

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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Overview for Request cder_mpl1r_wp020_nsdp_v01 (Report 2 of 3)

Request ID: cder_mpl1r_wp020_nsdp_v01

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

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 latest 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 (washout days = 0) use of the drug of interest were calculated overall and by year, then stratified by age group and sex.

Exposure of Interest: The exposure of interest was the use of Angiotensin Converting Enzyme (ACE) Inhibitor drugs including, Benazepril, Enalapril, Lisinopril, and Ramipril. 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@sentinelssystem.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel's routine querying modules, please refer to the documentation (<https://dev.sentinelssystem.org/projects/SENTINEL/repos/sentinel-routine-querying-tool-documentation/browse>).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Switch Gap Inclusion Indicator - indicator for whether gaps in treatment episodes that are included in a switch episode will be counted as part of the switch episode duration.

Switch Pattern Cohort Inclusion Date - indicates which date to use for inclusion into the switch pattern cohort of interest as well as optionally as the index date of the treatment episode initiating the switch pattern. Valid options are the product approval date, product marketing date, other requester defined date, or computed start marketing date.

Switch Pattern Cohort Inclusion Strategy - indicates how the switch pattern cohort inclusion date will be used: 01: used only as a switch cohort entry date. First treatment episode dispensing date is used as index for computing time to first switch; 02: used as switch cohort entry date and as initial switch step index date for computing time to first switch.

Treatment Episode Truncation Indicator - indicates whether the exposure episode will be truncated at the occurrence of a requester-specified code.

Washout Period (drug/exposure) - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.

Washout Period (event/outcome) - number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

Years at Risk - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

*all terms may not be used in this report

Table 1. Summary of 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										
Enalapril, Ramipril, Lisinopril, Benazepril										
	2,356,553	11,158,260	527,372,362	594,071,101	48,590,889	39,900,487.1	48.50	223.79	4.73	47.26
Benazepril										
	143,083	757,019	32,089,555	35,802,144	48,590,889	39,900,487.1	2.94	224.27	5.29	42.39
Enalapril										
	166,068	852,445	37,144,970	51,770,066	48,590,889	39,900,487.1	3.42	223.67	5.13	43.57
Lisinopril										
	1,879,334	8,499,932	412,971,039	454,085,343	48,590,889	39,900,487.1	38.68	219.74	4.52	48.59
Ramipril										
	180,988	1,048,864	45,166,798	52,413,549	48,590,889	39,900,487.1	3.72	249.56	5.80	43.06
2012										
Benazepril, Enalapril, Lisinopril, Ramipril										
	2,427,573	11,265,161	547,071,306	613,665,937	50,002,931	41,147,651.0	48.55	225.36	4.64	48.56
Benazepril										
	150,738	776,591	34,213,459	38,070,410	50,002,931	41,147,651.0	3.01	226.97	5.15	44.06
Enalapril										
	155,577	791,639	35,965,887	48,914,379	50,002,931	41,147,651.0	3.11	231.18	5.09	45.43
Lisinopril										
	1,961,725	8,725,170	433,783,058	476,464,665	50,002,931	41,147,651.0	39.23	221.12	4.45	49.72
Ramipril										
	170,771	971,761	43,108,902	50,216,483	50,002,931	41,147,651.0	3.42	252.44	5.69	44.36
2013										
Benazepril, Enalapril, Lisinopril, Ramipril										
	2,496,434	11,518,959	567,691,883	634,769,100	50,092,041	40,934,330.3	49.84	227.40	4.61	49.28
Benazepril										
	151,586	795,066	35,848,024	39,867,258	50,092,041	40,934,330.3	3.03	236.49	5.24	45.09
Enalapril										
	150,669	743,684	34,630,995	47,099,252	50,092,041	40,934,330.3	3.01	229.85	4.94	46.57
Lisinopril										
	2,044,386	9,081,011	456,480,858	500,122,783	50,092,041	40,934,330.3	40.81	223.29	4.44	50.27
Ramipril										
	160,094	899,198	40,732,006	47,679,807	50,092,041	40,934,330.3	3.20	254.43	5.62	45.30

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2014										
Benazepril, Enalapril, Lisinopril, Ramipril										
	2,593,565	11,397,380	576,003,673	640,899,203	52,192,175	42,131,001.3	49.69	222.09	4.39	50.54
Benazepril										
	150,538	762,881	35,799,912	39,801,993	52,192,175	42,131,001.3	2.88	237.81	5.07	46.93
Enalapril										
	134,308	569,252	26,934,625	36,816,642	52,192,175	42,131,001.3	2.57	200.54	4.24	47.32
Lisinopril										
	2,163,333	9,227,829	473,969,220	518,102,957	52,192,175	42,131,001.3	41.45	219.09	4.27	51.36
Ramipril										
	154,102	837,418	39,299,916	46,177,611	52,192,175	42,131,001.3	2.95	255.03	5.43	46.93
2015										
Benazepril, Enalapril, Lisinopril, Ramipril										
	2,300,336	7,761,924	356,143,318	394,791,007	48,252,032	29,099,337.9	47.67	154.82	3.37	45.88
Benazepril										
	132,521	486,429	20,708,488	22,980,066	48,252,032	29,099,337.9	2.75	156.27	3.67	42.57
Enalapril										
	95,846	349,689	14,039,289	19,106,000	48,252,032	29,099,337.9	1.99	146.48	3.65	40.15
Lisinopril										
	1,944,834	6,408,176	299,243,349	326,630,924	48,252,032	29,099,337.9	40.31	153.87	3.29	46.70
Ramipril										
	132,006	517,630	22,152,192	26,074,016	48,252,032	29,099,337.9	2.74	167.81	3.92	42.80
2011-2015										
Benazepril, Enalapril, Lisinopril, Ramipril										
	5,567,591	53,101,684	2,574,282,542	2,878,196,347	95,195,286	193,212,807.5	58.49	462.37	9.54	48.48
Benazepril										
	333,841	3,577,986	158,659,438	176,521,870	95,195,286	193,212,807.5	3.51	475.25	10.72	44.34
Enalapril										
	328,735	3,306,709	148,715,766	203,706,339	95,195,286	193,212,807.5	3.45	452.39	10.06	44.97
Lisinopril										
	4,638,871	41,942,118	2,076,447,524	2,275,406,672	95,195,286	193,212,807.5	48.73	447.62	9.04	49.51
Ramipril										
	338,105	4,274,871	190,459,814	222,561,466	95,195,286	193,212,807.5	3.55	563.32	12.64	44.55

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										
Enalapril, Ramipril, Lisinopril, Benazepril										
00-21 Years	13,565	59,902	2,047,269	4,044,964	14,021,420	11,122,212.1	0.97	150.92	4.42	34.18
22-44 Years	293,767	1,235,412	46,109,506	49,544,925	17,215,602	12,947,975.5	17.06	156.96	4.21	37.32
45-64 Years	1,170,271	5,644,670	245,099,870	271,271,659	14,146,778	11,616,603.0	82.72	209.44	4.82	43.42
65+ Years	921,235	4,218,276	234,115,717	269,209,553	4,705,738	4,213,696.5	195.77	254.13	4.58	55.50
Benazepril										
00-21 Years	301	1,133	34,604	39,821	14,021,420	11,122,212.1	0.02	114.96	3.76	30.54
22-44 Years	16,059	73,961	2,488,109	2,682,167	17,215,602	12,947,975.5	0.93	154.94	4.61	33.64
45-64 Years	69,470	374,523	14,202,703	15,725,528	14,146,778	11,616,603.0	4.91	204.44	5.39	37.92
65+ Years	59,639	307,402	15,364,139	17,354,628	4,705,738	4,213,696.5	12.67	257.62	5.15	49.98
Enalapril										
00-21 Years	4,271	23,271	750,838	2,543,747	14,021,420	11,122,212.1	0.30	175.80	5.45	32.26
22-44 Years	16,026	72,628	2,512,055	3,160,787	17,215,602	12,947,975.5	0.93	156.75	4.53	34.59
45-64 Years	72,278	370,964	14,581,786	19,237,321	14,146,778	11,616,603.0	5.11	201.75	5.13	39.31
65+ Years	76,197	385,582	19,300,291	26,828,211	4,705,738	4,213,696.5	16.19	253.29	5.06	50.05
Lisinopril										
00-21 Years	8,862	34,452	1,224,806	1,414,036	14,021,420	11,122,212.1	0.63	138.21	3.89	35.55
22-44 Years	246,815	1,005,319	38,075,242	40,257,780	17,215,602	12,947,975.5	14.34	154.27	4.07	37.87
45-64 Years	932,969	4,300,750	192,345,014	208,594,080	14,146,778	11,616,603.0	65.95	206.16	4.61	44.72
65+ Years	723,733	3,159,411	181,325,977	203,819,446	4,705,738	4,213,696.5	153.80	250.54	4.37	57.39
Ramipril										
00-21 Years	255	1,046	37,021	47,359	14,021,420	11,122,212.1	0.02	145.18	4.10	35.39
22-44 Years	16,081	83,504	3,034,100	3,444,192	17,215,602	12,947,975.5	0.93	188.68	5.19	36.33
45-64 Years	100,764	598,433	23,970,367	27,714,730	14,146,778	11,616,603.0	7.12	237.89	5.94	40.06
65+ Years	67,996	365,881	18,125,310	21,207,267	4,705,738	4,213,696.5	14.45	266.56	5.38	49.54

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										
Benazepril, Enalapril, Lisinopril, Ramipril										
00-21 Years	12,934	56,279	1,935,620	2,812,825	14,096,676	11,173,551.7	0.92	149.65	4.35	34.39
22-44 Years	291,187	1,225,293	46,055,360	49,424,582	17,663,114	13,289,779.9	16.49	158.16	4.21	37.59
45-64 Years	1,188,267	5,682,783	248,678,234	274,430,813	14,617,059	11,983,381.5	81.29	209.28	4.78	43.76
65+ Years	980,881	4,300,806	250,402,092	286,997,717	5,235,850	4,700,937.9	187.34	255.28	4.38	58.22
Benazepril										
00-21 Years	263	1,037	32,256	37,624	14,096,676	11,173,551.7	0.02	122.65	3.94	31.11
22-44 Years	15,578	74,701	2,524,026	2,715,610	17,663,114	13,289,779.9	0.88	162.03	4.80	33.79
45-64 Years	73,224	390,405	14,987,177	16,551,353	14,617,059	11,983,381.5	5.01	204.68	5.33	38.39
65+ Years	64,381	310,448	16,670,000	18,765,823	5,235,850	4,700,937.9	12.30	258.93	4.82	53.70
Enalapril										
00-21 Years	3,760	20,652	670,498	1,267,389	14,096,676	11,173,551.7	0.27	178.32	5.49	32.47
22-44 Years	14,306	65,344	2,289,515	2,877,013	17,663,114	13,289,779.9	0.81	160.04	4.57	35.04
45-64 Years	66,182	342,620	13,673,604	17,957,727	14,617,059	11,983,381.5	4.53	206.61	5.18	39.91
65+ Years	74,076	363,023	19,332,270	26,812,250	5,235,850	4,700,937.9	14.15	260.98	4.90	53.25
Lisinopril										
00-21 Years	8,810	33,719	1,201,182	1,467,831	14,096,676	11,173,551.7	0.62	136.34	3.83	35.62
22-44 Years	248,170	1,012,125	38,567,965	40,798,314	17,663,114	13,289,779.9	14.05	155.41	4.08	38.11
45-64 Years	961,282	4,406,502	198,079,895	214,488,911	14,617,059	11,983,381.5	65.76	206.06	4.58	44.95
65+ Years	779,867	3,272,824	195,934,016	219,709,610	5,235,850	4,700,937.9	148.95	251.24	4.20	59.87
Ramipril										
00-21 Years	222	871	31,684	39,981	14,096,676	11,173,551.7	0.02	142.72	3.92	36.38
22-44 Years	14,168	73,123	2,673,854	3,033,645	17,663,114	13,289,779.9	0.80	188.72	5.16	36.57
45-64 Years	91,980	543,256	21,937,558	25,432,823	14,617,059	11,983,381.5	6.29	238.50	5.91	40.38
65+ Years	68,212	354,511	18,465,806	21,710,034	5,235,850	4,700,937.9	13.03	270.71	5.20	52.09

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										
Benazepril, Enalapril, Lisinopril, Ramipril										
00-21 Years	12,714	56,217	1,936,430	2,754,470	13,906,114	10,929,960.7	0.91	152.31	4.42	34.45
22-44 Years	292,823	1,238,079	46,700,722	49,988,876	17,792,983	13,257,242.5	16.46	159.48	4.23	37.72
45-64 Years	1,219,077	5,847,166	256,418,676	282,177,874	14,579,539	11,915,058.8	83.62	210.34	4.80	43.85
65+ Years	1,016,317	4,377,497	262,636,055	299,847,879	5,383,559	4,832,068.2	188.78	258.42	4.31	60.00
Benazepril										
00-21 Years	222	900	27,981	31,896	13,906,114	10,929,960.7	0.02	126.04	4.05	31.09
22-44 Years	14,694	72,154	2,450,664	2,639,513	17,792,983	13,257,242.5	0.83	166.78	4.91	33.96
45-64 Years	73,428	405,470	15,667,809	17,252,210	14,579,539	11,915,058.8	5.04	213.38	5.52	38.64
65+ Years	65,864	316,542	17,701,570	19,943,639	5,383,559	4,832,068.2	12.23	268.76	4.81	55.92
Enalapril										
00-21 Years	3,761	20,099	660,705	1,300,710	13,906,114	10,929,960.7	0.27	175.67	5.34	32.87
22-44 Years	13,088	59,108	2,111,354	2,656,311	17,792,983	13,257,242.5	0.74	161.32	4.52	35.72
45-64 Years	64,167	326,112	13,186,157	17,284,412	14,579,539	11,915,058.8	4.40	205.50	5.08	40.43
65+ Years	72,104	338,365	18,672,779	25,857,819	5,383,559	4,832,068.2	13.39	258.97	4.69	55.19
Lisinopril										
00-21 Years	8,650	34,491	1,222,326	1,389,321	13,906,114	10,929,960.7	0.62	141.31	3.99	35.44
22-44 Years	253,634	1,043,511	39,812,761	42,042,498	17,792,983	13,257,242.5	14.25	156.97	4.11	38.15
45-64 Years	1,001,281	4,617,341	207,336,747	224,070,790	14,579,539	11,915,058.8	68.68	207.07	4.61	44.90
65+ Years	816,860	3,385,668	208,109,024	232,620,173	5,383,559	4,832,068.2	151.73	254.77	4.14	61.47
Ramipril										
00-21 Years	181	727	25,418	32,544	13,906,114	10,929,960.7	0.01	140.43	4.02	34.96
22-44 Years	12,354	63,306	2,325,943	2,650,554	17,792,983	13,257,242.5	0.69	188.27	5.12	36.74
45-64 Years	84,215	498,243	20,227,963	23,570,461	14,579,539	11,915,058.8	5.78	240.19	5.92	40.60
65+ Years	66,702	336,922	18,152,682	21,426,248	5,383,559	4,832,068.2	12.39	272.15	5.05	53.88

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										
Benazepril, Enalapril, Lisinopril, Ramipril										
00-21 Years	11,758	48,248	1,696,766	2,526,395	13,873,358	10,845,684.4	0.85	144.31	4.10	35.17
22-44 Years	293,205	1,190,296	45,663,676	48,719,844	18,683,301	13,717,389.5	15.69	155.74	4.06	38.36
45-64 Years	1,262,949	5,752,970	257,628,002	282,161,820	15,392,745	12,306,230.0	82.05	203.99	4.56	44.78
65+ Years	1,070,080	4,405,866	271,015,229	307,491,143	5,892,108	5,261,697.4	181.61	253.27	4.12	61.51
Benazepril										
00-21 Years	195	777	25,650	28,887	13,873,358	10,845,684.4	0.01	131.54	3.98	33.01
22-44 Years	12,965	62,221	2,160,580	2,329,146	18,683,301	13,717,389.5	0.69	166.65	4.80	34.72
45-64 Years	70,858	378,755	15,015,047	16,506,776	15,392,745	12,306,230.0	4.60	211.90	5.35	39.64
65+ Years	69,018	321,128	18,598,635	20,937,184	5,892,108	5,261,697.4	11.71	269.48	4.65	57.92
Enalapril										
00-21 Years	3,162	14,512	491,980	1,154,874	13,873,358	10,845,684.4	0.23	155.59	4.59	33.90
22-44 Years	10,231	40,268	1,496,298	1,898,930	18,683,301	13,717,389.5	0.55	146.25	3.94	37.16
45-64 Years	57,261	252,760	10,523,340	13,780,607	15,392,745	12,306,230.0	3.72	183.78	4.41	41.63
65+ Years	65,568	261,712	14,423,007	19,982,231	5,892,108	5,261,697.4	11.13	219.97	3.99	55.11
Lisinopril										
00-21 Years	8,343	32,261	1,155,394	1,313,337	13,873,358	10,845,684.4	0.60	138.49	3.87	35.81
22-44 Years	259,737	1,033,094	39,963,064	42,172,795	18,683,301	13,717,389.5	13.90	153.86	3.98	38.68
45-64 Years	1,059,467	4,673,818	213,460,755	230,100,690	15,392,745	12,306,230.0	68.83	201.48	4.41	45.67
65+ Years	872,547	3,488,656	219,390,007	244,516,135	5,892,108	5,261,697.4	148.09	251.44	4.00	62.89
Ramipril										
00-21 Years	154	698	23,742	29,297	13,873,358	10,845,684.4	0.01	154.17	4.53	34.01
22-44 Years	10,968	54,713	2,043,734	2,318,973	18,683,301	13,717,389.5	0.59	186.34	4.99	37.35
45-64 Years	78,846	447,637	18,628,860	21,773,747	15,392,745	12,306,230.0	5.12	236.27	5.68	41.62
65+ Years	67,360	334,370	18,603,580	22,055,594	5,892,108	5,261,697.4	11.43	276.18	4.96	55.64

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										
Benazepril, Enalapril, Lisinopril, Ramipril										
00-21 Years	7,706	26,031	892,226	1,403,608	11,862,418	6,975,681.5	0.65	115.78	3.38	34.28
22-44 Years	233,965	772,981	27,916,656	29,714,690	17,138,860	9,592,136.4	13.65	119.32	3.30	36.12
45-64 Years	1,107,740	3,962,326	162,361,413	177,225,935	14,500,050	8,708,542.1	76.40	146.57	3.58	40.98
65+ Years	979,250	3,000,586	164,973,023	186,446,774	5,904,954	3,822,977.9	165.84	168.47	3.06	54.98
Benazepril										
00-21 Years	90	332	10,231	11,305	11,862,418	6,975,681.5	0.01	113.68	3.69	30.82
22-44 Years	9,242	35,520	1,178,883	1,267,802	17,138,860	9,592,136.4	0.54	127.56	3.84	33.19
45-64 Years	59,457	244,917	8,987,406	9,849,002	14,500,050	8,708,542.1	4.10	151.16	4.12	36.70
65+ Years	65,245	205,660	10,531,968	11,851,957	5,904,954	3,822,977.9	11.05	161.42	3.15	51.21
Enalapril										
00-21 Years	2,075	8,015	258,736	675,364	11,862,418	6,975,681.5	0.17	124.69	3.86	32.28
22-44 Years	7,375	25,574	853,405	1,085,796	17,138,860	9,592,136.4	0.43	115.72	3.47	33.37
45-64 Years	44,494	170,724	6,146,764	7,973,823	14,500,050	8,708,542.1	3.07	138.15	3.84	36.00
65+ Years	42,959	145,376	6,780,384	9,371,018	5,904,954	3,822,977.9	7.28	157.83	3.38	46.64
Lisinopril										
00-21 Years	5,489	17,369	613,270	703,784	11,862,418	6,975,681.5	0.46	111.73	3.16	35.31
22-44 Years	209,589	680,274	24,785,420	26,103,113	17,138,860	9,592,136.4	12.23	118.26	3.25	36.43
45-64 Years	941,846	3,275,377	136,881,675	147,314,095	14,500,050	8,708,542.1	64.95	145.33	3.48	41.79
65+ Years	811,894	2,435,156	136,962,984	152,509,933	5,904,954	3,822,977.9	137.49	168.70	3.00	56.24
Ramipril										
00-21 Years	98	315	9,989	13,156	11,862,418	6,975,681.5	0.01	101.93	3.21	31.71
22-44 Years	8,057	31,613	1,098,948	1,257,980	17,138,860	9,592,136.4	0.47	136.40	3.92	34.76
45-64 Years	63,973	271,308	10,345,568	12,089,015	14,500,050	8,708,542.1	4.41	161.72	4.24	38.13
65+ Years	61,637	214,394	10,697,687	12,713,866	5,904,954	3,822,977.9	10.44	173.56	3.48	49.90

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										
Benazepril, Enalapril, Lisinopril, Ramipril										
00-21 Years	33,988	246,677	8,508,311	13,542,262	27,178,643	51,047,090.4	1.25	250.33	7.26	34.49
22-44 Years	816,011	5,662,061	212,445,920	227,392,917	38,224,633	62,804,523.7	21.35	260.35	6.94	37.52
45-64 Years	2,914,562	26,889,915	1,170,186,195	1,287,268,102	28,333,576	56,529,815.5	102.87	401.50	9.23	43.52
65+ Years	2,083,929	20,303,031	1,183,142,116	1,349,993,065	9,260,114	22,831,377.9	225.04	567.75	9.74	58.27
Benazepril										
00-21 Years	695	4,179	130,722	149,532	27,178,643	51,047,090.4	0.03	188.09	6.01	31.28
22-44 Years	39,310	318,557	10,802,262	11,634,238	38,224,633	62,804,523.7	1.03	274.80	8.10	33.91
45-64 Years	171,520	1,794,070	68,860,142	75,884,870	28,333,576	56,529,815.5	6.05	401.47	10.46	38.38
65+ Years	137,402	1,461,180	78,866,312	88,853,230	9,260,114	22,831,377.9	14.84	573.98	10.63	53.97
Enalapril										
00-21 Years	8,961	86,549	2,832,757	6,942,084	27,178,643	51,047,090.4	0.33	316.12	9.66	32.73
22-44 Years	35,869	262,922	9,262,627	11,678,837	38,224,633	62,804,523.7	0.94	258.23	7.33	35.23
45-64 Years	154,714	1,463,180	58,111,651	76,233,890	28,333,576	56,529,815.5	5.46	375.61	9.46	39.72
65+ Years	143,631	1,494,058	78,508,731	108,851,529	9,260,114	22,831,377.9	15.51	546.60	10.40	52.55
Lisinopril										
00-21 Years	24,445	152,292	5,416,978	6,288,310	27,178,643	51,047,090.4	0.90	221.60	6.23	35.57
22-44 Years	714,909	4,774,323	181,204,452	191,374,500	38,224,633	62,804,523.7	18.70	253.47	6.68	37.95
45-64 Years	2,428,803	21,273,788	948,104,086	1,024,568,566	28,333,576	56,529,815.5	85.72	390.36	8.76	44.57
65+ Years	1,700,629	15,741,715	941,722,008	1,053,175,296	9,260,114	22,831,377.9	183.65	553.75	9.26	59.82
Ramipril										
00-21 Years	572	3,657	127,854	162,337	27,178,643	51,047,090.4	0.02	223.52	6.39	34.96
22-44 Years	32,774	306,259	11,176,579	12,705,343	38,224,633	62,804,523.7	0.86	341.02	9.34	36.49
45-64 Years	187,976	2,358,877	95,110,316	110,580,776	28,333,576	56,529,815.5	6.63	505.97	12.55	40.32
65+ Years	137,093	1,606,078	84,045,065	99,113,010	9,260,114	22,831,377.9	14.80	613.05	11.72	52.33

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 Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
2011										
Benazepril, Enalapril, Lisinopril, Ramipril										
Female	1,023,418	4,812,179	229,041,957	259,226,389	24,758,280	20,439,743.4	41.34	223.80	4.70	47.60
Male	1,332,958	6,345,151	298,286,820	334,799,227	23,830,255	19,458,864.3	55.94	223.78	4.76	47.01
Unknown	177	930	43,585	45,485	2,354	1,879.3	75.19	246.24	5.25	46.87
Benazepril										
Female	65,087	343,918	14,730,180	16,529,247	24,758,280	20,439,743.4	2.63	226.32	5.28	42.83
Male	77,986	413,050	17,357,406	19,271,108	23,830,255	19,458,864.3	3.27	222.57	5.30	42.02
Unknown	10	51	1,969	1,789	2,354	1,879.3	4.25	196.90	5.10	38.61
Enalapril										
Female	77,125	396,557	17,432,725	24,062,009	24,758,280	20,439,743.4	3.12	226.03	5.14	43.96
Male	88,933	455,835	19,709,902	27,705,595	23,830,255	19,458,864.3	3.73	221.63	5.13	43.24
Unknown	10	53	2,343	2,463	2,354	1,879.3	4.25	234.30	5.30	44.21
Lisinopril										
Female	822,922	3,701,986	181,032,591	200,152,961	24,758,280	20,439,743.4	33.24	219.99	4.50	48.90
Male	1,056,267	4,797,202	231,903,060	253,895,283	23,830,255	19,458,864.3	44.32	219.55	4.54	48.34
Unknown	145	744	35,388	37,098	2,354	1,879.3	61.60	244.06	5.13	47.56
Ramipril										
Female	64,198	369,718	15,846,461	18,482,172	24,758,280	20,439,743.4	2.59	246.84	5.76	42.86
Male	116,778	679,064	29,316,452	33,927,241	23,830,255	19,458,864.3	4.90	251.04	5.81	43.17
Unknown	12	82	3,885	4,135	2,354	1,879.3	5.10	323.75	6.83	47.38

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 Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
2012										
Benazepril, Enalapril, Lisinopril, Ramipril										
Female	1,049,697	4,816,913	236,890,845	267,091,277	25,432,727	21,029,503.4	41.27	225.68	4.59	49.18
Male	1,377,706	6,447,436	310,139,731	346,531,305	24,567,557	20,116,040.2	56.08	225.11	4.68	48.10
Unknown	170	812	40,730	43,354	2,647	2,107.3	64.22	239.59	4.78	50.16
Benazepril										
Female	68,087	348,869	15,631,430	17,458,336	25,432,727	21,029,503.4	2.68	229.58	5.12	44.81
Male	82,643	427,685	18,580,458	20,610,683	24,567,557	20,116,040.2	3.36	224.83	5.18	43.44
Unknown	8	37	1,571	1,391	2,647	2,107.3	3.02	196.38	4.63	42.46
Enalapril										
Female	71,797	364,327	16,803,007	22,852,021	25,432,727	21,029,503.4	2.82	234.03	5.07	46.12
Male	83,772	427,255	19,160,295	26,059,322	24,567,557	20,116,040.2	3.41	228.72	5.10	44.85
Unknown	8	57	2,585	3,035	2,647	2,107.3	3.02	323.13	7.13	45.35
Lisinopril										
Female	854,211	3,762,188	189,294,208	209,046,038	25,432,727	21,029,503.4	33.59	221.60	4.40	50.31
Male	1,107,374	4,962,327	244,455,526	267,383,255	24,567,557	20,116,040.2	45.07	220.75	4.48	49.26
Unknown	140	655	33,324	35,373	2,647	2,107.3	52.89	238.03	4.68	50.88
Ramipril										
Female	60,601	341,529	15,162,200	17,734,883	25,432,727	21,029,503.4	2.38	250.20	5.64	44.40
Male	110,156	630,169	27,943,452	32,478,045	24,567,557	20,116,040.2	4.48	253.67	5.72	44.34
Unknown	14	63	3,250	3,555	2,647	2,107.3	5.29	232.14	4.50	51.59

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 Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
2013										
Benazepril, Enalapril, Lisinopril, Ramipril										
Female	1,074,171	4,892,374	244,978,280	275,233,396	25,429,877	20,893,234.8	42.24	228.06	4.55	50.07
Male	1,422,101	6,625,811	322,674,109	359,492,843	24,659,733	20,039,309.0	57.67	226.90	4.66	48.70
Unknown	162	774	39,494	42,860	2,431	1,786.4	66.64	243.79	4.78	51.03
Benazepril										
Female	68,003	353,799	16,295,562	18,198,730	25,429,877	20,893,234.8	2.67	239.63	5.20	46.06
Male	83,579	441,244	19,551,292	21,666,998	24,659,733	20,039,309.0	3.39	233.93	5.28	44.31
Unknown	4	23	1,170	1,530	2,431	1,786.4	1.65	292.50	5.75	50.87
Enalapril										
Female	69,150	340,364	16,124,350	21,914,393	25,429,877	20,893,234.8	2.72	233.18	4.92	47.37
Male	81,510	403,276	18,504,311	25,182,119	24,659,733	20,039,309.0	3.31	227.02	4.95	45.88
Unknown	9	44	2,334	2,739	2,431	1,786.4	3.70	259.33	4.89	53.05
Lisinopril										
Female	885,001	3,884,154	198,283,906	218,336,807	25,429,877	20,893,234.8	34.80	224.05	4.39	51.05
Male	1,159,246	5,196,212	258,163,811	281,750,383	24,659,733	20,039,309.0	47.01	222.70	4.48	49.68
Unknown	139	645	33,141	35,592	2,431	1,786.4	57.18	238.42	4.64	51.38
Ramipril										
Female	56,583	314,057	14,274,462	16,783,466	25,429,877	20,893,234.8	2.23	252.27	5.55	45.45
Male	103,501	585,079	26,454,695	30,893,343	24,659,733	20,039,309.0	4.20	255.60	5.65	45.22
Unknown	10	62	2,849	2,999	2,431	1,786.4	4.11	284.90	6.20	45.95

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

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2014										
Benazepril, Enalapril, Lisinopril, Ramipril										
Female	1,116,458	4,842,112	248,122,300	277,265,716	26,474,584	21,486,218.3	42.17	222.24	4.34	51.24
Male	1,476,966	6,554,677	327,849,937	363,599,454	25,715,224	20,643,097.6	57.44	221.98	4.44	50.02
Unknown	141	591	31,436	34,033	2,367	1,685.5	59.57	222.95	4.19	53.19
Benazepril										
Female	67,664	339,554	16,278,400	18,169,174	26,474,584	21,486,218.3	2.56	240.58	5.02	47.94
Male	82,872	423,313	19,521,059	21,631,693	25,715,224	20,643,097.6	3.22	235.56	5.11	46.11
Unknown	2	14	453	1,127	2,367	1,685.5	0.84	226.50	7.00	32.36
Enalapril										
Female	61,681	260,467	12,448,024	16,995,381	26,474,584	21,486,218.3	2.33	201.81	4.22	47.79
Male	72,619	308,753	14,484,732	19,819,167	25,715,224	20,643,097.6	2.82	199.46	4.25	46.91
Unknown	8	32	1,869	2,094	2,367	1,685.5	3.38	233.63	4.00	58.41
Lisinopril										
Female	936,529	3,948,434	205,552,381	225,725,202	26,474,584	21,486,218.3	35.37	219.48	4.22	52.06
Male	1,226,679	5,278,884	268,389,515	292,348,733	25,715,224	20,643,097.6	47.70	218.79	4.30	50.84
Unknown	125	511	27,324	29,022	2,367	1,685.5	52.81	218.59	4.09	53.47
Ramipril										
Female	54,381	293,657	13,843,495	16,375,959	26,474,584	21,486,218.3	2.05	254.56	5.40	47.14
Male	99,715	543,727	25,454,631	29,799,862	25,715,224	20,643,097.6	3.88	255.27	5.45	46.82
Unknown	6	34	1,790	1,790	2,367	1,685.5	2.53	298.33	5.67	52.65

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 Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
2015										
Benazepril, Enalapril, Lisinopril, Ramipril										
Female	981,577	3,263,871	152,009,569	169,171,905	24,392,996	14,787,700.3	40.24	154.86	3.33	46.57
Male	1,318,645	4,497,770	204,119,435	225,604,279	23,856,625	14,310,501.0	55.27	154.79	3.41	45.38
Unknown	114	283	14,314	14,823	2,411	1,136.6	47.28	125.56	2.48	50.58
Benazepril										
Female	59,241	212,950	9,276,725	10,332,463	24,392,996	14,787,700.3	2.43	156.59	3.59	43.56
Male	73,278	273,473	11,431,566	12,647,133	23,856,625	14,310,501.0	3.07	156.00	3.73	41.80
Unknown	2	6	197	471	2,411	1,136.6	0.83	98.50	3.00	32.83
Enalapril										
Female	43,675	157,482	6,405,814	8,719,244	24,392,996	14,787,700.3	1.79	146.67	3.61	40.68
Male	52,166	192,192	7,632,883	10,386,164	23,856,625	14,310,501.0	2.19	146.32	3.68	39.71
Unknown	5	15	592	592	2,411	1,136.6	2.07	118.40	3.00	39.47
Lisinopril										
Female	834,098	2,711,830	128,513,979	140,875,204	24,392,996	14,787,700.3	34.19	154.08	3.25	47.39
Male	1,110,634	3,696,098	170,716,545	185,742,660	23,856,625	14,310,501.0	46.55	153.71	3.33	46.19
Unknown	102	248	12,825	13,060	2,411	1,136.6	42.31	125.74	2.43	51.71
Ramipril										
Female	46,645	181,609	7,813,051	9,244,994	24,392,996	14,787,700.3	1.91	167.50	3.89	43.02
Male	85,356	336,007	14,338,441	16,828,322	23,856,625	14,310,501.0	3.58	167.98	3.94	42.67
Unknown	5	14	700	700	2,411	1,136.6	2.07	140.00	2.80	50.00

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 Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing
2011-2015										
Benazepril, Enalapril, Lisinopril, Ramipril										
Female	2,411,290	22,627,449	1,111,042,951	1,247,988,684	48,090,136	98,636,400.3	50.14	460.77	9.38	49.10
Male	3,156,002	30,470,845	1,463,070,032	1,630,027,109	47,099,887	94,567,812.2	67.01	463.58	9.65	48.02
Unknown	299	3,390	169,559	180,554	5,263	8,595.1	56.81	567.09	11.34	50.02
Benazepril										
Female	149,140	1,599,090	72,212,297	80,687,949	48,090,136	98,636,400.3	3.10	484.19	10.72	45.16
Male	184,687	1,978,765	86,441,781	95,827,614	47,099,887	94,567,812.2	3.92	468.04	10.71	43.68
Unknown	14	131	5,360	6,308	5,263	8,595.1	2.66	382.86	9.36	40.92
Enalapril										
Female	150,513	1,519,197	69,213,920	94,543,049	48,090,136	98,636,400.3	3.13	459.85	10.09	45.56
Male	178,209	1,787,311	79,492,123	109,152,367	47,099,887	94,567,812.2	3.78	446.06	10.03	44.48
Unknown	13	201	9,723	10,923	5,263	8,595.1	2.47	747.92	15.46	48.37
Lisinopril										
Female	2,021,885	18,008,592	902,677,065	994,136,213	48,090,136	98,636,400.3	42.04	446.45	8.91	50.12
Male	2,616,728	23,930,723	1,173,628,457	1,281,120,315	47,099,887	94,567,812.2	55.56	448.51	9.15	49.04
Unknown	258	2,803	142,002	150,145	5,263	8,595.1	49.02	550.40	10.86	50.66
Ramipril										
Female	121,604	1,500,570	66,939,669	78,621,474	48,090,136	98,636,400.3	2.53	550.47	12.34	44.61
Male	216,487	2,774,046	123,507,671	143,926,813	47,099,887	94,567,812.2	4.60	570.51	12.81	44.52
Unknown	14	255	12,474	13,179	5,263	8,595.1	2.66	891.00	18.21	48.92

Appendix A. Start and End Dates for Each Data Partner (DP) up to Request Distribution Date (June 17, 2016)

DP ID	Start Date¹	End Date¹
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

¹The 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 Angiotensin Converting Enzyme (ACE) Inhibitors of Interest in this Request

Generic Name	Brand Name
Benazepril	
Benazepril HCl	Benazepril HCl
Benazepril HCl	Lotensin
Enalapril	
Enalapril Maleate	Enalapril Maleate
Enalapril Maleate	Epaned
Enalapril Maleate	Vasotec
Lisinopril	
Lisinopril	Lisinopril
Lisinopril	Prinivil
Lisinopril	Zestril
Ramipril	
Ramipril	Ramipril
Ramipril	Altace

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 Angiotensin Converting Enzyme (ACE) Inhibitors in the Sentinel Distributed Database (SDD).

Enrollment Gap: 45 days

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

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

Scenario	Drug/Exposure			Pre-Existing Condition	Event/Outcome	
	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, Metoprolol, 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.