

Disclaimer

The following report(s) provides findings from an FDA-initiated query using its Mini-Sentinel pilot. While Mini-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 Mini-Sentinel, and seeking to better understand the capabilities of the Mini-Sentinel pilot.

Data obtained through Mini-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 the Mini-Sentinel pilot in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Mini-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 msy4_mpr49

Request ID: msy4_mpr49

Request Description: The goal of this request was to examine the number of new users of oral bisphosphonates (including oral formulations of generic alendronate sodium, etidronate disodium, ibandronate sodium, risedronate sodium, or tiludronate disodium) with continuous long-term treatment in the Mini-Sentinel Distributed Database (MSDD).

Mini-Sentinel Modular Program Tool Used: Modular Program #3 (MP3)

Data Source: Data from January 1, 2000 to December 31, 2012 from 18 Data Partners contributing to the MSDD were included in this report. This request was distributed to Data Partners on August 9, 2013. See Appendix A for a list of the dates of available data for each Data Partner.

Study Design: This request was designed to calculate the number of new oral bisphosphonate users. A new user was defined as an eligible member with a recorded dispensing of an oral bisphosphonate during the study period and no record of exposure to oral bisphosphonates in the 183 days preceding that dispensing. Five scenarios with varying minimum episode durations were examined:

1. No minimum episode duration
2. 365-day minimum episode duration
3. 730-day minimum episode duration
4. 1,095-day minimum episode duration
5. 1,825-day minimum episode duration

Exposure of Interest: The exposure of interest in this request was new oral bisphosphonate use and was defined using National Drug Codes (NDCs). See Appendix B for a list of generic and brand drug names used to define oral bisphosphonates.

Cohort Eligibility Criteria: Individuals included in the cohort were required to be continuously enrolled in health plans with both medical and drug coverage for at least 183 days prior to their first qualifying dispensing date (index), during which gaps in coverage of up to 45 days were allowed. Members were excluded if they had any oral bisphosphonate use in the six months (183 days) prior to their index dispensing. The following age groups were included in the cohort: 0-21, 22-44, 45-65, and 65+ years.

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

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

Notes: Please contact the Sentinel 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 in Modular Program 3*

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).

Days at Risk - number of days supplied plus any episode gaps and exposure extension periods.

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.

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

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode.

Incidence Type (drug/exposure)- *Minimum incidence type* will consider the first treatment episode in the query period as long as it is the first treatment episode in the user's entire available history. *Single* and *Multiple incidence types* will use the washout period to establish incidence, however *Single* will only consider the first treatment episode whereas *Multiple* will consider all qualifying incident treatment episodes.

Incidence Type (event/outcome)- *Minimum incidence type* considers the first event in a valid episode as long as it is the first event in the user's entire available history. *Multiple incidence type* uses the washout period to establish incidence and considers all qualifying incident treatment episodes. The program will only consider one event per episode, but the *Multiple incidence type* will consider more than one event per user if a user has more than one incident episode.

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

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

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.

New Episodes - new treatment episodes; length of episode is determined by days supplied in one dispensing (or

New Users - number of members with incident 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.

Principal Diagnosis - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital.

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

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

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.

*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 New Users of Bisphosphonates in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Minimum Episode Duration

Minimum Episode Duration	New Users	New Episodes*	Dispensings	Total Days Supplied	Years at Risk	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
No Minimum Episode Duration	986,781	1,184,952	6,505,700	299,547,577	923,503	89,792,632	226,620,779	10.99	303.56	6.59	46.04
At least 365 day Episode Duration	249,825	255,475	4,358,444	211,663,380	612,459	58,859,090	209,799,654	4.24	847.25	17.45	48.56
At least 730 day Episode Duration	113,153	114,047	2,838,400	146,452,262	416,804	39,267,834	178,534,102	2.88	1294.29	25.08	51.60
At least 1,095 day Episode Duration	59,885	60,062	1,836,959	101,421,219	285,950	27,010,687	146,985,835	2.22	1693.60	30.67	55.21
At least 1,825 day Episode Duration	19,082	19,083	718,857	46,918,268	130,702	10,252,482	79,269,601	1.86	2458.77	37.67	65.27

* Users may contribute more than one episode as long as all incidence criteria are satisfied

Table 2. Summary of New Users of Bisphosphonates in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Minimum Episode Duration and Age Group

	New Users	New Episodes*	Dispensings	Total Days Supplied	Years at Risk	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
No Minimum Episode Duration											
0 to 21 years	1,604	1,743	7,778	255,783	868	27,120,365	66,106,298	0.06	159.47	4.85	32.89
22 to 44 years	30,360	35,048	147,130	5,309,629	17,813	35,901,724	71,521,657	0.85	174.89	4.85	36.09
45 to 65 years	478,250	560,162	3,093,330	131,743,973	411,151	25,948,666	65,517,371	18.43	275.47	6.47	42.59
65+ years	488,366	587,999	3,257,462	162,238,192	493,671	8,191,352	23,475,454	59.62	332.21	6.67	49.81
At least 365 day Episode Duration											
0 to 21 years	204	206	4,350	142,000	427	17,741,798	60,973,416	0.01	696.08	21.32	32.64
22 to 44 years	4,117	4,162	76,909	2,899,174	8,641	22,692,198	64,655,533	0.18	704.20	18.68	37.70
45 to 65 years	112,884	114,575	2,023,788	91,033,979	265,342	18,714,216	61,681,403	6.03	806.44	17.93	44.98
65+ years	133,266	136,532	2,253,397	117,588,227	338,049	6,298,026	22,489,302	21.16	882.36	16.91	52.18
At least 730 day Episode Duration											
0 to 21 years	79	80	2,713	87,758	259	11,845,929	51,627,695	0.01	1110.86	34.34	32.35
22 to 44 years	1,481	1,486	43,658	1,721,189	4,998	14,721,136	52,754,673	0.10	1162.18	29.48	39.42
45 to 65 years	48,563	48,778	1,275,159	61,052,654	174,777	13,436,979	53,836,298	3.61	1257.18	26.26	47.88
65+ years	63,164	63,703	1,516,870	83,590,661	236,770	4,825,895	20,315,436	13.09	1323.39	24.01	55.11
At least 1,095 day Episode Duration											
0 to 21 years	28	28	1,356	45,882	134	8,119,234	42,193,808	0.00	1638.64	48.43	33.84
22 to 44 years	691	692	26,067	1,079,651	3,089	9,972,467	41,654,119	0.07	1562.45	37.72	41.42
45 to 65 years	24,662	24,707	801,046	41,182,032	116,677	9,812,421	45,389,027	2.51	1669.86	32.48	51.41
65+ years	34,536	34,635	1,008,490	59,113,654	166,050	3,712,484	17,748,881	9.30	1711.65	29.20	58.62
At least 1,825 day Episode Duration											
0 to 21 years	10	10	710	22,479	65	3,126,300	22,930,150	0.00	2247.90	71.00	31.66
22 to 44 years	171	171	8,796	402,573	1,133	3,800,844	20,643,305	0.04	2354.23	51.44	45.77
45 to 65 years	7,787	7,788	308,655	18,882,329	52,794	4,163,956	25,456,018	1.87	2424.85	39.64	61.18
65+ years	11,114	11,114	400,696	27,610,887	76,711	1,680,108	10,240,128	6.62	2484.33	36.05	68.91

* Users may contribute more than one episode as long as all incidence criteria are satisfied

Table 3. Summary of New Users of Bisphosphonates in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Minimum Episode Duration and Sex

	New Users	New Episodes*	Dispensings	Total Days Supplied	Years at Risk	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
No Minimum Episode Duration											
Female	894,541	1,078,915	5,923,294	272,597,124	841,167	45,557,302	115,940,505	19.64	304.73	6.62	46.02
Male	92,226	106,020	582,324	26,945,312	82,320	44,231,132	110,672,341	2.09	292.17	6.31	46.27
Unknown	14	17	82	5,141	16	4,198	7,933	3.33	367.21	5.86	62.70
At least 365 day Episode Duration											
Female	226,631	231,932	3,970,636	192,760,090	558,110	29,925,481	107,335,773	7.57	850.55	17.52	48.55
Male	23,191	23,540	387,756	18,899,953	54,339	28,931,399	102,456,821	0.80	814.97	16.72	48.74
Unknown	3	3	52	3,337	9	2,210	7,060	1.36	1112.33	17.33	64.17
At least 730 day Episode Duration											
Female	102,930	103,778	2,592,244	133,761,250	380,871	19,989,124	91,359,575	5.15	1299.54	25.18	51.60
Male	10,222	10,268	246,126	12,688,519	35,926	19,277,256	87,168,636	0.53	1241.30	24.08	51.55
Unknown	1	1	30	2,493	7	1,454	5,892	0.69	2493.00	30.00	83.10
At least 1,095 day Episode Duration											
Female	54,794	54,969	1,684,382	93,103,283	262,579	13,763,269	75,239,805	3.98	1699.15	30.74	55.27
Male	5,090	5,092	152,547	8,315,443	23,364	13,246,499	71,741,513	0.38	1633.68	29.97	54.51
Unknown	1	1	30	2,493	7	919	4,518	1.09	2493.00	30.00	83.10
At least 1,825 day Episode Duration											
Female	17,647	17,648	666,006	43,490,520	121,178	5,272,186	40,845,137	3.35	2464.47	37.74	65.30
Male	1,434	1,434	52,821	3,425,255	9,518	4,980,110	38,422,925	0.29	2388.60	36.83	64.85
Unknown	1	1	30	2,493	7	186	1,539	5.38	2493.00	30.00	83.10

* Users may contribute more than one episode as long as all incidence criteria are satisfied

Table 4. Summary of New Users of Bisphosphonates in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Minimum Episode Duration and Year

	New Users	New Episodes*	Dispensings	Total Days Supplied	Years at Risk	Eligible Members	Member-Years	New User per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
No Minimum Episode Duration											
2000	11,260	11,260	100,842	4,833,331	14,508	7,254,653	3,363,290	1.55	429.25	8.96	47.93
2001	30,689	30,891	289,026	13,675,006	41,006	7,824,696	6,647,300	3.92	445.60	9.42	47.31
2002	43,203	43,434	385,895	20,486,427	60,749	7,954,091	6,720,052	5.43	474.19	8.93	53.09
2003	47,042	47,293	387,924	21,293,538	63,285	7,879,925	6,648,814	5.97	452.65	8.25	54.89
2004	49,670	49,992	376,848	19,936,968	59,582	8,419,430	6,839,381	5.90	401.39	7.59	52.90
2005	44,731	45,018	284,872	15,255,799	45,958	8,667,888	7,203,624	5.16	341.06	6.37	53.55
2006	69,631	69,895	475,272	22,431,062	68,465	19,162,074	11,805,217	3.63	322.14	6.83	47.20
2007	96,055	96,744	623,479	27,591,707	85,434	22,836,353	16,704,639	4.21	287.25	6.49	44.25
2008	176,822	177,868	1,029,958	43,320,086	135,988	43,834,745	27,670,569	4.03	244.99	5.82	42.06
2009	201,760	203,211	1,045,314	44,525,464	140,476	45,772,779	35,664,681	4.41	220.69	5.18	42.60
2010	160,835	161,935	731,421	31,788,651	100,740	44,080,821	34,528,405	3.65	197.65	4.55	43.46
2011	138,211	139,082	521,154	23,057,808	73,123	43,045,933	34,083,258	3.21	166.83	3.77	44.24
2012	107,809	108,329	253,695	11,351,730	34,188	40,171,447	28,741,549	2.68	105.29	2.35	44.75
At least 365 day Episode Duration											
2000	3,310	3,310	82,515	4,120,071	11,862	5,981,810	2,891,440	0.55	1244.73	24.93	49.93
2001	9,779	9,779	239,105	11,761,501	33,870	6,953,977	6,372,489	1.41	1202.73	24.45	49.19
2002	14,665	14,665	318,962	17,749,587	50,743	7,402,103	6,532,309	1.98	1210.34	21.75	55.65
2003	15,434	15,434	314,554	18,208,863	52,032	7,340,691	6,475,990	2.10	1179.79	20.38	57.89
2004	15,684	15,684	292,691	16,658,400	47,601	7,764,539	6,636,765	2.02	1062.13	18.66	56.91
2005	11,247	11,247	207,691	12,171,952	34,839	7,973,067	6,966,307	1.41	1082.24	18.47	58.61
2006	18,627	18,627	360,919	17,666,482	51,207	15,788,350	10,609,463	1.18	948.43	19.38	48.95
2007	24,600	24,600	460,287	21,017,565	61,320	19,348,288	15,758,971	1.27	854.37	18.71	45.66
2008	40,700	40,700	707,033	30,813,650	90,322	34,633,840	24,379,963	1.18	757.09	17.37	43.58
2009	43,507	43,507	671,210	29,694,757	87,005	38,727,756	33,360,974	1.12	682.53	15.43	44.24
2010	32,646	32,646	440,978	19,903,622	57,731	39,119,076	32,864,916	0.83	609.68	13.51	45.14
2011	24,159	24,159	253,449	11,492,464	32,759	37,449,148	32,296,091	0.65	475.70	10.49	45.34
2012	1,117	1,117	9,050	404,466	1,167	29,909,050	24,653,977	0.04	362.10	8.10	44.69

Table 4. Summary of New Users of Bisphosphonates in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Minimum Episode Duration and Year

	New Users	New Episodes*	Dispensings	Total Days Supplied	Years at Risk	Eligible Members	Member-Years	New User per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
At least 730 day Episode Duration											
2000	2,055	2,055	68,664	3,548,424	10,109	5,088,288	2,469,601	0.40	1726.73	33.41	51.68
2001	6,005	6,005	195,532	10,018,844	28,535	5,824,738	5,439,382	1.03	1668.42	32.56	51.24
2002	8,974	8,974	257,943	15,084,862	42,651	6,558,928	6,101,865	1.37	1680.95	28.74	58.48
2003	9,607	9,607	251,952	15,487,901	43,714	6,806,594	6,145,941	1.41	1612.15	26.23	61.47
2004	8,389	8,389	207,053	13,269,595	37,347	7,145,354	6,286,448	1.17	1581.79	24.68	64.09
2005	6,538	6,538	164,680	9,966,319	28,230	7,293,880	6,532,226	0.90	1524.37	25.19	60.52
2006	10,391	10,391	275,642	13,880,143	39,720	13,401,676	9,416,718	0.78	1335.79	26.53	50.36
2007	12,624	12,624	328,854	15,565,136	44,678	15,991,378	13,512,351	0.79	1232.98	26.05	47.33
2008	18,858	18,858	464,454	20,920,650	60,163	27,191,967	20,496,801	0.69	1109.38	24.63	45.04
2009	18,301	18,301	399,915	18,315,054	52,361	30,530,876	27,163,337	0.60	1000.77	21.85	45.80
2010	11,941	11,941	218,528	10,132,315	28,547	32,377,263	29,255,098	0.37	848.53	18.30	46.37
2011	364	364	5,183	263,019	749	28,252,024	26,664,213	0.01	722.58	14.24	50.75
2012	0	0	0	0	0	22,933,664	19,050,122	0.00	---	---	---
At least 1,095 day Episode Duration											
2000	1,438	1,438	56,464	3,043,200	8,619	4,356,132	2,119,614	0.33	2116.27	39.27	53.90
2001	4,094	4,094	158,050	8,438,464	23,869	4,945,458	4,637,367	0.83	2061.18	38.61	53.39
2002	6,272	6,272	208,076	12,823,311	36,003	5,532,549	5,221,841	1.13	2044.53	33.18	61.63
2003	6,294	6,294	187,805	12,752,901	35,664	6,065,725	5,716,478	1.04	2026.20	29.84	67.91
2004	5,586	5,586	164,193	10,895,771	30,507	6,612,078	5,917,189	0.84	1950.55	29.39	66.36
2005	4,499	4,499	133,089	8,242,117	23,225	6,730,840	6,121,828	0.67	1831.99	29.58	61.93
2006	6,552	6,552	204,622	10,698,140	30,366	11,515,233	8,377,001	0.57	1632.81	31.23	52.28
2007	7,431	7,431	228,329	11,274,794	32,028	13,468,135	11,592,268	0.55	1517.26	30.73	49.38
2008	9,814	9,814	290,010	13,521,021	38,308	21,650,115	16,848,763	0.45	1377.73	29.55	46.62
2009	7,854	7,854	201,375	9,485,602	26,664	24,153,994	22,312,834	0.33	1207.74	25.64	47.10
2010	228	228	4,946	245,898	696	22,965,921	22,402,220	0.01	1078.50	21.69	49.72
2011	0	0	0	0	0	21,356,566	20,625,627	0.00	---	---	---
2012	0	0	0	0	0	18,083,217	15,092,806	0.00	---	---	---

Table 4. Summary of New Users of Bisphosphonates in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and December 31, 2012, by Minimum Episode Duration and Year

	New Users	New Episodes*	Dispensings	Total Days Supplied	Years at Risk	Eligible Members	Member-Years	New User per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
At least 1,825 day Episode Duration											
2000	787	787	36,173	2,180,151	6,106	3,409,064	1,665,046	0.23	2770.20	45.96	60.27
2001	2,095	2,095	91,794	5,740,586	16,035	3,804,926	3,598,185	0.55	2740.14	43.82	62.54
2002	3,089	3,089	120,723	8,531,952	23,732	4,201,346	3,989,925	0.74	2762.04	39.08	70.67
2003	3,355	3,355	122,812	8,773,948	24,398	4,576,115	4,364,543	0.73	2615.19	36.61	71.44
2004	2,985	2,985	106,155	7,360,014	20,461	5,194,247	4,854,308	0.57	2465.67	35.56	69.33
2005	2,278	2,278	79,441	5,221,115	14,558	5,658,761	5,328,204	0.40	2291.97	34.87	65.72
2006	2,454	2,454	89,603	5,156,822	14,409	9,006,929	6,885,147	0.27	2101.39	36.51	57.55
2007	1,969	1,969	69,753	3,826,318	10,645	9,515,103	8,931,469	0.21	1943.28	35.43	54.86
2008	71	71	2,403	127,362	358	9,162,027	9,032,110	0.01	1793.83	33.85	53.00
2009	0	0	0	0	0	8,812,313	8,658,580	0.00	---	---	---
2010	0	0	0	0	0	8,389,717	8,243,025	0.00	---	---	---
2011	0	0	0	0	0	7,952,051	7,766,373	0.00	---	---	---
2012	0	0	0	0	0	6,945,559	5,952,685	0.00	---	---	---

* Users may contribute more than one episode as long as all incidence criteria are satisfied

Appendix A. List of Dates of Available Data for Each Data Partner (DP) in the Mini-Sentinel Distributed Database (MSDD) as of Request End Date (December 31, 2012)

DPID	DP Start Date	DP End Date
DP0001	1/31/2000	12/31/2012
DP0002	1/2/2000	6/30/2012
DP0003	1/31/2004	12/31/2012
DP0004	1/2/2000	12/31/2012
DP0005	1/2/2000	12/31/2012
DP0006	1/1/2000	12/31/2012
DP0007	1/2/2000	12/31/2011
DP0008	1/2/2000	6/30/2012
DP0009	1/31/2000	9/30/2012
DP0010	1/2/2000	12/31/2012
DP0011	6/2/2007	10/31/2012
DP0012	1/2/2008	11/30/2012
DP0013	1/1/2000	4/30/2012
DP0014	1/2/2008	9/30/2012
DP0015	1/2/2005	9/30/2012
DP0016	1/1/2000	12/31/2012
DP0017	1/1/2000	12/31/2011
DP0018	1/2/2006	12/30/2012

Appendix B. Generic and Brand Drug Names used to Define Exposure in this Request

Generic Name	Brand Name
ALENDRONATE SODIUM	ALENDRONATE SODIUM
ALENDRONATE SODIUM	BINOSTO
ALENDRONATE SODIUM	FOSAMAX
ALENDRONATE SODIUM/VITAMIN D3	FOSAMAX PLUS D
ETIDRONATE DISODIUM	DIDRONEL
ETIDRONATE DISODIUM	ETIDRONATE DISODIUM
IBANDRONATE SODIUM	BONIVA
IBANDRONATE SODIUM	IBANDRONATE SODIUM
RISEDRONATE SOD/CALCIUM CARB	ACTONEL WITH CALCIUM
RISEDRONATE SODIUM	ACTONEL
RISEDRONATE SODIUM	ATELVIA
TILUDRONATE DISODIUM	SKELID

Appendix C. Specifications Defining Parameters in this Request

This request used Modular Program #3 to investigate the number of bisphosphonate (oral formulations of generic alendronate sodium, etidronate disodium, ibandronate sodium, risedronate sodium, or tiludronate disodium) users with continuous long-term treatment.

Query period: January 1, 2000 to December 31, 2012

Coverage requirement: Medical and Drug Coverage

Pre-index enrollment requirement: 183 days

Post-index enrollment requirement: 0 days

Enrollment gap: 45 days

Age groups: 0-21, 22-44, 45-64, 65+ years

Race groups: None

Stratifications: Age group, sex, calendar year

Exposure

Scenario	Incident Exposure	Incident with Respect to:	Washout (days)	Incidence Type ¹	Episode Gap (days)	Exposure Extension Period (days)	Minimum Episode Duration (days)
1	Bisphosphonates	Bisphosphonates	183	Multiple	30	30	0
2	Bisphosphonates	Bisphosphonates	183	Multiple	30	30	365 (1 year)
3	Bisphosphonates	Bisphosphonates	183	Multiple	30	30	730 (2 years)
4	Bisphosphonates	Bisphosphonates	183	Multiple	30	30	1,095 (3 years)
5	Bisphosphonates	Bisphosphonates	183	Multiple	30	30	1,825 (5 years)

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

¹Multiple incidence type considers all qualifying incident treatment episodes.