Disclaimer

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

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

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

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

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Request ID: cder_mpl1r_wp020_nsdp_v01

Query Description: This query investigated use of Statin drugs. Separate reports in this request examine Angiotensin Converting Enzyme (ACE) Inhibitor drugs and Beta Blocker drugs. This is report 1 of 3. Report 2 presents results on ACE inhibitors, and report 3 presents results on beta blockers.

Sentinel Modular Program Tool Used: Cohort Identification and Descriptive Analysis (CIDA) tool, version 2.2.1

Data Source: Data from January 1, 2011 to December 31, 2015, from 15 Data Partners contributing to the Sentinel Distributed Database (SDD) were included in this report. This request was distributed on June 17, 2016. See Appendix A for a list of the dates of available data for each Data Partner.

Study Design: This request was designed to calculate background rates for years 2011-2015. The number of qualifying patients with prevalent use of the drug of interest were calculated overall and by year, then stratified by age group and sex.

Exposure of Interest: The exposures of interest was use of Statin drugs, including Atorvastatin, Simvastatin, Rosuvastatin, and Pravastatin. Please see Appendix B for a list of generic and brand names of medical products used in this request.

Cohort Eligibility Criteria: Patients were required to be continuously enrolled in plans with both medical and drug coverage for at least 1 day, during which gaps in coverage of up to 45 days were allowed. The following age groups were included in the cohort: 0-21, 22-44, 45-64, and 65+ years.

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

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

Notes: Please contact the Sentinel Operations Center (info@sentinelsystem.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.sentinelsystem.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 Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug and Year

Year	New Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member- Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
2011										
Atorvastatin, Simvastatin, Rosuvastatin, Pravastatin										
	4,278,500	20,171,342	941,125,226	924,169,057	48,590,889	39,900,487.1	88.05	219.97	4.71	46.66
Atorvastatin										
	1,124,683	5,447,071	236,689,480	226,721,769	48,590,889	39,900,487.1	23.15	210.45	4.84	43.45
Pravastatin										
	585,224	2,393,784	109,578,648	111,636,281	48,590,889	39,900,487.1	12.04	187.24	4.09	45.78
Rosuvastatin										
	627,747	3,033,077	121,759,077	117,946,525	48,590,889	39,900,487.1	12.92	193.96	4.83	40.14
Simvastatin										
	2,208,981	9,297,410	473,098,021	467,864,483	48,590,889	39,900,487.1	45.46	214.17	4.21	50.88
2012										
Atorvastatin, Pravastatin, Rosuvastatin, Simvastatin										
	4,489,872	21,203,506	1,008,344,154	983,483,915	50,002,931	41,147,651.0	89.79	224.58	4.72	47.56
Atorvastatin										
	1,485,142	6,731,000	296,902,294	280,301,221	50,002,931	41,147,651.0	29.70	199.92	4.53	44.11
Pravastatin										
	695,171	2,965,563	144,300,158	146,634,840	50,002,931	41,147,651.0	13.90	207.58	4.27	48.66
Rosuvastatin										
	630,036	3,116,274	126,034,034	121,535,775	50,002,931	41,147,651.0	12.60	200.04	4.95	40.44
Simvastatin										
	1,933,641	8,390,669	441,107,668	435,012,078	50,002,931	41,147,651.0	38.67	228.12	4.34	52.57
2013										
Atorvastatin, Pravastatin, Rosuvastatin, Simvastatin										
	4,490,771	20,412,266	1,003,444,890	982,076,955	50,092,041	40,934,330.3	89.65	223.45	4.55	49.16
Atorvastatin										
	1,625,394	6,821,379	323,359,360	308,947,307	50,092,041	40,934,330.3	32.45	198.94	4.20	47.40
Pravastatin										
	730,103	3,126,488	154,964,038	157,392,072	50,092,041	40,934,330.3	14.58	212.25	4.28	49.56
Rosuvastatin										
	596,596	3,003,407	122,540,696	118,598,689	50,092,041	40,934,330.3	11.91	205.40	5.03	40.80
Simvastatin										
	1,735,379	7,460,992	402,580,796	397,138,887	50,092,041	40,934,330.3	34.64	231.98	4.30	53.96

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2014										
Atorvastatin, Pravastatin, Rosuvastatin, Simvastatin										
	4,704,096	21,391,925	1,078,512,648	1,060,229,736	52,192,175	42,131,001.3	90.13	229.27	4.55	50.42
Atorvastatin										
	1,895,490	7,932,944	398,346,743	385,980,108	52,192,175	42,131,001.3	36.32	210.16	4.19	50.21
Pravastatin										
	783,260	3,433,685	169,557,796	171,965,963	52,192,175	42,131,001.3	15.01	216.48	4.38	49.38
Rosuvastatin										
	582,727	2,870,674	120,358,410	116,748,201	52,192,175	42,131,001.3	11.17	206.54	4.93	41.93
Simvastatin										
	1,647,756	7,154,622	390,249,699	385,535,464	52,192,175	42,131,001.3	31.57	236.84	4.34	54.55
2015										
Atorvastatin, Pravastatin, Rosuvastatin, Simvastatin										
	4,256,836	14,611,879	676,677,449	665,283,152	48,252,032	29,099,337.9	88.22	158.96	3.43	46.31
Atorvastatin										
	1,842,551	6,072,176	283,252,099	275,416,946	48,252,032	29,099,337.9	38.19	153.73	3.30	46.65
Pravastatin										
	670,097	2,240,834	100,026,603	101,121,420	48,252,032	29,099,337.9	13.89	149.27	3.34	44.64
Rosuvastatin										
	483,907	1,780,572	68,475,850	66,425,775	48,252,032	29,099,337.9	10.03	141.51	3.68	38.46
Simvastatin										
	1,365,910	4,518,297	224,922,897	222,319,011	48,252,032	29,099,337.9	28.31	164.67	3.31	49.78
2011-2015										
Atorvastatin, Pravastatin, Rosuvastatin, Simvastatin										
	9,388,198	97,790,918	4,708,104,367	4,615,242,815	95,195,286	193,212,807.5	98.62	501.49	10.42	48.14
Atorvastatin										
	3,881,989	33,004,570	1,538,549,976	1,477,367,351	95,195,286	193,212,807.5	40.78	396.33	8.50	46.62
Pravastatin										
	1,676,677	14,160,354	678,427,243	688,750,576	95,195,286	193,212,807.5	17.61	404.63	8.45	47.91
Rosuvastatin										
	1,359,223	13,804,004	559,168,067	541,254,966	95,195,286	193,212,807.5	14.28	411.39	10.16	40.51
Simvastatin										
	3,945,379	36,821,990	1,931,959,081	1,907,869,923	95,195,286	193,212,807.5	41.45	489.68	9.33	52.47

Table 2. Summary of Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Age Group

Year	New Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
2011										
Atorvastatin, Simvastatin, Rosuvastatin, Pravastatin										
00-21 Years	4,605	17,219	634,121	626,897	14,021,420	11,122,212.1	0.33	137.70	3.74	36.83
22-44 Years	385,134	1,561,038	59,989,716	59,373,907	17,215,602	12,947,975.5	22.37	155.76	4.05	38.43
45-64 Years	2,370,605	11,278,924	486,544,088	478,433,127	14,146,778	11,616,603.0	167.57	205.24	4.76	43.14
65+ Years	1,599,881	7,314,161	393,957,301	385,735,128	4,705,738	4,213,696.5	339.99	246.24	4.57	53.86
Atorvastatin										
00-21 Years	1,412	5,389	203,272	196,710	14,021,420	11,122,212.1	0.10	143.96	3.82	37.72
22-44 Years	88,480	358,803	13,308,164	12,870,660	17,215,602	12,947,975.5	5.14	150.41	4.06	37.09
45-64 Years	650,308	3,187,290	131,466,366	125,974,831	14,146,778	11,616,603.0	45.97	202.16	4.90	41.25
65+ Years	406,248	1,895,589	91,711,678	87,679,568	4,705,738	4,213,696.5	86.33	225.75	4.67	48.38
Pravastatin										
00-21 Years	702	2,681	92,475	88,879	14,021,420	11,122,212.1	0.05	131.73	3.82	34.49
22-44 Years	50,803	186,320	6,781,133	6,886,083	17,215,602	12,947,975.5	2.95	133.48	3.67	36.40
45-64 Years	299,090	1,245,845	51,430,174	52,533,069	14,146,778	11,616,603.0	21.14	171.96	4.17	41.28
65+ Years	242,752	958,938	51,274,866	52,128,250	4,705,738	4,213,696.5	51.59	211.22	3.95	53.47
Rosuvastatin										
00-21 Years	606	2,171	80,733	80,155	14,021,420	11,122,212.1	0.04	133.22	3.58	37.19
22-44 Years	68,810	286,495	10,205,216	9,982,886	17,215,602	12,947,975.5	4.00	148.31	4.16	35.62
45-64 Years	401,618	1,967,987	76,700,045	74,479,679	14,146,778	11,616,603.0	28.39	190.98	4.90	38.97
65+ Years	168,985	776,424	34,773,083	33,403,805	4,705,738	4,213,696.5	35.91	205.78	4.59	44.79
Simvastatin										
00-21 Years	2,046	6,978	257,641	261,153	14,021,420	11,122,212.1	0.15	125.92	3.41	36.92
22-44 Years	193,723	729,420	29,695,203	29,634,278	17,215,602	12,947,975.5	11.25	153.29	3.77	40.71
45-64 Years	1,149,264	4,877,802	226,947,503	225,445,547	14,146,778	11,616,603.0	81.24	197.47	4.24	46.53
65+ Years	901,650	3,683,210	216,197,674	212,523,504	4,705,738	4,213,696.5	191.61	239.78	4.08	58.70

Table 2. Summary of Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Age Group

Year	New Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
2012										
Atorvastatin, Pravastatin, Rosuvastatin, Simvastatin										
00-21 Years	4,590	17,377	634,692	622,798	14,096,676	11,173,551.7	0.33	138.28	3.79	36.52
22-44 Years	381,813	1,583,241	60,823,178	59,821,369	17,663,114	13,289,779.9	21.62	159.30	4.15	38.42
45-64 Years	2,430,474	11,687,924	505,119,307	493,642,708	14,617,059	11,983,381.5	166.28	207.83	4.81	43.22
65+ Years	1,762,887	7,914,964	441,766,977	429,397,040	5,235,850	4,700,937.9	336.70	250.59	4.49	55.81
Atorvastatin										
00-21 Years	1,765	6,495	237,996	228,235	14,096,676	11,173,551.7	0.13	134.84	3.68	36.64
22-44 Years	126,335	493,800	18,151,567	17,439,282	17,663,114	13,289,779.9	7.15	143.68	3.91	36.76
45-64 Years	835,788	3,892,602	159,300,403	151,333,634	14,617,059	11,983,381.5	57.18	190.60	4.66	40.92
65+ Years	549,055	2,338,103	119,212,328	111,300,071	5,235,850	4,700,937.9	104.86	217.12	4.26	50.99
Pravastatin										
00-21 Years	733	2,827	99,062	95,825	14,096,676	11,173,551.7	0.05	135.15	3.86	35.04
22-44 Years	56,244	215,112	8,040,259	8,147,925	17,663,114	13,289,779.9	3.18	142.95	3.82	37.38
45-64 Years	342,488	1,482,349	63,667,323	64,842,068	14,617,059	11,983,381.5	23.43	185.90	4.33	42.95
65+ Years	306,944	1,265,275	72,493,514	73,549,023	5,235,850	4,700,937.9	58.62	236.18	4.12	57.29
Rosuvastatin										
00-21 Years	588	2,212	80,055	77,704	14,096,676	11,173,551.7	0.04	136.15	3.76	36.19
22-44 Years	62,785	270,149	9,628,596	9,359,536	17,663,114	13,289,779.9	3.55	153.36	4.30	35.64
45-64 Years	398,548	2,003,993	78,143,058	75,448,115	14,617,059	11,983,381.5	27.27	196.07	5.03	38.99
65+ Years	181,215	839,920	38,182,325	36,650,421	5,235,850	4,700,937.9	34.61	210.70	4.63	45.46
Simvastatin										
00-21 Years	1,654	5,843	217,579	221,035	14,096,676	11,173,551.7	0.12	131.55	3.53	37.24
22-44 Years	153,244	604,180	25,002,756	24,874,627	17,663,114	13,289,779.9	8.68	163.16	3.94	41.38
45-64 Years	975,922	4,308,980	204,008,523	202,018,892	14,617,059	11,983,381.5	66.77	209.04	4.42	47.34
65+ Years	839,046	3,471,666	211,878,810	207,897,526	5,235,850	4,700,937.9	160.25	252.52	4.14	61.03

Table 2. Summary of Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Age Group

Year	New Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
2013										
Atorvastatin, Pravastatin, Rosuvastatin, Simvastatin										
00-21 Years	4,295	16,012	585,900	574,124	13,906,114	10,929,960.7	0.31	136.41	3.73	36.59
22-44 Years	362,746	1,462,105	56,721,210	56,028,621	17,792,983	13,257,242.5	20.39	156.37	4.03	38.79
45-64 Years	2,380,367	11,095,998	486,376,281	477,137,549	14,579,539	11,915,058.8	163.27	204.33	4.66	43.83
65+ Years	1,825,476	7,838,151	459,761,499	448,336,662	5,383,559	4,832,068.2	339.08	251.86	4.29	58.66
Atorvastatin										
00-21 Years	1,755	6,259	230,852	220,847	13,906,114	10,929,960.7	0.13	131.54	3.57	36.88
22-44 Years	140,025	512,767	19,666,778	19,148,387	17,792,983	13,257,242.5	7.87	140.45	3.66	38.35
45-64 Years	889,927	3,837,743	164,473,997	157,987,813	14,579,539	11,915,058.8	61.04	184.82	4.31	42.86
65+ Years	620,774	2,464,610	138,987,733	131,590,260	5,383,559	4,832,068.2	115.31	223.89	3.97	56.39
Pravastatin										
00-21 Years	707	2,815	98,182	96,092	13,906,114	10,929,960.7	0.05	138.87	3.98	34.88
22-44 Years	56,193	217,342	8,127,141	8,225,082	17,792,983	13,257,242.5	3.16	144.63	3.87	37.39
45-64 Years	356,031	1,561,696	67,044,262	68,230,380	14,579,539	11,915,058.8	24.42	188.31	4.39	42.93
65+ Years	328,586	1,344,635	79,694,453	80,840,517	5,383,559	4,832,068.2	61.04	242.54	4.09	59.27
Rosuvastatin										
00-21 Years	538	1,982	72,940	71,949	13,906,114	10,929,960.7	0.04	135.58	3.68	36.80
22-44 Years	54,922	241,769	8,607,855	8,431,730	17,792,983	13,257,242.5	3.09	156.73	4.40	35.60
45-64 Years	376,070	1,927,046	75,078,795	72,764,111	14,579,539	11,915,058.8	25.79	199.64	5.12	38.96
65+ Years	177,212	832,610	38,781,106	37,330,900	5,383,559	4,832,068.2	32.92	218.84	4.70	46.58
Simvastatin										
00-21 Years	1,409	4,956	183,926	185,236	13,906,114	10,929,960.7	0.10	130.54	3.52	37.11
22-44 Years	124,143	490,227	20,319,436	20,223,422	17,792,983	13,257,242.5	6.98	163.68	3.95	41.45
45-64 Years	852,771	3,769,513	179,779,227	178,155,244	14,579,539	11,915,058.8	58.49	210.82	4.42	47.69
65+ Years	787,409	3,196,296	202,298,207	198,574,985	5,383,559	4,832,068.2	146.26	256.92	4.06	63.29

Table 2. Summary of Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Age Group

Year	New Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
2014										
Atorvastatin, Pravastatin, Rosuvastatin, Simvastatin										
00-21 Years	4,058	15,254	567,733	554,660	13,873,358	10,845,684.4	0.29	139.90	3.76	37.22
22-44 Years	350,386	1,423,058	55,935,090	55,460,034	18,683,301	13,717,389.5	18.75	159.64	4.06	39.31
45-64 Years	2,409,997	11,240,068	500,480,338	493,254,601	15,392,745	12,306,230.0	156.57	207.67	4.66	44.53
65+ Years	2,025,639	8,713,545	521,529,487	510,960,441	5,892,108	5,261,697.4	343.79	257.46	4.30	59.85
Atorvastatin										
00-21 Years	1,820	6,353	241,924	233,218	13,873,358	10,845,684.4	0.13	132.93	3.49	38.08
22-44 Years	153,345	574,675	22,873,018	22,491,335	18,683,301	13,717,389.5	8.21	149.16	3.75	39.80
45-64 Years	990,027	4,258,904	191,503,712	186,325,168	15,392,745	12,306,230.0	64.32	193.43	4.30	44.97
65+ Years	782,787	3,093,012	183,728,089	176,930,387	5,892,108	5,261,697.4	132.85	234.71	3.95	59.40
Pravastatin										
00-21 Years	653	2,631	93,454	90,527	13,873,358	10,845,684.4	0.05	143.11	4.03	35.52
22-44 Years	54,336	218,837	8,147,289	8,234,536	18,683,301	13,717,389.5	2.91	149.94	4.03	37.23
45-64 Years	377,160	1,711,731	72,408,903	73,544,242	15,392,745	12,306,230.0	24.50	191.98	4.54	42.30
65+ Years	363,362	1,500,486	88,908,150	90,096,658	5,892,108	5,261,697.4	61.67	244.68	4.13	59.25
Rosuvastatin										
00-21 Years	481	1,739	65,698	63,492	13,873,358	10,845,684.4	0.03	136.59	3.62	37.78
22-44 Years	47,850	206,935	7,476,945	7,350,805	18,683,301	13,717,389.5	2.56	156.26	4.32	36.13
45-64 Years	353,711	1,768,124	70,545,757	68,550,420	15,392,745	12,306,230.0	22.98	199.44	5.00	39.90
65+ Years	192,379	893,876	42,270,010	40,783,485	5,892,108	5,261,697.4	32.65	219.72	4.65	47.29
Simvastatin										
00-21 Years	1,214	4,531	166,657	167,423	13,873,358	10,845,684.4	0.09	137.28	3.73	36.78
22-44 Years	106,204	422,611	17,437,838	17,383,359	18,683,301	13,717,389.5	5.68	164.19	3.98	41.26
45-64 Years	781,723	3,501,309	166,021,966	164,834,771	15,392,745	12,306,230.0	50.79	212.38	4.48	47.42
65+ Years	787,070	3,226,171	206,623,238	203,149,911	5,892,108	5,261,697.4	133.58	262.52	4.10	64.05

Table 2. Summary of Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Age Group

Year	New Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
2015										
Atorvastatin, Pravastatin, Rosuvastatin, Simvastatin										
00-21 Years	2,731	8,579	302,650	296,464	11,862,418	6,975,681.5	0.23	110.82	3.14	35.28
22-44 Years	270,169	889,620	32,883,137	32,588,011	17,138,860	9,592,136.4	15.76	121.71	3.29	36.96
45-64 Years	2,078,729	7,566,837	309,927,790	305,510,576	14,500,050	8,708,542.1	143.36	149.09	3.64	40.96
65+ Years	1,957,998	6,146,843	333,563,872	326,888,101	5,904,954	3,822,977.9	331.59	170.36	3.14	54.27
Atorvastatin										
00-21 Years	1,308	3,974	141,541	137,096	11,862,418	6,975,681.5	0.11	108.21	3.04	35.62
22-44 Years	130,393	409,175	15,362,265	15,135,639	17,138,860	9,592,136.4	7.61	117.82	3.14	37.54
45-64 Years	917,053	3,184,084	132,522,672	129,393,562	14,500,050	8,708,542.1	63.24	144.51	3.47	41.62
65+ Years	816,509	2,474,943	135,225,621	130,750,649	5,904,954	3,822,977.9	138.28	165.61	3.03	54.64
Pravastatin										
00-21 Years	443	1,484	50,450	48,854	11,862,418	6,975,681.5	0.04	113.88	3.35	34.00
22-44 Years	38,256	127,699	4,441,023	4,465,511	17,138,860	9,592,136.4	2.23	116.09	3.34	34.78
45-64 Years	306,812	1,111,602	42,891,654	43,355,544	14,500,050	8,708,542.1	21.16	139.80	3.62	38.59
65+ Years	331,513	1,000,049	52,643,476	53,251,511	5,904,954	3,822,977.9	56.14	158.80	3.02	52.64
Rosuvastatin										
00-21 Years	314	964	35,107	34,282	11,862,418	6,975,681.5	0.03	111.81	3.07	36.42
22-44 Years	34,301	117,524	3,957,548	3,899,901	17,138,860	9,592,136.4	2.00	115.38	3.43	33.67
45-64 Years	284,834	1,081,766	39,553,946	38,466,027	14,500,050	8,708,542.1	19.64	138.87	3.80	36.56
65+ Years	170,738	580,318	24,929,249	24,025,565	5,904,954	3,822,977.9	28.91	146.01	3.40	42.96
Simvastatin										
00-21 Years	708	2,157	75,552	76,232	11,862,418	6,975,681.5	0.06	106.71	3.05	35.03
22-44 Years	72,495	235,222	9,122,301	9,086,960	17,138,860	9,592,136.4	4.23	125.83	3.24	38.78
45-64 Years	617,442	2,189,385	94,959,518	94,295,444	14,500,050	8,708,542.1	42.58	153.80	3.55	43.37
65+ Years	691,642	2,091,533	120,765,526	118,860,376	5,904,954	3,822,977.9	117.13	174.61	3.02	57.74

Table 2. Summary of Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Age Group

Year	New Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
2011-2015										
Atorvastatin, Pravastatin, Rosuvastatin, Simvastatin										
00-21 Years	12,575	74,441	2,725,096	2,674,942	27,178,643	51,047,090.4	0.46	216.71	5.92	36.61
22-44 Years	971,437	6,919,062	266,352,331	263,271,941	38,224,633	62,804,523.7	25.41	274.18	7.12	38.50
45-64 Years	5,332,300	52,869,751	2,288,447,804	2,247,978,560	28,333,576	56,529,815.5	188.20	429.17	9.91	43.28
65+ Years	3,622,935	37,927,664	2,150,579,136	2,101,317,371	9,260,114	22,831,377.9	391.24	593.60	10.47	56.70
Atorvastatin										
00-21 Years	5,110	28,470	1,055,585	1,016,106	27,178,643	51,047,090.4	0.19	206.57	5.57	37.08
22-44 Years	386,204	2,349,220	89,361,792	87,085,302	38,224,633	62,804,523.7	10.10	231.38	6.08	38.04
45-64 Years	2,188,452	18,360,623	779,267,150	751,015,008	28,333,576	56,529,815.5	77.24	356.08	8.39	42.44
65+ Years	1,481,926	12,266,257	668,865,449	638,250,934	9,260,114	22,831,377.9	160.03	451.35	8.28	54.53
Pravastatin										
00-21 Years	2,111	12,438	433,623	420,176	27,178,643	51,047,090.4	0.08	205.41	5.89	34.86
22-44 Years	156,523	965,310	35,536,845	35,959,137	38,224,633	62,804,523.7	4.09	227.04	6.17	36.81
45-64 Years	883,571	7,113,223	297,442,316	302,505,304	28,333,576	56,529,815.5	31.18	336.64	8.05	41.82
65+ Years	702,283	6,069,383	345,014,459	349,865,959	9,260,114	22,831,377.9	75.84	491.28	8.64	56.85
Rosuvastatin										
00-21 Years	1,571	9,068	334,533	327,581	27,178,643	51,047,090.4	0.06	212.94	5.77	36.89
22-44 Years	151,840	1,122,872	39,876,160	39,024,858	38,224,633	62,804,523.7	3.97	262.62	7.40	35.51
45-64 Years	860,946	8,748,916	340,021,601	329,708,351	28,333,576	56,529,815.5	30.39	394.94	10.16	38.86
65+ Years	418,008	3,923,148	178,935,773	172,194,176	9,260,114	22,831,377.9	45.14	428.07	9.39	45.61
Simvastatin										
00-21 Years	4,646	24,465	901,355	911,078	27,178,643	51,047,090.4	0.17	194.01	5.27	36.84
22-44 Years	377,007	2,481,660	101,577,534	101,202,644	38,224,633	62,804,523.7	9.86	269.43	6.58	40.93
45-64 Years	2,117,041	18,646,989	871,716,737	864,749,898	28,333,576	56,529,815.5	74.72	411.76	8.81	46.75
65+ Years	1,653,240	15,668,876	957,763,455	941,006,302	9,260,114	22,831,377.9	178.53	579.33	9.48	61.13

Table 3. Summary of Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Sex

Year	New Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member- Years	New Users per 1,000 Eligible	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
2011										
Atorvastatin, Simvastatin, Rosuvastatin, Pravastatin										
Female	1,956,442	9,085,365	429,117,612	421,616,002	24,758,280	20,439,743.4	79.02	219.34	4.64	47.23
Male	2,321,779	11,084,597	511,940,745	502,486,457	23,830,255	19,458,864.3	97.43	220.50	4.77	46.18
Unknown	279	1,380	66,869	66,598	2,354	1,879.3	118.52	239.67	4.95	48.46
Atorvastatin										
Female	464,902	2,202,560	96,094,625	91,806,981	24,758,280	20,439,743.4	18.78	206.70	4.74	43.63
Male	659,694	3,244,036	140,574,312	134,894,651	23,830,255	19,458,864.3	27.68	213.09	4.92	43.33
Unknown	87	475	20,543	20,138	2,354	1,879.3	36.96	236.13	5.46	43.25
Pravastatin										
Female	298,517	1,206,636	55,845,631	56,814,814	24,758,280	20,439,743.4	12.06	187.08	4.04	46.28
Male	286,665	1,186,958	53,723,228	54,811,216	23,830,255	19,458,864.3	12.03	187.41	4.14	45.26
Unknown	42	190	9,789	10,250	2,354	1,879.3	17.84	233.07	4.52	51.52
Rosuvastatin										
Female	266,496	1,248,252	50,268,399	48,550,722	24,758,280	20,439,743.4	10.76	188.63	4.68	40.27
Male	361,200	1,784,596	71,480,754	69,385,995	23,830,255	19,458,864.3	15.16	197.90	4.94	40.05
Unknown	51	229	9,924	9,807	2,354	1,879.3	21.67	194.59	4.49	43.34
Simvastatin										
Female	1,054,384	4,427,917	226,908,957	224,443,485	24,758,280	20,439,743.4	42.59	215.21	4.20	51.25
Male	1,154,482	4,869,007	246,162,451	243,394,594	23,830,255	19,458,864.3	48.45	213.22	4.22	50.56
Unknown	115	486	26,613	26,403	2,354	1,879.3	48.85	231.42	4.23	54.76

Table 3. Summary of Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Sex

Year	New Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member- Years	New Users per 1,000 Eligible	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
2012										
Atorvastatin, Pravastatin, Rosuvastatin, Simvastatin										
Female	2,046,313	9,473,802	458,366,183	447,802,294	25,432,727	21,029,503.4	80.46	224.00	4.63	48.38
Male	2,443,270	11,728,318	549,908,889	535,612,541	24,567,557	20,116,040.2	99.45	225.07	4.80	46.89
Unknown	289	1,386	69,082	69,080	2,647	2,107.3	109.18	239.04	4.80	49.84
Atorvastatin										
Female	625,949	2,732,793	122,062,555	114,763,445	25,432,727	21,029,503.4	24.61	195.00	4.37	44.67
Male	859,071	3,997,628	174,811,670	165,510,454	24,567,557	20,116,040.2	34.97	203.49	4.65	43.73
Unknown	122	579	28,069	27,322	2,647	2,107.3	46.09	230.07	4.75	48.48
Pravastatin										
Female	354,296	1,486,444	73,384,194	74,476,266	25,432,727	21,029,503.4	13.93	207.13	4.20	49.37
Male	340,832	1,478,928	70,905,657	72,147,422	24,567,557	20,116,040.2	13.87	208.04	4.34	47.94
Unknown	43	191	10,307	11,152	2,647	2,107.3	16.24	239.70	4.44	53.96
Rosuvastatin										
Female	266,699	1,275,827	51,917,525	49,944,348	25,432,727	21,029,503.4	10.49	194.67	4.78	40.69
Male	363,293	1,840,240	74,108,048	71,583,011	24,567,557	20,116,040.2	14.79	203.99	5.07	40.27
Unknown	44	207	8,461	8,416	2,647	2,107.3	16.62	192.30	4.70	40.87
Simvastatin										
Female	919,902	3,978,738	211,001,909	208,618,235	25,432,727	21,029,503.4	36.17	229.37	4.33	53.03
Male	1,013,641	4,411,522	230,083,514	226,371,653	24,567,557	20,116,040.2	41.26	226.99	4.35	52.16
Unknown	98	409	22,245	22,190	2,647	2,107.3	37.02	226.99	4.17	54.39

Table 3. Summary of Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Sex

Year	New Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member- Years	New Users per 1,000 Eligible	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
2013										
Atorvastatin, Pravastatin, Rosuvastatin, Simvastatin										
Female	2,053,697	9,160,478	459,050,965	450,102,601	25,429,877	20,893,234.8	80.76	223.52	4.46	50.11
Male	2,436,803	11,250,497	544,332,911	531,913,822	24,659,733	20,039,309.0	98.82	223.38	4.62	48.38
Unknown	271	1,291	61,014	60,532	2,431	1,786.4	111.48	225.14	4.76	47.26
Atorvastatin										
Female	690,902	2,802,296	135,354,946	129,188,312	25,429,877	20,893,234.8	27.17	195.91	4.06	48.30
Male	934,377	4,018,557	187,980,642	179,735,643	24,659,733	20,039,309.0	37.89	201.18	4.30	46.78
Unknown	115	526	23,772	23,352	2,431	1,786.4	47.31	206.71	4.57	45.19
Pravastatin										
Female	373,632	1,570,522	79,248,637	80,415,334	25,429,877	20,893,234.8	14.69	212.10	4.20	50.46
Male	356,425	1,555,756	75,705,359	76,966,361	24,659,733	20,039,309.0	14.45	212.40	4.36	48.66
Unknown	46	210	10,042	10,377	2,431	1,786.4	18.92	218.30	4.57	47.82
Rosuvastatin										
Female	254,245	1,235,114	50,749,897	48,952,303	25,429,877	20,893,234.8	10.00	199.61	4.86	41.09
Male	342,316	1,768,099	71,783,037	69,638,837	24,659,733	20,039,309.0	13.88	209.70	5.17	40.60
Unknown	35	194	7,762	7,550	2,431	1,786.4	14.40	221.77	5.54	40.01
Simvastatin										
Female	830,298	3,552,546	193,697,485	191,546,653	25,429,877	20,893,234.8	32.65	233.29	4.28	54.52
Male	904,998	3,908,085	208,863,873	205,572,981	24,659,733	20,039,309.0	36.70	230.79	4.32	53.44
Unknown	83	361	19,438	19,253	2,431	1,786.4	34.14	234.19	4.35	53.84

Table 3. Summary of Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Sex

Year	New Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member- Years	New Users per 1,000 Eligible	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
2014										
Atorvastatin, Pravastatin, Rosuvastatin, Simvastatin										
Female	2,160,474	9,644,631	495,249,732	487,468,254	26,474,584	21,486,218.3	81.61	229.23	4.46	51.35
Male	2,543,377	11,746,175	583,207,572	572,706,845	25,715,224	20,643,097.6	98.91	229.30	4.62	49.65
Unknown	245	1,119	55,344	54,638	2,367	1,685.5	103.51	225.89	4.57	49.46
Atorvastatin										
Female	807,210	3,274,388	167,803,313	162,511,303	26,474,584	21,486,218.3	30.49	207.88	4.06	51.25
Male	1,088,178	4,658,064	230,520,038	223,445,772	25,715,224	20,643,097.6	42.32	211.84	4.28	49.49
Unknown	102	492	23,392	23,033	2,367	1,685.5	43.09	229.33	4.82	47.54
Pravastatin										
Female	403,060	1,735,155	87,320,658	88,468,653	26,474,584	21,486,218.3	15.22	216.64	4.30	50.32
Male	380,162	1,698,368	82,228,598	83,488,815	25,715,224	20,643,097.6	14.78	216.30	4.47	48.42
Unknown	38	162	8,540	8,495	2,367	1,685.5	16.05	224.74	4.26	52.72
Rosuvastatin										
Female	251,333	1,194,648	50,436,828	48,744,630	26,474,584	21,486,218.3	9.49	200.68	4.75	42.22
Male	331,363	1,675,897	69,916,312	67,998,547	25,715,224	20,643,097.6	12.89	211.00	5.06	41.72
Unknown	31	129	5,270	5,025	2,367	1,685.5	13.10	170.00	4.16	40.85
Simvastatin										
Female	796,580	3,440,440	189,688,933	187,743,668	26,474,584	21,486,218.3	30.09	238.13	4.32	55.14
Male	851,096	3,713,846	200,542,624	197,773,711	25,715,224	20,643,097.6	33.10	235.63	4.36	54.00
Unknown	80	336	18,142	18,085	2,367	1,685.5	33.80	226.78	4.20	53.99

Table 3. Summary of Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Sex

Year	New Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member- Years	New Users per 1,000 Eligible	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
2015										
Atorvastatin, Pravastatin, Rosuvastatin, Simvastatin										
Female	1,956,347	6,575,821	310,100,540	305,222,731	24,392,996	14,787,700.3	80.20	158.51	3.36	47.16
Male	2,300,283	8,035,527	366,551,974	360,035,775	23,856,625	14,310,501.0	96.42	159.35	3.49	45.62
Unknown	206	531	24,935	24,645	2,411	1,136.6	85.44	121.04	2.58	46.96
Atorvastatin										
Female	785,329	2,516,898	119,744,738	116,386,090	24,392,996	14,787,700.3	32.19	152.48	3.20	47.58
Male	1,057,123	3,555,016	163,495,512	159,019,142	23,856,625	14,310,501.0	44.31	154.66	3.36	45.99
Unknown	99	262	11,849	11,714	2,411	1,136.6	41.06	119.69	2.65	45.23
Pravastatin										
Female	347,229	1,135,250	51,617,584	52,137,039	24,392,996	14,787,700.3	14.23	148.66	3.27	45.47
Male	322,836	1,105,518	48,405,508	48,980,916	23,856,625	14,310,501.0	13.53	149.94	3.42	43.79
Unknown	32	66	3,511	3,466	2,411	1,136.6	13.27	109.72	2.06	53.20
Rosuvastatin										
Female	208,662	744,328	28,806,748	27,837,783	24,392,996	14,787,700.3	8.55	138.05	3.57	38.70
Male	275,228	1,036,204	39,667,158	38,586,200	23,856,625	14,310,501.0	11.54	144.12	3.76	38.28
Unknown	17	40	1,944	1,792	2,411	1,136.6	7.05	114.35	2.35	48.60
Simvastatin										
Female	665,303	2,179,345	109,931,470	108,861,820	24,392,996	14,787,700.3	27.27	165.24	3.28	50.44
Male	700,547	2,338,789	114,983,796	113,449,518	23,856,625	14,310,501.0	29.36	164.13	3.34	49.16
Unknown	60	163	7,631	7,674	2,411	1,136.6	24.89	127.18	2.72	46.82

Table 3. Summary of Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Sex

Year	New Users	Dispensings	Days Supplied	Amount Supplied	Eligible Members	Member- Years	New Users per 1,000 Eligible	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
2011-2015										
Atorvastatin, Pravastatin, Rosuvastatin, Simvastatin										
Female	4,290,176	43,940,097	2,151,885,032	2,112,211,883	48,090,136	98,636,400.3	89.21	501.58	10.24	48.97
Male	5,097,551	53,845,114	2,555,942,091	2,502,755,440	47,099,887	94,567,812.2	108.23	501.41	10.56	47.47
Unknown	471	5,707	277,244	275,492	5,263	8,595.1	89.49	588.63	12.12	48.58
Atorvastatin										
Female	1,665,868	13,528,935	641,060,177	614,656,130	48,090,136	98,636,400.3	34.64	384.82	8.12	47.38
Male	2,215,902	19,473,301	897,382,174	862,605,663	47,099,887	94,567,812.2	47.05	404.97	8.79	46.08
Unknown	219	2,334	107,625	105,558	5,263	8,595.1	41.61	491.44	10.66	46.11
Pravastatin										
Female	860,323	7,134,007	347,416,704	352,312,106	48,090,136	98,636,400.3	17.89	403.82	8.29	48.70
Male	816,270	7,025,528	330,968,350	336,394,730	47,099,887	94,567,812.2	17.33	405.46	8.61	47.11
Unknown	84	819	42,189	43,740	5,263	8,595.1	15.96	502.25	9.75	51.51
Rosuvastatin										
Female	592,784	5,698,169	232,179,397	224,029,786	48,090,136	98,636,400.3	12.33	391.68	9.61	40.75
Male	766,356	8,105,036	326,955,309	317,192,590	47,099,887	94,567,812.2	16.27	426.64	10.58	40.34
Unknown	83	799	33,361	32,590	5,263	8,595.1	15.77	401.94	9.63	41.75
Simvastatin										
Female	1,881,377	17,578,986	931,228,754	921,213,861	48,090,136	98,636,400.3	39.12	494.97	9.34	52.97
Male	2,063,827	19,241,249	1,000,636,258	986,562,457	47,099,887	94,567,812.2	43.82	484.85	9.32	52.00
Unknown	175	1,755	94,069	93,605	5,263	8,595.1	33.25	537.54	10.03	53.60

DP ID	Start Date[1]	End Date[1]
DP0001	1/1/2011	7/31/2015
DP0002	1/1/2011	10/31/2014
DP0003	1/1/2011	9/30/2015
DP0004	1/1/2011	12/31/2015
DP0005	1/1/2011	2/28/2015
DP0006	1/1/2011	10/31/2015
DP0007	1/1/2011	12/31/2014
DP0008	1/1/2011	11/30/2015
DP0009	1/1/2011	11/30/2015
DP0010	1/1/2011	9/30/2015
DP0011	1/1/2011	6/30/2015
DP0012	1/1/2011	6/30/2015
DP0013	1/1/2011	6/30/2012
DP0014	1/1/2011	7/31/2014
DP0015	1/1/2011	4/30/2015

[1]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 Name Medical Products Used to Define Statins of Interest in this Request

Generic Name	Brand Name
Atorvastatin	
Atorvastatin Calcium	Atorvastatin Calcium
Atorvastatin Calcium	Lipitor
Simvastatin	
Simvastatin	Simvastatin
Simvastatin	Zocor
Rosuvastatin	
Rosuvastatin Calcium	Crestor
Pravastatin	
Pravastatin Sodium	Pravastatin Sodium
Pravastatin Sodium	Pravachol

Appendix C. Specifications Defining Parameters in this Request

This request used Sentinel's Cohort Identification and Descriptive Analysis (CIDA) tool, version 2.2.1 to identify prevalent use of statin drugs in the Sentinel Distributed Database (SDD).

Enrollment Gap: 45 days
Age Groups: 0-21, 22-44, 45-64, 65+ years
Query Period: All Years AND One year at a time: Jan 1, 2011 - Dec 31, 2015
Coverage Requirement Medical and Drug Coverage
Enrollment Requirement: 1 day

		Drug/Exposure			Pre-Existing Condition	Event/Outcome
Scenario	Exposure	Incident with respect to:	Washout (days)	Cohort Definition	Pre-Existing Condition	Event/ Outcome
1	**Atorvastatin, Simvastatin, Rosuvastatin, Pravastatin**	NA	0	02	None	Dummy
2	Atorvastatin	NA	0	02	None	Dummy
3	Simvastatin	NA	0	02	None	Dummy
4	Rosuvastatin	NA	0	02	None	Dummy
5	Pravastatin	NA	0	02	None	Dummy
6	**Enalapril, Ramipril, Lisinopril, Benazepril**	NA	0	02	None	Dummy
7	Enalapril	NA	0	02	None	Dummy
8	Ramipril	NA	0	02	None	Dummy
9	Lisinopril	NA	0	02	None	Dummy
10	Benazepril	NA	0	02	None	Dummy
11	**Propranolol, Metoproloo, Atenolol, Nebivolol**	NA	0	02	None	Dummy
12	Propranolol	NA	0	02	None	Dummy
13	Metoprolol	NA	0	02	None	Dummy
14	Atenolol	NA	0	02	None	Dummy
15	Nebivolol	NA	0	02	None	Dummy
16	**Ferumoxytol, Ferric Carboxymaltose, Iron Dextran, Ferric Gluconate, Iron Sucrose**	NA	0	02	None	Dummy
17	Ferumoxytol	NA	0	02	None	Dummy
18	Ferric Carboxymaltose	NA	0	02	None	Dummy
19	Iron Dextran	NA	0	02	None	Dummy
20	Ferric Gluconate	NA	0	02	None	Dummy
21	Iron Sucrose	NA	0	02	None	Dummy

Appendix C. Specifications Defining Parameters in this Request

| Scenario | Drug/Exposure | | | | Pre-Existing Condition | Event/Outcome |
	Exposure	Incident with respect to:	Washout (days)	Cohort Definition	Pre-Existing Condition	Event/ Outcome
22	**Infliximab, Etanercept, Adalimumab, Golimumab, Certolizumab**	NA	0	02	None	Dummy
23	Infliximab	NA	0	02	None	Dummy
24	Etanercept	NA	0	02	None	Dummy
25	Adalimumab	NA	0	02	None	Dummy
26	Golimumab	NA	0	02	None	Dummy
27	Certolizumab	NA	0	02	None	Dummy
28	**Filgrastim, Pegfilgrastim, GM-CSF**	NA	0	02	None	Dummy
29	Filgrastim	NA	0	02	None	Dummy
30	Pegfilgrastim	NA	0	02	None	Dummy
31	GM-CSF	NA	0	02	None	Dummy

International Classification of Diseases, Ninth Revision (ICD-9), International Classification of Diseases, Tenth Revision (ICD-10), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology (CPT) codes are provided by Optum360. National Drug Codes (NDCs) are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."

NOTE: Other scenarios can be viewed in the two other reports in this request.