,205.3	0.00	---
Male	0	0	0	0	37,011,226	74,869,411.5	0.00	---
Unknown	0	0	0	0	3,166	5,645.5	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>								
Female	0	0	0	0	40,827,691	83,763,342.8	0.00	---
Male	0	0	0	0	40,225,959	81,217,041.1	0.00	---
Unknown	0	0	0	0	3,649	6,191.8	0.00	---
Zohydro ER								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	0	0	0	0	37,698,806	77,381,205.3	0.00	---
Male	0	0	0	0	37,011,226	74,869,411.5	0.00	---
Unknown	0	0	0	0	3,166	5,645.5	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>								
Female	0	0	0	0	40,827,691	83,763,342.8	0.00	---
Male	0	0	0	0	40,225,959	81,217,041.1	0.00	---
Unknown	0	0	0	0	3,649	6,191.8	0.00	---

Table 3: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Sex

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
Exalgo ER								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	1,552	1,575	42,478	50,791	37,698,806	77,381,205.3	4.12	26.97
Male	1,143	1,157	30,665	36,582	37,011,226	74,869,411.5	3.09	26.50
Unknown	0	0	0	0	3,166	5,645.5	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>								
Female	1,939	1,998	53,742	64,684	40,827,691	83,763,342.8	4.75	26.90
Male	1,437	1,481	39,432	47,213	40,225,959	81,217,041.1	3.57	26.63
Unknown	0	0	0	0	3,649	6,191.8	0.00	---
Generic ER/LA hydromorphone								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	0	0	0	0	37,698,806	77,381,205.3	0.00	---
Male	0	0	0	0	37,011,226	74,869,411.5	0.00	---
Unknown	0	0	0	0	3,166	5,645.5	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>								
Female	0	0	0	0	40,827,691	83,763,342.8	0.00	---
Male	0	0	0	0	40,225,959	81,217,041.1	0.00	---
Unknown	0	0	0	0	3,649	6,191.8	0.00	---
Palladone								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	0	0	0	0	37,698,806	77,381,205.3	0.00	---
Male	0	0	0	0	37,011,226	74,869,411.5	0.00	---
Unknown	0	0	0	0	3,166	5,645.5	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>								
Female	0	0	0	0	40,827,691	83,763,342.8	0.00	---
Male	0	0	0	0	40,225,959	81,217,041.1	0.00	---
Unknown	0	0	0	0	3,649	6,191.8	0.00	---
Avinza								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	1,830	1,883	51,482	58,580	37,698,806	77,381,205.3	4.85	27.34
Male	1,628	1,665	44,886	50,724	37,011,226	74,869,411.5	4.40	26.96
Unknown	0	0	0	0	3,166	5,645.5	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>								
Female	2,281	2,450	68,136	80,266	40,827,691	83,763,342.8	5.59	27.81
Male	1,970	2,084	56,872	65,019	40,225,959	81,217,041.1	4.90	27.29
Unknown	0	0	0	0	3,649	6,191.8	0.00	---
Kadian								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	3,286	3,359	86,536	146,859	37,698,806	77,381,205.3	8.72	25.76
Male	2,406	2,456	63,432	109,038	37,011,226	74,869,411.5	6.50	25.83
Unknown	1	1	20	20	3,166	5,645.5	31.59	20.00
<i>90-Day Washout/Enrollment Requirement</i>								
Female	3,946	4,170	108,917	187,449	40,827,691	83,763,342.8	9.67	26.12
Male	2,885	3,024	79,076	137,316	40,225,959	81,217,041.1	7.17	26.15
Unknown	1	1	20	20	3,649	6,191.8	27.40	20.00

Table 3: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Sex

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
Generic ER/LA morphine								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	65,786	69,303	1,656,915	3,579,133	37,698,806	77,381,205.3	174.50	23.91
Male	61,178	64,153	1,514,083	3,323,738	37,011,226	74,869,411.5	165.30	23.60
Unknown	5	5	113	198	3,166	5,645.5	157.93	22.60
<i>90-Day Washout/Enrollment Requirement</i>								
Female	74,894	82,803	2,018,665	4,443,447	40,827,691	83,763,342.8	183.44	24.38
Male	69,735	76,458	1,837,335	4,088,715	40,225,959	81,217,041.1	173.36	24.03
Unknown	5	5	113	198	3,649	6,191.8	137.02	22.60
MS Contin								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	95	99	2,419	6,139	37,698,806	77,381,205.3	0.25	24.43
Male	73	74	1,746	3,860	37,011,226	74,869,411.5	0.20	23.59
Unknown	0	0	0	0	3,166	5,645.5	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>								
Female	108	119	3,003	8,095	40,827,691	83,763,342.8	0.26	25.24
Male	91	97	2,392	5,452	40,225,959	81,217,041.1	0.23	24.66
Unknown	0	0	0	0	3,649	6,191.8	0.00	---
Oramorph SR								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	96	96	1,455	3,422	37,698,806	77,381,205.3	0.25	15.16
Male	107	107	1,474	3,199	37,011,226	74,869,411.5	0.29	13.78
Unknown	0	0	0	0	3,166	5,645.5	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>								
Female	116	117	1,980	4,722	40,827,691	83,763,342.8	0.28	16.92
Male	126	127	1,908	4,183	40,225,959	81,217,041.1	0.31	15.02
Unknown	0	0	0	0	3,649	6,191.8	0.00	---
Embeda								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	1,176	1,181	31,283	52,715	37,698,806	77,381,205.3	3.12	26.49
Male	1,025	1,027	26,686	45,862	37,011,226	74,869,411.5	2.77	25.98
Unknown	1	1	30	60	3,166	5,645.5	31.59	30.00
<i>90-Day Washout/Enrollment Requirement</i>								
Female	1,362	1,374	36,360	61,210	40,827,691	83,763,342.8	3.34	26.46
Male	1,205	1,215	31,716	54,491	40,225,959	81,217,041.1	3.00	26.10
Unknown	1	1	30	60	3,649	6,191.8	27.40	30.00
Generic ER/LA Oxycodone								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	12,697	12,796	221,592	485,169	37,698,806	77,381,205.3	33.68	17.32
Male	13,374	13,482	232,647	509,232	37,011,226	74,869,411.5	36.13	17.26
Unknown	2	2	60	90	3,166	5,645.5	63.17	30.00
<i>90-Day Washout/Enrollment Requirement</i>								
Female	14,574	14,870	266,820	588,834	40,827,691	83,763,342.8	35.70	17.94
Male	15,460	15,795	281,329	621,383	40,225,959	81,217,041.1	38.43	17.81
Unknown	2	2	60	90	3,649	6,191.8	54.81	30.00

Table 3: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Sex

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
OxyContin								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	85,453	89,345	1,574,023	3,406,420	37,698,806	77,381,205.3	226.67	17.62
Male	90,526	94,539	1,658,843	3,617,191	37,011,226	74,869,411.5	244.59	17.55
Unknown	14	14	191	422	3,166	5,645.5	442.20	13.64
<i>90-Day Washout/Enrollment Requirement</i>								
Female	95,312	103,044	1,870,252	4,083,862	40,827,691	83,763,342.8	233.45	18.15
Male	101,181	109,029	1,969,831	4,325,954	40,225,959	81,217,041.1	251.53	18.07
Unknown	14	15	221	482	3,649	6,191.8	383.67	14.73
Opana ER								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	11,643	11,997	314,395	632,223	37,698,806	77,381,205.3	30.88	26.21
Male	10,008	10,369	263,225	538,583	37,011,226	74,869,411.5	27.04	25.39
Unknown	1	1	30	60	3,166	5,645.5	31.59	30.00
<i>90-Day Washout/Enrollment Requirement</i>								
Female	13,881	14,836	391,827	796,832	40,827,691	83,763,342.8	34.00	26.41
Male	11,984	12,826	328,528	674,594	40,225,959	81,217,041.1	29.79	25.61
Unknown	2	2	60	120	3,649	6,191.8	54.81	30.00
Generic ER/LA Oxymorphone								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	332	332	9,019	19,101	37,698,806	77,381,205.3	0.88	27.17
Male	329	331	8,925	18,178	37,011,226	74,869,411.5	0.89	26.96
Unknown	0	0	0	0	3,166	5,645.5	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>								
Female	439	442	11,902	25,200	40,827,691	83,763,342.8	1.08	26.93
Male	425	431	11,787	24,443	40,225,959	81,217,041.1	1.06	27.35
Unknown	0	0	0	0	3,649	6,191.8	0.00	---
Nucynta ER								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	3,817	3,880	99,044	196,111	37,698,806	77,381,205.3	10.12	25.53
Male	2,660	2,708	69,446	136,852	37,011,226	74,869,411.5	7.19	25.64
Unknown	0	0	0	0	3,166	5,645.5	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>								
Female	4,349	4,530	116,396	230,677	40,827,691	83,763,342.8	10.65	25.69
Male	3,045	3,175	81,640	161,134	40,225,959	81,217,041.1	7.57	25.71
Unknown	0	0	0	0	3,649	6,191.8	0.00	---
Dolophine								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	0	0	0	0	37,698,806	77,381,205.3	0.00	---
Male	0	0	0	0	37,011,226	74,869,411.5	0.00	---
Unknown	0	0	0	0	3,166	5,645.5	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>								
Female	0	0	0	0	40,827,691	83,763,342.8	0.00	---
Male	1	1	30	270	40,225,959	81,217,041.1	0.00	30.00
Unknown	0	0	0	0	3,649	6,191.8	0.00	---

Table 3: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Sex

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
Generic Methadone (5-10 mg tablets)								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	13,078	13,712	352,036	1,018,579	37,698,806	77,381,205.3	34.69	25.67
Male	13,557	14,222	358,438	1,191,039	37,011,226	74,869,411.5	36.63	25.20
Unknown	1	1	30	60	3,166	5,645.5	31.59	30.00
<i>90-Day Washout/Enrollment Requirement</i>								
Female	17,067	19,371	517,548	1,664,853	40,827,691	83,763,342.8	41.80	26.72
Male	17,245	19,338	499,680	1,744,685	40,225,959	81,217,041.1	42.87	25.84
Unknown	1	3	80	210	3,649	6,191.8	27.40	26.67
Generic Methadone (40 mg soluble tablets)								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	9	9	196	496	37,698,806	77,381,205.3	0.02	21.78
Male	19	19	400	2,065	37,011,226	74,869,411.5	0.05	21.05
Unknown	0	0	0	0	3,166	5,645.5	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>								
Female	11	11	207	526	40,827,691	83,763,342.8	0.03	18.82
Male	22	23	538	2,471	40,225,959	81,217,041.1	0.05	23.39
Unknown	0	0	0	0	3,649	6,191.8	0.00	---
Generic Methadone (liquid formulations)								
<i>183-Day Washout/Enrollment Requirement</i>								
Female	625	639	11,703	122,154	37,698,806	77,381,205.3	1.66	18.31
Male	666	680	12,085	90,362	37,011,226	74,869,411.5	1.80	17.77
Unknown	0	0	0	0	3,166	5,645.5	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>								
Female	790	827	15,390	149,360	40,827,691	83,763,342.8	1.93	18.61
Male	829	866	15,279	108,640	40,225,959	81,217,041.1	2.06	17.64
Unknown	0	0	0	0	3,649	6,191.8	0.00	---

Table 4: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Year

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
Butrans								
<i>183-Day Washout/Enrollment Requirement</i>								
2009	0	0	0	0	42,570,274	32,833,913.4	0.00	---
2010	0	0	0	0	40,361,536	31,323,326.9	0.00	---
2011	5,986	5,995	163,984	23,704	38,902,982	30,404,304.0	15.39	27.35
2012	5,713	5,718	157,853	22,660	37,646,762	29,525,134.4	15.18	27.61
2013	5,642	5,649	155,497	22,255	36,291,223	28,169,583.6	15.55	27.53
<i>90-Day Washout/Enrollment Requirement</i>								
2009	0	0	0	0	45,859,022	35,655,399.1	0.00	---
2010	0	0	0	0	43,603,075	33,918,464.7	0.00	---
2011	6,813	6,891	188,436	27,254	42,081,122	32,920,647.2	16.19	27.35
2012	6,596	6,681	184,703	26,513	40,745,292	31,921,086.6	16.19	27.65
2013	6,572	6,639	182,896	26,174	39,269,898	30,570,978.1	16.74	27.55
Duragesic								
<i>183-Day Washout/Enrollment Requirement</i>								
2009	239	239	6,419	2,308	42,570,274	32,833,913.4	0.56	26.86
2010	147	147	3,767	1,431	40,361,536	31,323,326.9	0.36	25.63
2011	320	320	7,943	2,947	38,902,982	30,404,304.0	0.82	24.82
2012	499	501	13,175	4,626	37,646,762	29,525,134.4	1.33	26.30
2013	405	405	10,606	3,690	36,291,223	28,169,583.6	1.12	26.19
<i>90-Day Washout/Enrollment Requirement</i>								
2009	316	322	8,740	3,272	45,859,022	35,655,399.1	0.69	27.14
2010	192	194	4,917	1,926	43,603,075	33,918,464.7	0.44	25.35
2011	391	392	10,067	3,765	42,081,122	32,920,647.2	0.93	25.68
2012	631	640	17,063	6,076	40,745,292	31,921,086.6	1.55	26.66
2013	505	510	13,640	4,799	39,269,898	30,570,978.1	1.29	26.75
Generic fentanyl patch								
<i>183-Day Washout/Enrollment Requirement</i>								
2009	20,138	20,195	508,668	176,904	42,570,274	32,833,913.4	47.31	25.19
2010	18,201	18,256	458,858	160,055	40,361,536	31,323,326.9	45.09	25.13
2011	16,594	16,637	418,831	145,697	38,902,982	30,404,304.0	42.65	25.17
2012	15,070	15,123	382,839	132,769	37,646,762	29,525,134.4	40.03	25.32
2013	13,855	13,896	353,302	121,702	36,291,223	28,169,583.6	38.18	25.42
<i>90-Day Washout/Enrollment Requirement</i>								
2009	23,571	23,988	610,818	213,868	45,859,022	35,655,399.1	51.40	25.46
2010	21,300	21,698	551,403	193,642	43,603,075	33,918,464.7	48.85	25.41
2011	19,469	19,795	504,343	176,424	42,081,122	32,920,647.2	46.27	25.48
2012	17,865	18,183	465,749	162,961	40,745,292	31,921,086.6	43.85	25.61
2013	16,409	16,670	429,590	149,116	39,269,898	30,570,978.1	41.79	25.77
Hysingla ER								
<i>183-Day Washout/Enrollment Requirement</i>								
2009	0	0	0	0	42,570,274	32,833,913.4	0.00	---
2010	0	0	0	0	40,361,536	31,323,326.9	0.00	---
2011	0	0	0	0	38,902,982	30,404,304.0	0.00	---
2012	0	0	0	0	37,646,762	29,525,134.4	0.00	---
2013	0	0	0	0	36,291,223	28,169,583.6	0.00	---

Table 4: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Year

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
90-Day Washout/Enrollment Requirement								
2009	0	0	0	0	45,859,022	35,655,399.1	0.00	---
2010	0	0	0	0	43,603,075	33,918,464.7	0.00	---
2011	0	0	0	0	42,081,122	32,920,647.2	0.00	---
2012	0	0	0	0	40,745,292	31,921,086.6	0.00	---
2013	0	0	0	0	39,269,898	30,570,978.1	0.00	---
Zohydro ER								
183-Day Washout/Enrollment Requirement								
2009	0	0	0	0	42,570,274	32,833,913.4	0.00	---
2010	0	0	0	0	40,361,536	31,323,326.9	0.00	---
2011	0	0	0	0	38,902,982	30,404,304.0	0.00	---
2012	0	0	0	0	37,646,762	29,525,134.4	0.00	---
2013	0	0	0	0	36,291,223	28,169,583.6	0.00	---
90-Day Washout/Enrollment Requirement								
2009	0	0	0	0	45,859,022	35,655,399.1	0.00	---
2010	0	0	0	0	43,603,075	33,918,464.7	0.00	---
2011	0	0	0	0	42,081,122	32,920,647.2	0.00	---
2012	0	0	0	0	40,745,292	31,921,086.6	0.00	---
2013	0	0	0	0	39,269,898	30,570,978.1	0.00	---
Exalgo ER								
183-Day Washout/Enrollment Requirement								
2009	0	0	0	0	42,570,274	32,833,913.4	0.00	---
2010	232	232	6,111	7,350	40,361,536	31,323,326.9	0.57	26.34
2011	589	590	15,884	19,863	38,902,982	30,404,304.0	1.51	26.92
2012	912	914	24,602	29,578	37,646,762	29,525,134.4	2.42	26.92
2013	995	996	26,546	30,582	36,291,223	28,169,583.6	2.74	26.65
90-Day Washout/Enrollment Requirement								
2009	0	0	0	0	45,859,022	35,655,399.1	0.00	---
2010	278	279	7,272	8,939	43,603,075	33,918,464.7	0.64	26.06
2011	745	753	20,273	25,373	42,081,122	32,920,647.2	1.77	26.92
2012	1,132	1,141	30,661	37,283	40,745,292	31,921,086.6	2.78	26.87
2013	1,292	1,306	34,968	40,302	39,269,898	30,570,978.1	3.29	26.77
Generic ER/LA hydromorphone								
183-Day Washout/Enrollment Requirement								
2009	0	0	0	0	42,570,274	32,833,913.4	0.00	---
2010	0	0	0	0	40,361,536	31,323,326.9	0.00	---
2011	0	0	0	0	38,902,982	30,404,304.0	0.00	---
2012	0	0	0	0	37,646,762	29,525,134.4	0.00	---
2013	0	0	0	0	36,291,223	28,169,583.6	0.00	---
90-Day Washout/Enrollment Requirement								
2009	0	0	0	0	45,859,022	35,655,399.1	0.00	---
2010	0	0	0	0	43,603,075	33,918,464.7	0.00	---
2011	0	0	0	0	42,081,122	32,920,647.2	0.00	---
2012	0	0	0	0	40,745,292	31,921,086.6	0.00	---
2013	0	0	0	0	39,269,898	30,570,978.1	0.00	---

Table 4: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Year

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
Palladone								
<i>183-Day Washout/Enrollment Requirement</i>								
2009	0	0	0	0	42,570,274	32,833,913.4	0.00	---
2010	0	0	0	0	40,361,536	31,323,326.9	0.00	---
2011	0	0	0	0	38,902,982	30,404,304.0	0.00	---
2012	0	0	0	0	37,646,762	29,525,134.4	0.00	---
2013	0	0	0	0	36,291,223	28,169,583.6	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>								
2009	0	0	0	0	45,859,022	35,655,399.1	0.00	---
2010	0	0	0	0	43,603,075	33,918,464.7	0.00	---
2011	0	0	0	0	42,081,122	32,920,647.2	0.00	---
2012	0	0	0	0	40,745,292	31,921,086.6	0.00	---
2013	0	0	0	0	39,269,898	30,570,978.1	0.00	---
Avinza								
<i>183-Day Washout/Enrollment Requirement</i>								
2009	2,025	2,028	55,204	61,794	42,570,274	32,833,913.4	4.76	27.22
2010	649	650	17,317	19,985	40,361,536	31,323,326.9	1.61	26.64
2011	410	410	11,278	12,547	38,902,982	30,404,304.0	1.05	27.51
2012	281	283	7,633	8,890	37,646,762	29,525,134.4	0.75	26.97
2013	177	177	4,936	6,088	36,291,223	28,169,583.6	0.49	27.89
<i>90-Day Washout/Enrollment Requirement</i>								
2009	2,479	2,519	68,927	78,303	45,859,022	35,655,399.1	5.41	27.36
2010	851	867	23,569	28,166	43,603,075	33,918,464.7	1.95	27.18
2011	513	524	14,616	16,923	42,081,122	32,920,647.2	1.22	27.89
2012	371	383	10,936	13,331	40,745,292	31,921,086.6	0.91	28.55
2013	235	241	6,960	8,562	39,269,898	30,570,978.1	0.60	28.88
Kadian								
<i>183-Day Washout/Enrollment Requirement</i>								
2009	2,043	2,049	52,344	89,411	42,570,274	32,833,913.4	4.80	25.55
2010	1,593	1,596	41,130	70,746	40,361,536	31,323,326.9	3.95	25.77
2011	1,276	1,280	33,607	57,907	38,902,982	30,404,304.0	3.28	26.26
2012	792	796	20,502	33,661	37,646,762	29,525,134.4	2.10	25.76
2013	95	95	2,405	4,191	36,291,223	28,169,583.6	0.26	25.32
<i>90-Day Washout/Enrollment Requirement</i>								
2009	2,487	2,530	65,724	113,708	45,859,022	35,655,399.1	5.42	25.98
2010	1,947	1,978	51,856	89,682	43,603,075	33,918,464.7	4.47	26.22
2011	1,583	1,604	42,606	74,809	42,081,122	32,920,647.2	3.76	26.56
2012	935	951	24,452	40,719	40,745,292	31,921,086.6	2.29	25.71
2013	131	132	3,375	5,867	39,269,898	30,570,978.1	0.33	25.57
Generic ER/LA morphine								
<i>183-Day Washout/Enrollment Requirement</i>								
2009	25,712	25,825	619,336	1,376,806	42,570,274	32,833,913.4	60.40	23.98
2010	26,307	26,424	636,751	1,389,159	40,361,536	31,323,326.9	65.18	24.10
2011	27,999	28,112	673,320	1,468,234	38,902,982	30,404,304.0	71.97	23.95
2012	29,298	29,430	704,137	1,507,977	37,646,762	29,525,134.4	77.82	23.93
2013	23,578	23,670	537,567	1,160,894	36,291,223	28,169,583.6	64.97	22.71

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	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
90-Day Washout/Enrollment Requirement								
2009	30,029	30,772	750,942	1,700,809	45,859,022	35,655,399.1	65.48	24.40
2010	30,691	31,421	769,676	1,712,297	43,603,075	33,918,464.7	70.39	24.50
2011	32,772	33,562	819,418	1,812,586	42,081,122	32,920,647.2	77.88	24.42
2012	34,217	35,039	852,550	1,856,471	40,745,292	31,921,086.6	83.98	24.33
2013	27,827	28,472	663,527	1,450,197	39,269,898	30,570,978.1	70.86	23.30
MS Contin								
183-Day Washout/Enrollment Requirement								
2009	71	71	1,665	3,849	42,570,274	32,833,913.4	0.17	23.45
2010	42	43	1,011	2,661	40,361,536	31,323,326.9	0.10	23.51
2011	26	26	772	1,794	38,902,982	30,404,304.0	0.07	29.69
2012	16	16	374	934	37,646,762	29,525,134.4	0.04	23.38
2013	17	17	343	761	36,291,223	28,169,583.6	0.05	20.18
90-Day Washout/Enrollment Requirement								
2009	85	90	2,217	5,608	45,859,022	35,655,399.1	0.19	24.63
2010	48	50	1,177	3,186	43,603,075	33,918,464.7	0.11	23.54
2011	32	33	1,012	2,364	42,081,122	32,920,647.2	0.08	30.67
2012	23	23	594	1,524	40,745,292	31,921,086.6	0.06	25.83
2013	20	20	395	865	39,269,898	30,570,978.1	0.05	19.75
Oramorph SR								
183-Day Washout/Enrollment Requirement								
2009	130	130	1,996	4,437	42,570,274	32,833,913.4	0.31	15.35
2010	51	51	658	1,438	40,361,536	31,323,326.9	0.13	12.90
2011	21	21	245	506	38,902,982	30,404,304.0	0.05	11.67
2012	1	1	30	240	37,646,762	29,525,134.4	0.00	30.00
2013	0	0	0	0	36,291,223	28,169,583.6	0.00	---
90-Day Washout/Enrollment Requirement								
2009	154	154	2,597	5,997	45,859,022	35,655,399.1	0.34	16.86
2010	61	61	849	1,822	43,603,075	33,918,464.7	0.14	13.92
2011	28	28	412	846	42,081,122	32,920,647.2	0.07	14.71
2012	1	1	30	240	40,745,292	31,921,086.6	0.00	30.00
2013	0	0	0	0	39,269,898	30,570,978.1	0.00	---
Embeda								
183-Day Washout/Enrollment Requirement								
2009	316	316	8,353	14,281	42,570,274	32,833,913.4	0.74	26.43
2010	1,625	1,626	42,661	71,952	40,361,536	31,323,326.9	4.03	26.24
2011	267	267	6,985	12,404	38,902,982	30,404,304.0	0.69	26.16
2012	0	0	0	0	37,646,762	29,525,134.4	0.00	---
2013	0	0	0	0	36,291,223	28,169,583.6	0.00	---
90-Day Washout/Enrollment Requirement								
2009	363	363	9,587	16,430	45,859,022	35,655,399.1	0.79	26.41
2010	1,905	1,912	50,299	84,893	43,603,075	33,918,464.7	4.37	26.31
2011	315	315	8,220	14,438	42,081,122	32,920,647.2	0.75	26.10
2012	0	0	0	0	40,745,292	31,921,086.6	0.00	---
2013	0	0	0	0	39,269,898	30,570,978.1	0.00	---

Table 4: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Year

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
Generic ER/LA Oxycodone								
<i>183-Day Washout/Enrollment Requirement</i>								
2009	12,485	12,506	222,367	489,168	42,570,274	32,833,913.4	29.33	17.78
2010	12,517	12,547	214,720	468,564	40,361,536	31,323,326.9	31.01	17.11
2011	1,056	1,056	15,222	32,618	38,902,982	30,404,304.0	2.71	14.41
2012	170	170	1,960	4,081	37,646,762	29,525,134.4	0.45	11.53
2013	1	1	30	60	36,291,223	28,169,583.6	0.00	30.00
<i>90-Day Washout/Enrollment Requirement</i>								
2009	14,623	14,755	272,368	605,092	45,859,022	35,655,399.1	31.89	18.46
2010	14,343	14,502	255,086	559,480	43,603,075	33,918,464.7	32.89	17.59
2011	1,223	1,229	18,631	41,247	42,081,122	32,920,647.2	2.91	15.16
2012	180	180	2,094	4,428	40,745,292	31,921,086.6	0.44	11.63
2013	1	1	30	60	39,269,898	30,570,978.1	0.00	30.00
OxyContin								
<i>183-Day Washout/Enrollment Requirement</i>								
2009	39,511	39,683	737,863	1,653,804	42,570,274	32,833,913.4	92.81	18.59
2010	34,881	35,032	639,857	1,413,814	40,361,536	31,323,326.9	86.42	18.26
2011	38,619	38,832	669,252	1,452,293	38,902,982	30,404,304.0	99.27	17.23
2012	36,256	36,452	619,410	1,327,914	37,646,762	29,525,134.4	96.31	16.99
2013	33,685	33,899	566,675	1,176,207	36,291,223	28,169,583.6	92.82	16.72
<i>90-Day Washout/Enrollment Requirement</i>								
2009	45,277	46,150	882,564	1,998,439	45,859,022	35,655,399.1	98.73	19.12
2010	39,816	40,593	765,376	1,708,816	43,603,075	33,918,464.7	91.31	18.85
2011	43,700	44,692	793,204	1,732,982	42,081,122	32,920,647.2	103.85	17.75
2012	40,907	41,823	731,940	1,579,689	40,745,292	31,921,086.6	100.40	17.50
2013	37,980	38,830	667,220	1,390,372	39,269,898	30,570,978.1	96.72	17.18
Opana ER								
<i>183-Day Washout/Enrollment Requirement</i>								
2009	5,184	5,196	136,107	274,540	42,570,274	32,833,913.4	12.18	26.19
2010	5,741	5,755	151,413	302,638	40,361,536	31,323,326.9	14.22	26.31
2011	5,120	5,140	132,744	272,719	38,902,982	30,404,304.0	13.16	25.83
2012	3,647	3,657	92,746	189,785	37,646,762	29,525,134.4	9.69	25.36
2013	2,611	2,619	64,640	131,184	36,291,223	28,169,583.6	7.19	24.68
<i>90-Day Washout/Enrollment Requirement</i>								
2009	6,188	6,278	165,148	335,708	45,859,022	35,655,399.1	13.49	26.31
2010	6,852	6,950	184,083	371,151	43,603,075	33,918,464.7	15.71	26.49
2011	6,310	6,437	167,903	348,041	42,081,122	32,920,647.2	14.99	26.08
2012	4,563	4,637	118,921	244,463	40,745,292	31,921,086.6	11.20	25.65
2013	3,310	3,362	84,360	172,183	39,269,898	30,570,978.1	8.43	25.09
Generic ER/LA Oxymorphone								
<i>183-Day Washout/Enrollment Requirement</i>								
2009	0	0	0	0	42,570,274	32,833,913.4	0.00	---
2010	0	0	0	0	40,361,536	31,323,326.9	0.00	---
2011	67	67	1,766	3,849	38,902,982	30,404,304.0	0.17	26.36
2012	214	214	5,956	12,247	37,646,762	29,525,134.4	0.57	27.83
2013	382	382	10,222	21,183	36,291,223	28,169,583.6	1.05	26.76

Table 4: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Year

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
90-Day Washout/Enrollment Requirement								
2009	0	0	0	0	45,859,022	35,655,399.1	0.00	---
2010	0	0	0	0	43,603,075	33,918,464.7	0.00	---
2011	75	75	2,004	4,325	42,081,122	32,920,647.2	0.18	26.72
2012	283	285	7,890	16,098	40,745,292	31,921,086.6	0.69	27.68
2013	511	513	13,795	29,220	39,269,898	30,570,978.1	1.30	26.89
Nucynta ER								
183-Day Washout/Enrollment Requirement								
2009	0	0	0	0	42,570,274	32,833,913.4	0.00	---
2010	0	0	0	0	40,361,536	31,323,326.9	0.00	---
2011	850	850	22,356	44,047	38,902,982	30,404,304.0	2.18	26.30
2012	3,722	3,732	94,669	187,166	37,646,762	29,525,134.4	9.89	25.37
2013	2,001	2,006	51,465	101,750	36,291,223	28,169,583.6	5.51	25.66
90-Day Washout/Enrollment Requirement								
2009	0	0	0	0	45,859,022	35,655,399.1	0.00	---
2010	0	0	0	0	43,603,075	33,918,464.7	0.00	---
2011	939	939	24,712	48,784	42,081,122	32,920,647.2	2.23	26.32
2012	4,278	4,332	110,458	218,985	40,745,292	31,921,086.6	10.50	25.50
2013	2,396	2,434	62,866	124,042	39,269,898	30,570,978.1	6.10	25.83
Dolophine								
183-Day Washout/Enrollment Requirement								
2009	0	0	0	0	42,570,274	32,833,913.4	0.00	---
2010	0	0	0	0	40,361,536	31,323,326.9	0.00	---
2011	0	0	0	0	38,902,982	30,404,304.0	0.00	---
2012	0	0	0	0	37,646,762	29,525,134.4	0.00	---
2013	0	0	0	0	36,291,223	28,169,583.6	0.00	---
90-Day Washout/Enrollment Requirement								
2009	1	1	30	270	45,859,022	35,655,399.1	0.00	30.00
2010	0	0	0	0	43,603,075	33,918,464.7	0.00	---
2011	0	0	0	0	42,081,122	32,920,647.2	0.00	---
2012	0	0	0	0	40,745,292	31,921,086.6	0.00	---
2013	0	0	0	0	39,269,898	30,570,978.1	0.00	---
Generic Methadone (5-10 mg tablets)								
183-Day Washout/Enrollment Requirement								
2009	7,193	7,228	187,423	580,806	42,570,274	32,833,913.4	16.90	25.93
2010	6,018	6,041	152,466	476,821	40,361,536	31,323,326.9	14.91	25.24
2011	5,627	5,651	143,901	454,136	38,902,982	30,404,304.0	14.46	25.46
2012	4,895	4,917	124,697	387,453	37,646,762	29,525,134.4	13.00	25.36
2013	4,079	4,098	102,017	310,463	36,291,223	28,169,583.6	11.24	24.89
90-Day Washout/Enrollment Requirement								
2009	9,567	9,854	262,355	884,289	45,859,022	35,655,399.1	20.86	26.62
2010	8,024	8,279	217,781	732,093	43,603,075	33,918,464.7	18.40	26.31
2011	7,565	7,830	205,053	691,940	42,081,122	32,920,647.2	17.98	26.19
2012	6,644	6,868	180,251	604,887	40,745,292	31,921,086.6	16.31	26.25
2013	5,674	5,881	151,868	496,538	39,269,898	30,570,978.1	14.45	25.82

Table 4: Summary of Incident Extended-Release and Long-Acting (ER/LA) Opioid Analgesics use in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2009 and December 31, 2013, by Exposure, Washout/Enrollment Requirement, and Year

	New Users	New Episodes	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users/100K Eligible Members	Days Supplied/Episode
Generic Methadone (40 mg soluble tablets)								
<i>183-Day Washout/Enrollment Requirement</i>								
2009	16	16	290	1,756	42,570,274	32,833,913.4	0.04	18.13
2010	4	4	62	197	40,361,536	31,323,326.9	0.01	15.50
2011	5	5	191	492	38,902,982	30,404,304.0	0.01	38.20
2012	3	3	53	117	37,646,762	29,525,134.4	0.01	17.67
2013	0	0	0	0	36,291,223	28,169,583.6	0.00	---
<i>90-Day Washout/Enrollment Requirement</i>								
2009	19	19	316	1,828	45,859,022	35,655,399.1	0.04	16.63
2010	5	5	78	247	43,603,075	33,918,464.7	0.01	15.60
2011	6	7	298	806	42,081,122	32,920,647.2	0.01	42.57
2012	3	3	53	117	40,745,292	31,921,086.6	0.01	17.67
2013	0	0	0	0	39,269,898	30,570,978.1	0.00	---
Generic Methadone (liquid formulations)								
<i>183-Day Washout/Enrollment Requirement</i>								
2009	294	294	5,286	42,938	42,570,274	32,833,913.4	0.69	17.98
2010	272	273	5,203	39,281	40,361,536	31,323,326.9	0.67	19.06
2011	269	272	4,665	33,769	38,902,982	30,404,304.0	0.69	17.15
2012	255	255	4,839	67,531	37,646,762	29,525,134.4	0.68	18.98
2013	225	225	3,795	28,997	36,291,223	28,169,583.6	0.62	16.87
<i>90-Day Washout/Enrollment Requirement</i>								
2009	369	370	6,529	49,325	45,859,022	35,655,399.1	0.80	17.65
2010	360	368	6,879	52,725	43,603,075	33,918,464.7	0.83	18.69
2011	330	335	6,052	40,624	42,081,122	32,920,647.2	0.78	18.07
2012	317	321	6,118	76,012	40,745,292	31,921,086.6	0.78	19.06
2013	293	299	5,091	39,313	39,269,898	30,570,978.1	0.75	17.03

Appendix A: Generic and Brand Names

Generic Name	Brand Name	Route	Form	Strength	Unit
Butrans					
BUPRENORPHINE	Butrans	transdermal	patch weekly	5	mcg/hr
BUPRENORPHINE	Butrans	transdermal	patch weekly	7.5	mcg/hr
BUPRENORPHINE	Butrans	transdermal	patch weekly	10	mcg/hr
BUPRENORPHINE	Butrans	transdermal	patch weekly	15	mcg/hr
BUPRENORPHINE	Butrans	transdermal	patch weekly	20	mcg/hr
Duragesic					
FENTANYL	Duragesic	transdermal	patch 72 hour	12	mcg/hr
FENTANYL	Duragesic	transdermal	patch 72 hour	25	mcg/hr
FENTANYL	Duragesic	transdermal	patch 72 hour	50	mcg/hr
FENTANYL	Duragesic	transdermal	patch 72 hour	75	mcg/hr
FENTANYL	Duragesic	transdermal	patch 72 hour	100	mcg/hr
Fentanyl					
FENTANYL	Fentanyl	transdermal	patch 72 hour	12	mcg/hr
FENTANYL	Fentanyl	transdermal	patch 72 hour	25	mcg/hr
FENTANYL	Fentanyl	transdermal	patch 72 hour	50	mcg/hr
FENTANYL	Fentanyl	transdermal	patch 72 hour	75	mcg/hr
FENTANYL	Fentanyl	transdermal	patch 72 hour	100	mcg/hr
Hysingla ER					
HYDROCODONE BITARTRATE	Hysingla ER	oral	tablet,oral only,ext.rel.24 hr	20	mg
HYDROCODONE BITARTRATE	Hysingla ER	oral	tablet,oral only,ext.rel.24 hr	30	mg
HYDROCODONE BITARTRATE	Hysingla ER	oral	tablet,oral only,ext.rel.24 hr	40	mg
HYDROCODONE BITARTRATE	Hysingla ER	oral	tablet,oral only,ext.rel.24 hr	60	mg
HYDROCODONE BITARTRATE	Hysingla ER	oral	tablet,oral only,ext.rel.24 hr	80	mg
HYDROCODONE BITARTRATE	Hysingla ER	oral	tablet,oral only,ext.rel.24 hr	100	mg
HYDROCODONE BITARTRATE	Hysingla ER	oral	tablet,oral only,ext.rel.24 hr	120	mg
Zohydro ER					
HYDROCODONE BITARTRATE	Zohydro ER	oral	capsule,extended release 12 hr	10	mg
HYDROCODONE BITARTRATE	Zohydro ER	oral	capsule,extended release 12 hr	15	mg
HYDROCODONE BITARTRATE	Zohydro ER	oral	capsule,extended release 12 hr	20	mg
HYDROCODONE BITARTRATE	Zohydro ER	oral	capsule,extended release 12 hr	30	mg
HYDROCODONE BITARTRATE	Zohydro ER	oral	capsule,extended release 12 hr	40	mg
HYDROCODONE BITARTRATE	Zohydro ER	oral	capsule,extended release 12 hr	50	mg
Exalgo ER					
HYDROMORPHONE HCL	Exalgo ER	oral	tablet extended release 24 hr	8	mg
HYDROMORPHONE HCL	Exalgo ER	oral	tablet extended release 24 hr	12	mg
HYDROMORPHONE HCL	Exalgo ER	oral	tablet extended release 24 hr	16	mg
HYDROMORPHONE HCL	Exalgo ER	oral	tablet extended release 24 hr	32	mg
Hydromorphone					
HYDROMORPHONE HCL	Hydromorphone	oral	tablet extended release 24 hr	8	mg
HYDROMORPHONE HCL	Hydromorphone	oral	tablet extended release 24 hr	12	mg
HYDROMORPHONE HCL	Hydromorphone	oral	tablet extended release 24 hr	16	mg
HYDROMORPHONE HCL	Hydromorphone	oral	tablet extended release 24 hr	32	mg

Palladone						
HYDROMORPHONE HCL	Palladone	oral	capsule,ext rel. pellets 24 hr	12	mg	
HYDROMORPHONE HCL	Palladone	oral	capsule,ext rel. pellets 24 hr	16	mg	
HYDROMORPHONE HCL	Palladone	oral	capsule,ext rel. pellets 24 hr	24	mg	
HYDROMORPHONE HCL	Palladone	oral	capsule,ext rel. pellets 24 hr	32	mg	
Avinza						
MORPHINE SULFATE	Avinza	oral	capsule, ER multiphase 24 hr	30	mg	
MORPHINE SULFATE	Avinza	oral	capsule, ER multiphase 24 hr	45	mg	
MORPHINE SULFATE	Avinza	oral	capsule, ER multiphase 24 hr	60	mg	
MORPHINE SULFATE	Avinza	oral	capsule, ER multiphase 24 hr	75	mg	
MORPHINE SULFATE	Avinza	oral	capsule, ER multiphase 24 hr	90	mg	
MORPHINE SULFATE	Avinza	oral	capsule, ER multiphase 24 hr	120	mg	
Kadian						
MORPHINE SULFATE	Kadian	oral	capsule,extend.release pellets	10	mg	
MORPHINE SULFATE	Kadian	oral	capsule,extend.release pellets	20	mg	
MORPHINE SULFATE	Kadian	oral	capsule,extend.release pellets	30	mg	
MORPHINE SULFATE	Kadian	oral	capsule,extend.release pellets	40	mg	
MORPHINE SULFATE	Kadian	oral	capsule,extend.release pellets	50	mg	
MORPHINE SULFATE	Kadian	oral	capsule,extend.release pellets	60	mg	
MORPHINE SULFATE	Kadian	oral	capsule,extend.release pellets	70	mg	
MORPHINE SULFATE	Kadian	oral	capsule,extend.release pellets	80	mg	
MORPHINE SULFATE	Kadian	oral	capsule,extend.release pellets	100	mg	
MORPHINE SULFATE	Kadian	oral	capsule,extend.release pellets	130	mg	
MORPHINE SULFATE	Kadian	oral	capsule,extend.release pellets	200	mg	
Morphine						
MORPHINE SULFATE	Morphine	oral	tablet extended release	15	mg	
MORPHINE SULFATE	Morphine	oral	tablet extended release	30	mg	
MORPHINE SULFATE	Morphine	oral	tablet extended release	60	mg	
MORPHINE SULFATE	Morphine	oral	tablet extended release	100	mg	
MORPHINE SULFATE	Morphine	oral	tablet extended release	200	mg	
MORPHINE SULFATE	Morphine	oral	capsule,extend.release pellets	10	mg	
MORPHINE SULFATE	Morphine	oral	capsule,extend.release pellets	15	mg	
MORPHINE SULFATE	Morphine	oral	capsule,extend.release pellets	20	mg	
MORPHINE SULFATE	Morphine	oral	capsule,extend.release pellets	30	mg	
MORPHINE SULFATE	Morphine	oral	capsule,extend.release pellets	50	mg	
MORPHINE SULFATE	Morphine	oral	capsule,extend.release pellets	60	mg	
MORPHINE SULFATE	Morphine	oral	capsule,extend.release pellets	80	mg	
MORPHINE SULFATE	Morphine	oral	capsule,extend.release pellets	100	mg	
MORPHINE SULFATE	Morphine	oral	capsule, ER multiphase 24 hr	30	mg	
MORPHINE SULFATE	Morphine	oral	capsule, ER multiphase 24 hr	45	mg	
MORPHINE SULFATE	Morphine	oral	capsule, ER multiphase 24 hr	60	mg	
MORPHINE SULFATE	Morphine	oral	capsule, ER multiphase 24 hr	75	mg	
MORPHINE SULFATE	Morphine	oral	capsule, ER multiphase 24 hr	90	mg	
MORPHINE SULFATE	Morphine	oral	capsule, ER multiphase 24 hr	120	mg	
MS Contin						
MORPHINE SULFATE	MS Contin	oral	tablet extended release	15	mg	
MORPHINE SULFATE	MS Contin	oral	tablet extended release	30	mg	
MORPHINE SULFATE	MS Contin	oral	tablet extended release	60	mg	

MORPHINE SULFATE	MS Contin	oral	tablet extended release	100	mg
MORPHINE SULFATE	MS Contin	oral	tablet extended release	200	mg
Oramorph SR					
MORPHINE SULFATE	Oramorph SR	oral	tablet extended release	15	mg
MORPHINE SULFATE	Oramorph SR	oral	tablet extended release	30	mg
MORPHINE SULFATE	Oramorph SR	oral	tablet extended release	60	mg
MORPHINE SULFATE	Oramorph SR	oral	tablet extended release	100	mg
Embeda					
MORPHINE SULFATE/NALTREXONE HCL	Embeda	oral	capsule,extend.release pellets	20-0.8	mg
MORPHINE SULFATE/NALTREXONE HCL	Embeda	oral	capsule,extend.release pellets	30-1.2	mg
MORPHINE SULFATE/NALTREXONE HCL	Embeda	oral	capsule,extend.release pellets	30-1.2	mg
MORPHINE SULFATE/NALTREXONE HCL	Embeda	oral	capsule,extend.release pellets	60-2.4	mg
MORPHINE SULFATE/NALTREXONE HCL	Embeda	oral	capsule,extend.release pellets	100-4	mg
Oxycodone					
OXYCODONE HCL	oxycodone	oral	tablet extended release 12 hr	10	mg
OXYCODONE HCL	oxycodone	oral	tablet extended release 12 hr	20	mg
OXYCODONE HCL	oxycodone	oral	tablet extended release 12 hr	40	mg
OXYCODONE HCL	oxycodone	oral	tablet extended release 12 hr	80	mg
OxyContin					
OXYCODONE HCL	OxyContin	oral	tablet extended release 12 hr	10	mg
OXYCODONE HCL	OxyContin	oral	tablet extended release 12 hr	15	mg
OXYCODONE HCL	OxyContin	oral	tablet extended release 12 hr	20	mg
OXYCODONE HCL	OxyContin	oral	tablet extended release 12 hr	30	mg
OXYCODONE HCL	OxyContin	oral	tablet extended release 12 hr	40	mg
OXYCODONE HCL	OxyContin	oral	tablet extended release 12 hr	60	mg
OXYCODONE HCL	OxyContin	oral	tablet extended release 12 hr	80	mg
OXYCODONE HCL	OxyContin	oral	tablet extended release 12 hr	160	mg
Opana ER					
OXYMORPHONE HCL	Opana ER	oral	tablet extended release 12 hr	5	mg
OXYMORPHONE HCL	Opana ER	oral	tablet extended release 12 hr	7.5	mg
OXYMORPHONE HCL	Opana ER	oral	tablet extended release 12 hr	10	mg
OXYMORPHONE HCL	Opana ER	oral	tablet extended release 12 hr	15	mg
OXYMORPHONE HCL	Opana ER	oral	tablet extended release 12 hr	20	mg
OXYMORPHONE HCL	Opana ER	oral	tablet extended release 12 hr	30	mg
OXYMORPHONE HCL	Opana ER	oral	tablet extended release 12 hr	40	mg
Oxymorphone					
OXYMORPHONE HCL	Oxymorphone	oral	tablet extended release 12 hr	5	mg
OXYMORPHONE HCL	Oxymorphone	oral	tablet extended release 12 hr	7.5	mg
OXYMORPHONE HCL	Oxymorphone	oral	tablet extended release 12 hr	10	mg
OXYMORPHONE HCL	Oxymorphone	oral	tablet extended release 12 hr	15	mg
OXYMORPHONE HCL	Oxymorphone	oral	tablet extended release 12 hr	20	mg
OXYMORPHONE HCL	Oxymorphone	oral	tablet extended release 12 hr	30	mg
OXYMORPHONE HCL	Oxymorphone	oral	tablet extended release 12 hr	40	mg
Nucynta ER					
TAPENTADOL HCL	Nucynta ER	oral	tablet extended release 12 hr	50	mg
TAPENTADOL HCL	Nucynta ER	oral	tablet extended release 12 hr	100	mg
TAPENTADOL HCL	Nucynta ER	oral	tablet extended release 12 hr	150	mg
TAPENTADOL HCL	Nucynta ER	oral	tablet extended release 12 hr	200	mg

TAPENTADOL HCL	Nucynta ER	oral	tablet extended release 12 hr	250	mg
Dolophine					
METHADONE HCL	Dolophine	oral	tablet	5	mg
METHADONE HCL	Dolophine	oral	tablet	10	mg
Methadone/Methadose					
METHADONE HCL	Methadone	oral	tablet	5	mg
METHADONE HCL	Methadone	oral	tablet	10	mg
METHADONE HCL	Methadone	oral	tablet,soluble	40	mg
METHADONE HCL	Methadone	oral	concentrate	10	mg
METHADONE HCL	Methadone	oral	solution	5	mg
METHADONE HCL	Methadone	oral	solution	10	mg
METHADONE HCL	Methadone	oral	syringe	5	mg
METHADONE HCL	Methadone	oral	syringe	10	mg
METHADONE HCL	Methadose	oral	tablet	5	mg
METHADONE HCL	Methadose	oral	tablet,soluble	40	mg
METHADONE HCL	Methadose	oral	concentrate	10	mg

Appendix B: Modular Program Specifications for to16_cap_mpl1r_wp035_nsdp_v01

The Opioid Analgesics Prescribing Trends Workgroup has requested the use of the Cohort Identification and Descriptive Analysis (CIDA) Tool, version 2.0.8, to quantify incident Extended-Release and Long-Acting (ER/LA) opioid analgesics use in the Mini-Sentinel Distributed Database (MSDD). In total, 46 different scenarios were examined in this report.

Enrollment Gap: 45 days		Query Period: 1/1/2009 - 12/31/2013			
Age Groups: , 12-17, 18-24, 25-34, 35-44, 45-54, 55-64		Coverage Requirement: Drug and Medical Coverage			
Pre-exposure		Drug/Exposure			
Scenario	Enrollment Requirement	Incident exposure	Incident w/ respect to:	Washout (days)	Cohort Definition
1	183	Butrans	All ER/LA opioid analgesics	183	02
2	90	Butrans	All ER/LA opioid analgesics	90	02
3	183	Duragesic	All ER/LA opioid analgesics	183	02
4	90	Duragesic	All ER/LA opioid analgesics	90	02
5	183	Generic fentanyl patch	All ER/LA opioid analgesics	183	02
6	90	Generic fentanyl patch	All ER/LA opioid analgesics	90	02
7	183	Hysingla ER	All ER/LA opioid analgesics	183	02
8	90	Hysingla ER	All ER/LA opioid analgesics	90	02
9	183	Zohydro ER	All ER/LA opioid analgesics	183	02
10	90	Zohydro ER	All ER/LA opioid analgesics	90	02
11	183	Exalgo ER	All ER/LA opioid analgesics	183	02
12	90	Exalgo ER	All ER/LA opioid analgesics	90	02
13	183	Generic ER/LA hydromorphone	All ER/LA opioid analgesics	183	02
14	90	Generic ER/LA hydromorphone	All ER/LA opioid analgesics	90	02
15	183	Palladone	All ER/LA opioid analgesics	183	02
16	90	Palladone	All ER/LA opioid analgesics	90	02
17	183	Avinza	All ER/LA opioid analgesics	183	02
18	90	Avinza	All ER/LA opioid analgesics	90	02
19	183	Kadian	All ER/LA opioid analgesics	183	02
20	90	Kadian	All ER/LA opioid analgesics	90	02
21	183	Generic ER/LA morphine	All ER/LA opioid analgesics	183	02
22	90	Generic ER/LA morphine	All ER/LA opioid analgesics	90	02
23	183	MS Contin	All ER/LA opioid analgesics	183	02
24	90	MS Contin	All ER/LA opioid analgesics	90	02
25	183	Oramorph SR	All ER/LA opioid analgesics	183	02
26	90	Oramorph SR	All ER/LA opioid analgesics	90	02
27	183	Embeda	All ER/LA opioid analgesics	183	02
28	90	Embeda	All ER/LA opioid analgesics	90	02
29	183	Generic ER/LA Oxycodone	All ER/LA opioid analgesics	183	02
30	90	Generic ER/LA Oxycodone	All ER/LA opioid analgesics	90	02
31	183	OxyContin	All ER/LA opioid analgesics	183	02
32	90	OxyContin	All ER/LA opioid analgesics	90	02
33	183	Opana ER	All ER/LA opioid analgesics	183	02
34	90	Opana ER	All ER/LA opioid analgesics	90	02
35	183	Generic ER/LA Oxymorphone	All ER/LA opioid analgesics	183	02
36	90	Generic ER/LA Oxymorphone	All ER/LA opioid analgesics	90	02
37	183	Nucynta ER	All ER/LA opioid analgesics	183	02
38	90	Nucynta ER	All ER/LA opioid analgesics	90	02
39	183	Dolophine	All ER/LA opioid analgesics	183	02
40	90	Dolophine	All ER/LA opioid analgesics	90	02
41	183	Generic Methadone (5-10 mg tablets)	All ER/LA opioid analgesics	183	02
42	90	Generic Methadone (5-10 mg tablets)	All ER/LA opioid analgesics	90	02
43	183	Generic Methadone (40 mg soluble tablets)	All ER/LA opioid analgesics	183	02
44	90	Generic Methadone (40 mg soluble tablets)	All ER/LA opioid analgesics	90	02
45	183	Generic Methadone (liquid formulations)	All ER/LA opioid analgesics	183	02
46	90	Generic Methadone (liquid formulations)	All ER/LA opioid analgesics	90	02

International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) diagnosis and procedure codes checked against "Ingenix 2012 ICD-9-CM Data File" provided by OptumInsight

Healthcare Common Procedure Coding System (HCPCS) codes checked against "Optum 2012 HCPCS Level II Data File" provided by OptumInsight

Current Procedural Terminology (CPT) codes checked against "Optum 2012 Current Procedure Codes & Relative Values Data File" provided by OptumInsight

Appendix C: Latest Date of Available Data for Each Data Partner up to Request Send Date (July 29, 2015)

DP ID	Start Date	End Date
DP0001	1/1/2009	12/31/2013
DP0002	1/1/2009	12/31/2013
DP0003	1/1/2009	12/31/2013
DP0004	1/1/2009	12/31/2013
DP0005	1/1/2009	12/31/2013
DP0006	1/1/2009	12/31/2013
DP0007	1/1/2009	12/31/2012
DP0008	1/1/2009	12/31/2013
DP0009	1/1/2009	12/31/2013
DP0010	1/1/2009	12/31/2013
DP0011	1/1/2009	12/31/2013
DP0012	1/1/2009	12/31/2013
DP0013	1/1/2009	6/30/2012
DP0014	1/1/2009	12/31/2013
DP0015	1/1/2009	12/31/2013