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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.

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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\_wp001\_nsdp\_v02

**Query Description:** This report contains the estimated rates of outpatient rhabdomyolysis and/or creatine kinase (CK) laboratory results following new use of statins or angiotensin-converting enzyme (ACE) inhibitors. This is Report 2 of 2.

**Data Source:** Data from January 1, 2006 to December 31, 2015 from 11 Data Partners contributing to the Sentinel Distributed Database (SDD) were included in this report. This request was distributed on February 19, 2016. See Appendix A for dates of available data for each Data Partner.

**Study Design:** This request was designed to identify exposures and follow-up time. The exposure of interest and the occurrence of the health outcome of interest during exposed time were identified. The number of exposure episodes, number of individuals, number of events, and days at risk in the SDD were calculated overall and were stratified by age group, sex, and year.

**Exposures of Interest:** The exposures of interest were statins and ACE inhibitors, which were defined using National Drug Codes (NDCs). Please refer to Appendix B for generic names evaluated.

**Cohort Eligibility Criteria:** Patients were required to be continuously enrolled in plans with both medical and drug coverage for at least six months (183 days) before their dispensing date, during which gaps in coverage of up to 45 days were allowed. Members were excluded if they had the exposure of interest, the outcome of interest, an inpatient rhabdomyolysis diagnosis, or a CK laboratory result  $\geq 1,000$  U/L in the six months (183 days) prior to the exposure of interest. The following age groups were included in the cohort: <22, 22- <45, 45-<65, and 65+ years.

**Follow-Up Time:** Follow-up time for the outcome was determined by the length of the exposure episodes. Exposure episode lengths were defined using outpatient pharmacy dispensing days supplied to create a sequence of continuous exposure. Exposure episodes were considered continuous if gaps in days supply were less than 10 days. The end date of each exposure episode was extended by 10 additional days. Follow-up began on the day on which the first exposure of interest was dispensed and continued until the first occurrence of any of the following: 1) the outcome of interest; 2) any codes defining incidence criteria; 3) disenrollment; 4) the study end date (December 31, 2015); 5) the end date of the data provided by each Data Partner (see Appendix A); or 6) the end of the exposure episode. Only the first valid incident exposure episode that occurred during the study period was included per patient.

**Outcome of Interest:** There were eight outcome definitions of interest:

- 1) an incident rhabdomyolysis diagnosis (International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code 728.88)
- 2) an incident rhabdomyolysis diagnosis (ICD-9-CM code 728.88) without a CK laboratory value  $\geq 1,000$  U/L within +/- 14 days
- 3) an incident rhabdomyolysis diagnosis (ICD-9-CM code 728.88) and a CK laboratory value  $\geq 0$  U/L within +/- 14 days
- 4) an incident rhabdomyolysis diagnosis (ICD-9-CM code 728.88) and a CK laboratory value  $> 0$  U/L and  $< 1,000$  U/L within +/- 14 days
- 5) an incident rhabdomyolysis diagnosis (ICD-9-CM code 728.88) and an incident CK laboratory value  $\geq 1,000$  U/L within +/- 14 days
- 6) an incident CK laboratory value  $\geq 1,000$  U/L
- 7) an incident CK laboratory value  $\geq 1,000$  U/L without a rhabdomyolysis diagnosis (ICD-9-CM code 728.88) within +/- 14 days
- 8) a prevalent CK laboratory value  $\geq 0$  U/L

Rhabdomyolysis diagnoses were restricted to occurrences in the inpatient setting and were defined by ICD-9-CM diagnosis code 728.88. CK laboratory tests could use any specimen source and CK results with either U/L or unknown result units were evaluated. For outcomes requiring both a diagnosis code and a laboratory result, the first code or result to occur was used as the outcome date.

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

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

**Notes:** Please contact the Sentinel Operations Center Query Fulfillment Team (qf@sentinelssystem.org) for questions and to provide comments/suggestions for future enhancements to this document.

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

- Amount Supplied** - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing. This is equivalent to the "RxAmt" value in the Sentinel Common Data Model.
- Blackout Period** - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.
- Care Setting** - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or Missing (U). Along with the Principal Diagnosis Indicator, forms the Care Setting/PDX 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.
- Cohort Definition (drug/exposure)** - indicates how the cohort will be defined: (1) 01: Cohort includes only the first valid treatment episode during the query period; (2) 02: Cohort includes all valid treatment episodes during the query period; (3) 03: Cohort includes all valid
- 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.
- Episode Gap** - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same
- Episodes** - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the
- Event Deduplication** - specifies how events are counted by the MP algorithm: (0) 0: Counts all occurrences of an HOI during an exposure episode; (1) 1: de-duplicates occurrences of the same HOI code and code type on the same day; (2) 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 days are added after any episode gaps have been bridged
- Lookback Period (pre-existing condition)** - 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
- 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.
- Principal Diagnosis (PDX)** - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the
- Query Period** - period in which the modular program looks for exposures and outcomes of interest.
- Treatment Episode Truncation Indicator** - indicates whether observation of the incident query code during follow-up requires truncation of valid treatment episodes. A value of Y indicates that the treatment episodes should be truncated at the first occurrence of an incident query code. A value of N indicates that the treatment episodes should not be truncated at the occurrence of the incident query code.
- Users** - number of members with exposure during the query period. Member must have no evidence of exposure(s) of interest (defined by incidence criteria) in the prior washout period. A user may only be counted once in a query period.
- Washout Period (drug/exposure)\*\*** - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.

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

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

\*all terms may not be used in this report

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

**Table 1: Incident Angiotensin-Converting-Enzyme (ACE) Inhibitor or Statin Use and Subsequent Outpatient Rhabdomyolysis and/or Creatine Kinase (CK) Laboratory Values in the Sentinel Distributed Database (SDD) between January 1, 2006 and December 31, 2015, by Event Definition and Exposure**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied / Dispensing	New Episodes w/ Events / 10K Years at Risk
<b>Rhabdomyolysis International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code 728.88</b>														
<i>ACE Inhibitors</i>	4,097,483	4,097,483	20,066,571	931,984,241	1,005,948,360	2,661,587.4	1,634	73,772,486	181,895,885.0	55.54	227.45	4.90	46.44	6.14
<i>Statins</i>	5,145,067	5,145,067	22,125,382	1,021,518,789	1,009,773,547	2,944,708.0	1,635	72,364,853	174,037,725.1	71.10	198.54	4.30	46.17	5.55
<b>Rhabdomyolysis without CK value <math>\geq</math> 1,000 U/L within +/- 14 days</b>														
<i>ACE Inhibitors</i>	4,097,483	4,097,483	20,066,571	931,984,241	1,005,948,360	2,661,761.4	1,460	73,772,486	181,895,885.0	55.54	227.45	4.90	46.44	5.49
<i>Statins</i>	5,145,067	5,145,067	22,125,382	1,021,518,789	1,009,773,547	2,944,777.4	1,416	72,364,853	174,037,725.1	71.10	198.54	4.30	46.17	4.81
<b>Rhabdomyolysis and CK value <math>\geq</math> 0 U/L within +/- 14 days</b>														
<i>ACE Inhibitors</i>	4,097,474	4,097,474	20,066,530	931,981,851	1,005,946,415	2,662,272.9	466	73,772,482	181,895,886.8	55.54	227.45	4.90	46.44	1.75
<i>Statins</i>	5,145,062	5,145,062	22,125,358	1,021,516,609	1,009,771,427	2,945,202.0	551	72,364,852	174,037,719.8	71.10	198.54	4.30	46.17	1.87
<b>Rhabdomyolysis and CK value <math>&gt;</math> 0 U/L and <math>&lt;</math> 1,000 U/L within +/- 14 days</b>														
<i>ACE Inhibitors</i>	4,097,474	4,097,474	20,066,530	931,981,851	1,005,946,415	2,662,320.3	402	73,772,482	181,895,886.8	55.54	227.45	4.90	46.44	1.51
<i>Statins</i>	5,145,062	5,145,062	22,125,358	1,021,516,609	1,009,771,427	2,945,222.2	474	72,364,852	174,037,719.8	71.10	198.54	4.30	46.17	1.61
<b>Rhabdomyolysis and CK value <math>\geq</math> 1,000 U/L within +/- 14 days</b>														
<i>ACE Inhibitors</i>	4,097,483	4,097,483	20,066,571	931,984,241	1,005,948,360	2,662,486.6	234	73,772,486	181,895,885.0	55.54	227.45	4.90	46.44	0.88
<i>Statins</i>	5,145,067	5,145,067	22,125,382	1,021,518,789	1,009,773,547	2,945,341.1	272	72,364,853	174,037,725.1	71.10	198.54	4.30	46.17	0.92
<b>CK value <math>\geq</math> 1,000 U/L</b>														
<i>ACE Inhibitors</i>	4,097,483	4,097,483	20,066,571	931,984,241	1,005,948,360	2,660,649.1	2,282	73,772,486	181,895,885.0	55.54	227.45	4.90	46.44	8.58
<i>Statins</i>	5,145,067	5,145,067	22,125,382	1,021,518,789	1,009,773,547	2,943,869.1	2,690	72,364,853	174,037,725.1	71.10	198.54	4.30	46.17	9.14
<b>CK value <math>\geq</math> 1,000 U/L without Rhabdomyolysis within +/- 14 days</b>														
<i>ACE Inhibitors</i>	4,097,483	4,097,483	20,066,571	931,984,241	1,005,948,360	2,660,863.5	2,068	73,772,486	181,895,885.0	55.54	227.45	4.90	46.44	7.77
<i>Statins</i>	5,145,067	5,145,067	22,125,382	1,021,518,789	1,009,773,547	2,943,962.0	2,436	72,364,853	174,037,725.1	71.10	198.54	4.30	46.17	8.27
<b>CK value <math>\geq</math> 0 U/L</b>														
<i>ACE Inhibitors</i>	4,101,748	4,101,748	20,090,215	933,470,561	1,007,665,994	2,495,580.8	149,125	73,773,810	181,920,009.2	55.60	227.58	4.90	46.46	597.56
<i>Statins</i>	5,149,244	5,149,244	22,150,545	1,023,060,966	1,011,307,293	2,710,334.4	251,456	72,366,323	174,060,493.0	71.16	198.68	4.30	46.19	927.77

**Table 2: Incident Angiotensin-Converting-Enzyme (ACE) Inhibitor or Statin Use and Subsequent Outpatient Rhabdomyolysis and/or Creatine Kinase (CK) Laboratory Values in the Sentinel Distributed Database (SDD) between January 1, 2006 and December 31, 2015, by Event Definition, Exposure, and Age Group**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied / User	Dispensings / User	Days Supplied / Dispensing	New Episodes w/ Events / 10K Years at Risk
<b>Rhabdomyolysis International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code 728.88</b>														
<b>ACE Inhibitors</b>														
0-21 Years	25,891	25,891	86,261	3,184,574	5,098,708	9,489.8	10	21,737,106	50,886,483.5	1.19	123.00	3.33	36.92	10.54
22-44 Years	716,004	716,004	2,762,962	108,448,661	113,887,912	318,434.7	165	30,605,094	59,661,198.8	23.39	151.46	3.86	39.25	5.18
45-64 Years	2,047,792	2,047,792	10,158,710	449,416,837	480,096,176	1,287,466.0	522	21,242,604	51,231,352.5	96.40	219.46	4.96	44.24	4.05
65+ Years	1,307,796	1,307,796	7,058,638	370,934,169	406,865,564	1,046,197.0	937	7,610,659	20,116,850.2	171.84	283.63	5.40	52.55	8.96
<b>Statins</b>														
0-21 Years	10,899	10,899	30,871	1,197,302	1,176,050	3,602.8	2	21,743,365	50,928,007.3	0.50	109.85	2.83	38.78	5.55
22-44 Years	706,870	706,870	2,335,088	91,331,772	90,595,833	272,265.9	128	30,624,978	59,727,745.7	23.08	129.21	3.30	39.11	4.70
45-64 Years	2,783,916	2,783,916	12,018,979	522,904,757	517,578,367	1,514,857.4	565	20,422,717	47,136,680.5	136.31	187.83	4.32	43.51	3.73
65+ Years	1,643,382	1,643,382	7,740,444	406,084,958	400,423,297	1,153,982.0	940	6,701,903	16,245,291.6	245.21	247.10	4.71	52.46	8.15
<b>Rhabdomyolysis without CK value <math>\geq</math> 1,000 U/L within +/- 14 days</b>														
<b>ACE Inhibitors</b>														
0-21 Years	25,891	25,891	86,261	3,184,574	5,098,708	9,489.8	10	21,737,106	50,886,483.5	1.19	123.00	3.33	36.92	10.54
22-44 Years	716,004	716,004	2,762,962	108,448,661	113,887,912	318,454.4	144	30,605,094	59,661,198.8	23.39	151.46	3.86	39.25	4.52
45-64 Years	2,047,792	2,047,792	10,158,710	449,416,837	480,096,176	1,287,527.2	466	21,242,604	51,231,352.5	96.40	219.46	4.96	44.24	3.62
65+ Years	1,307,796	1,307,796	7,058,638	370,934,169	406,865,564	1,046,290.0	840	7,610,659	20,116,850.2	171.84	283.63	5.40	52.55	8.03
<b>Statins</b>														
0-21 Years	10,899	10,899	30,871	1,197,302	1,176,050	3,602.8	2	21,743,365	50,928,007.3	0.50	109.85	2.83	38.78	5.55
22-44 Years	706,870	706,870	2,335,088	91,331,772	90,595,833	272,269.3	106	30,624,978	59,727,745.7	23.08	129.21	3.30	39.11	3.89
45-64 Years	2,783,916	2,783,916	12,018,979	522,904,757	517,578,367	1,514,881.2	489	20,422,717	47,136,680.5	136.31	187.83	4.32	43.51	3.23
65+ Years	1,643,382	1,643,382	7,740,444	406,084,958	400,423,297	1,154,024.2	819	6,701,903	16,245,291.6	245.21	247.10	4.71	52.46	7.10
<b>Rhabdomyolysis and CK value <math>\geq</math> 0 U/L within +/- 14 days</b>														
<b>ACE Inhibitors</b>														
0-21 Years	25,891	25,891	86,261	3,184,574	5,098,708	9,492.6	1	21,737,106	50,886,482.3	1.19	123.00	3.33	36.92	1.05
22-44 Years	716,002	716,002	2,762,951	108,448,331	113,887,582	318,474.9	56	30,605,093	59,661,196.7	23.39	151.46	3.86	39.25	1.76
45-64 Years	2,047,789	2,047,789	10,158,704	449,416,477	480,095,821	1,287,728.1	154	21,242,603	51,231,351.9	96.40	219.46	4.96	44.24	1.20
65+ Years	1,307,792	1,307,792	7,058,614	370,932,469	406,864,304	1,046,577.3	255	7,610,659	20,116,855.9	171.84	283.63	5.40	52.55	2.44
<b>Statins</b>														
0-21 Years	10,899	10,899	30,871	1,197,302	1,176,050	3,602.8	1	21,743,365	50,928,006.2	0.50	109.85	2.83	38.78	2.78
22-44 Years	706,869	706,869	2,335,087	91,331,742	90,595,818	272,290.8	59	30,624,977	59,727,742.1	23.08	129.21	3.30	39.11	2.17
45-64 Years	2,783,916	2,783,916	12,018,979	522,904,757	517,578,367	1,515,012.7	207	20,422,717	47,136,677.2	136.31	187.83	4.32	43.51	1.37
65+ Years	1,643,378	1,643,378	7,740,421	406,082,808	400,421,192	1,154,295.7	284	6,701,903	16,245,294.3	245.21	247.10	4.71	52.46	2.46

<b>Rhabdomyolysis and CK value &gt; 0 U/L and &lt; 1,000 U/L within +/- 14 days</b>														
<b>ACE Inhibitors</b>														
0-21 Years	25,891	25,891	86,261	3,184,574	5,098,708	9,492.6	1	21,737,106	50,886,482.3	1.19	123.00	3.33	36.92	1.05
22-44 Years	716,002	716,002	2,762,951	108,448,331	113,887,582	318,477.2	49	30,605,093	59,661,196.7	23.39	151.46	3.86	39.25	1.54
45-64 Years	2,047,789	2,047,789	10,158,704	449,416,477	480,095,821	1,287,753.1	128	21,242,603	51,231,351.9	96.40	219.46	4.96	44.24	0.99
65+ Years	1,307,792	1,307,792	7,058,614	370,932,469	406,864,304	1,046,597.5	224	7,610,659	20,116,855.9	171.84	283.63	5.40	52.55	2.14
<b>Statins</b>														
0-21 Years	10,899	10,899	30,871	1,197,302	1,176,050	3,602.8	1	21,743,365	50,928,006.2	0.50	109.85	2.83	38.78	2.78
22-44 Years	706,869	706,869	2,335,087	91,331,742	90,595,818	272,292.3	49	30,624,977	59,727,742.1	23.08	129.21	3.30	39.11	1.80
45-64 Years	2,783,916	2,783,916	12,018,979	522,904,757	517,578,367	1,515,019.0	181	20,422,717	47,136,677.2	136.31	187.83	4.32	43.51	1.19
65+ Years	1,643,378	1,643,378	7,740,421	406,082,808	400,421,192	1,154,308.1	243	6,701,903	16,245,294.3	245.21	247.10	4.71	52.46	2.11
<b>Rhabdomyolysis and CK value ≥ 1,000 U/L within +/- 14 days</b>														
<b>ACE Inhibitors</b>														
0-21 Years	25,891	25,891	86,261	3,184,574	5,098,708	9,493.0	0	21,737,106	50,886,483.5	1.19	123.00	3.33	36.92	0.00
22-44 Years	716,004	716,004	2,762,962	108,448,661	113,887,912	318,492.7	27	30,605,094	59,661,198.8	23.39	151.46	3.86	39.25	0.85
45-64 Years	2,047,792	2,047,792	10,158,710	449,416,837	480,096,176	1,287,792.4	75	21,242,604	51,231,352.5	96.40	219.46	4.96	44.24	0.58
65+ Years	1,307,796	1,307,796	7,058,638	370,934,169	406,865,564	1,046,708.4	132	7,610,659	20,116,850.2	171.84	283.63	5.40	52.55	1.26
<b>Statins</b>														
0-21 Years	10,899	10,899	30,871	1,197,302	1,176,050	3,603.1	0	21,743,365	50,928,007.3	0.50	109.85	2.83	38.78	0.00
22-44 Years	706,870	706,870	2,335,088	91,331,772	90,595,833	272,301.3	28	30,624,978	59,727,745.7	23.08	129.21	3.30	39.11	1.03
45-64 Years	2,783,916	2,783,916	12,018,979	522,904,757	517,578,367	1,515,066.2	95	20,422,717	47,136,680.5	136.31	187.83	4.32	43.51	0.63
65+ Years	1,643,382	1,643,382	7,740,444	406,084,958	400,423,297	1,154,370.5	149	6,701,903	16,245,291.6	245.21	247.10	4.71	52.46	1.29
<b>CK value ≥ 1,000 U/L</b>														
<b>ACE Inhibitors</b>														
0-21 Years	25,891	25,891	86,261	3,184,574	5,098,708	9,487.6	8	21,737,106	50,886,483.5	1.19	123.00	3.33	36.92	8.43
22-44 Years	716,004	716,004	2,762,962	108,448,661	113,887,912	318,322.2	225	30,605,094	59,661,198.8	23.39	151.46	3.86	39.25	7.07
45-64 Years	2,047,792	2,047,792	10,158,710	449,416,837	480,096,176	1,286,893.5	930	21,242,604	51,231,352.5	96.40	219.46	4.96	44.24	7.23
65+ Years	1,307,796	1,307,796	7,058,638	370,934,169	406,865,564	1,045,945.7	1,119	7,610,659	20,116,850.2	171.84	283.63	5.40	52.55	10.70
<b>Statins</b>														
0-21 Years	10,899	10,899	30,871	1,197,302	1,176,050	3,599.3	4	21,743,365	50,928,007.3	0.50	109.85	2.83	38.78	11.11
22-44 Years	706,870	706,870	2,335,088	91,331,772	90,595,833	272,190.6	311	30,624,978	59,727,745.7	23.08	129.21	3.30	39.11	11.43
45-64 Years	2,783,916	2,783,916	12,018,979	522,904,757	517,578,367	1,514,359.2	1,167	20,422,717	47,136,680.5	136.31	187.83	4.32	43.51	7.71
65+ Years	1,643,382	1,643,382	7,740,444	406,084,958	400,423,297	1,153,719.9	1,208	6,701,903	16,245,291.6	245.21	247.10	4.71	52.46	10.47
<b>CK value ≥ 1,000 U/L without Rhabdomyolysis within +/- 14 days</b>														
<b>ACE Inhibitors</b>														
0-21 Years	25,891	25,891	86,261	3,184,574	5,098,708	9,487.6	8	21,737,106	50,886,483.5	1.19	123.00	3.33	36.92	8.43
22-44 Years	716,004	716,004	2,762,962	108,448,661	113,887,912	318,344.4	199	30,605,094	59,661,198.8	23.39	151.46	3.86	39.25	6.25
45-64 Years	2,047,792	2,047,792	10,158,710	449,416,837	480,096,176	1,286,972.2	865	21,242,604	51,231,352.5	96.40	219.46	4.96	44.24	6.72
65+ Years	1,307,796	1,307,796	7,058,638	370,934,169	406,865,564	1,046,059.3	996	7,610,659	20,116,850.2	171.84	283.63	5.40	52.55	9.52



<b>Statins</b>														
0-21 Years	10,899	10,899	30,871	1,197,302	1,176,050	3,599.3	4	21,743,365	50,928,007.3	0.50	109.85	2.83	38.78	11.11
22-44 Years	706,870	706,870	2,335,088	91,331,772	90,595,833	272,194.8	284	30,624,978	59,727,745.7	23.08	129.21	3.30	39.11	10.43
45-64 Years	2,783,916	2,783,916	12,018,979	522,904,757	517,578,367	1,514,386.5	1,082	20,422,717	47,136,680.5	136.31	187.83	4.32	43.51	7.14
65+ Years	1,643,382	1,643,382	7,740,444	406,084,958	400,423,297	1,153,781.3	1,066	6,701,903	16,245,291.6	245.21	247.10	4.71	52.46	9.24
<b>CK value ≥ 0 U/L</b>														
<b>ACE Inhibitors</b>														
0-21 Years	25,926	25,926	86,384	3,190,681	5,107,501	9,365.8	263	21,737,226	50,889,104.1	1.19	123.07	3.33	36.94	280.81
22-44 Years	716,479	716,479	2,765,266	108,591,655	114,045,832	308,066.1	12,712	30,605,583	59,668,304.6	23.41	151.56	3.86	39.27	412.64
45-64 Years	2,049,535	2,049,535	10,168,500	450,093,290	480,878,511	1,209,297.2	68,983	21,242,972	51,238,444.0	96.48	219.61	4.96	44.26	570.44
65+ Years	1,309,808	1,309,808	7,070,065	371,594,935	407,634,149	968,851.6	67,167	7,610,978	20,124,156.6	172.09	283.70	5.40	52.56	693.26
<b>Statins</b>														
0-21 Years	10,905	10,905	30,889	1,198,350	1,177,048	3,346.9	483	21,743,487	50,930,685.2	0.50	109.89	2.83	38.80	1443.12
22-44 Years	707,288	707,288	2,336,780	91,443,026	90,704,666	257,899.8	23,238	30,625,493	59,734,888.9	23.09	129.29	3.30	39.13	901.05
45-64 Years	2,785,646	2,785,646	12,029,617	523,584,747	518,256,356	1,398,905.4	127,522	20,423,171	47,143,131.8	136.40	187.96	4.32	43.52	911.58
65+ Years	1,645,405	1,645,405	7,753,259	406,834,843	401,169,223	1,050,182.4	100,213	6,702,361	16,251,787.1	245.50	247.26	4.71	52.47	954.24

**Table 3: Incident Angiotensin-Converting-Enzyme (ACE) Inhibitor or Statin Use and Subsequent Outpatient Rhabdomyolysis and/or Creatine Kinase (CK) Laboratory Values in the Sentinel Distributed Database (SDD) between January 1, 2006 and December 31, 2015, by Event Definition, Exposure, and Sex**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied / User	Dispensings / User	Days Supplied / Dispensing	New Episodes w/ Events / 10K Years at Risk
<b>Rhabdomyolysis International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code 728.88</b>														
<b>ACE Inhibitors</b>														
Female	1,895,836	1,895,836	9,174,817	429,146,907	463,082,855	1,224,574.3	737	37,751,327	94,657,285.1	50.22	226.36	4.84	46.77	6.02
Male	2,201,529	2,201,529	10,891,237	502,813,416	542,839,238	1,436,943.8	897	36,019,217	87,234,466.3	61.12	228.39	4.95	46.17	6.24
Unknown	118	118	517	23,918	26,267	69.2	0	1,942	4,133.5	60.76	202.69	4.38	46.26	0.00
<b>Statins</b>														
Female	2,464,485	2,464,485	10,490,314	490,630,328	485,522,985	1,413,335.2	713	37,105,494	90,743,258.2	66.42	199.08	4.26	46.77	5.04
Male	2,680,432	2,680,432	11,634,507	530,860,139	524,221,119	1,531,290.9	922	35,257,438	83,290,452.0	76.02	198.05	4.34	45.63	6.02
Unknown	150	150	561	28,322	29,443	82.0	0	1,921	4,014.8	78.08	188.81	3.74	50.48	0.00
<b>Rhabdomyolysis without CK value <math>\geq</math> 1,000 U/L within +/- 14 days</b>														
<b>ACE Inhibitors</b>														
Female	1,895,836	1,895,836	9,174,817	429,146,907	463,082,855	1,224,656.9	664	37,751,327	94,657,285.1	50.22	226.36	4.84	46.77	5.42
Male	2,201,529	2,201,529	10,891,237	502,813,416	542,839,238	1,437,035.3	796	36,019,217	87,234,466.3	61.12	228.39	4.95	46.17	5.54
Unknown	118	118	517	23,918	26,267	69.2	0	1,942	4,133.5	60.76	202.69	4.38	46.26	0.00
<b>Statins</b>														
Female	2,464,485	2,464,485	10,490,314	490,630,328	485,522,985	1,413,365.6	620	37,105,494	90,743,258.2	66.42	199.08	4.26	46.77	4.39
Male	2,680,432	2,680,432	11,634,507	530,860,139	524,221,119	1,531,329.8	796	35,257,438	83,290,452.0	76.02	198.05	4.34	45.63	5.20
Unknown	150	150	561	28,322	29,443	82.0	0	1,921	4,014.8	78.08	188.81	3.74	50.48	0.00
<b>Rhabdomyolysis and CK value <math>\geq</math> 0 U/L within +/- 14 days</b>														
<b>ACE Inhibitors</b>														
Female	1,895,833	1,895,833	9,174,789	429,145,087	463,081,505	1,224,892.7	205	37,751,326	94,657,280.8	50.22	226.36	4.84	46.77	1.67
Male	2,201,523	2,201,523	10,891,224	502,812,846	542,838,643	1,437,311.0	261	36,019,214	87,234,472.4	61.12	228.39	4.95	46.17	1.82
Unknown	118	118	517	23,918	26,267	69.2	0	1,942	4,133.5	60.76	202.69	4.38	46.26	0.00
<b>Statins</b>														
Female	2,464,480	2,464,480	10,490,290	490,628,148	485,520,865	1,413,565.1	224	37,105,493	90,743,259.9	66.42	199.08	4.26	46.77	1.58
Male	2,680,432	2,680,432	11,634,507	530,860,139	524,221,119	1,531,554.8	327	35,257,438	83,290,445.1	76.02	198.05	4.34	45.63	2.14
Unknown	150	150	561	28,322	29,443	82.0	0	1,921	4,014.8	78.08	188.81	3.74	50.48	0.00
<b>Rhabdomyolysis and CK value <math>&gt;</math> 0 U/L and <math>&lt;</math> 1,000 U/L within +/- 14 days</b>														
<b>ACE Inhibitors</b>														
Female	1,895,833	1,895,833	9,174,789	429,145,087	463,081,505	1,224,919.7	180	37,751,326	94,657,280.8	50.22	226.36	4.84	46.77	1.47
Male	2,201,523	2,201,523	10,891,224	502,812,846	542,838,643	1,437,331.4	222	36,019,214	87,234,472.4	61.12	228.39	4.95	46.17	1.54
Unknown	118	118	517	23,918	26,267	69.2	0	1,942	4,133.5	60.76	202.69	4.38	46.26	0.00
<b>Statins</b>														
Female	2,464,480	2,464,480	10,490,290	490,628,148	485,520,865	1,413,575.6	193	37,105,493	90,743,259.9	66.42	199.08	4.26	46.77	1.37
Male	2,680,432	2,680,432	11,634,507	530,860,139	524,221,119	1,531,564.6	281	35,257,438	83,290,445.1	76.02	198.05	4.34	45.63	1.83
Unknown	150	150	561	28,322	29,443	82.0	0	1,921	4,014.8	78.08	188.81	3.74	50.48	0.00

<b>Rhabdomyolysis and CK value <math>\geq</math> 1,000 U/L within +/- 14 days</b>														
<b>ACE Inhibitors</b>														
Female	1,895,836	1,895,836	9,174,817	429,146,907	463,082,855	1,224,984.6	103	37,751,327	94,657,285.1	50.22	226.36	4.84	46.77	0.84
Male	2,201,529	2,201,529	10,891,237	502,813,416	542,839,238	1,437,432.7	131	36,019,217	87,234,466.3	61.12	228.39	4.95	46.17	0.91
Unknown	118	118	517	23,918	26,267	69.2	0	1,942	4,133.5	60.76	202.69	4.38	46.26	0.00
<b>Statins</b>														
Female	2,464,485	2,464,485	10,490,314	490,630,328	485,522,985	1,413,631.4	114	37,105,494	90,743,258.2	66.42	199.08	4.26	46.77	0.81
Male	2,680,432	2,680,432	11,634,507	530,860,139	524,221,119	1,531,627.7	158	35,257,438	83,290,452.0	76.02	198.05	4.34	45.63	1.03
Unknown	150	150	561	28,322	29,443	82.0	0	1,921	4,014.8	78.08	188.81	3.74	50.48	0.00
<b>CK value <math>\geq</math> 1,000 U/L</b>														
<b>ACE Inhibitors</b>														
Female	1,895,836	1,895,836	9,174,817	429,146,907	463,082,855	1,224,449.8	782	37,751,327	94,657,285.1	50.22	226.36	4.84	46.77	6.39
Male	2,201,529	2,201,529	10,891,237	502,813,416	542,839,238	1,436,130.1	1,500	36,019,217	87,234,466.3	61.12	228.39	4.95	46.17	10.44
Unknown	118	118	517	23,918	26,267	69.2	0	1,942	4,133.5	60.76	202.69	4.38	46.26	0.00
<b>Statins</b>														
Female	2,464,485	2,464,485	10,490,314	490,630,328	485,522,985	1,413,238.7	825	37,105,494	90,743,258.2	66.42	199.08	4.26	46.77	5.84
Male	2,680,432	2,680,432	11,634,507	530,860,139	524,221,119	1,530,548.3	1,865	35,257,438	83,290,452.0	76.02	198.05	4.34	45.63	12.19
Unknown	150	150	561	28,322	29,443	82.0	0	1,921	4,014.8	78.08	188.81	3.74	50.48	0.00
<b>CK value <math>\geq</math> 1,000 U/L without Rhabdomyolysis within +/- 14 days</b>														
<b>ACE Inhibitors</b>														
Female	1,895,836	1,895,836	9,174,817	429,146,907	463,082,855	1,224,568.1	687	37,751,327	94,657,285.1	50.22	226.36	4.84	46.77	5.61
Male	2,201,529	2,201,529	10,891,237	502,813,416	542,839,238	1,436,226.2	1,381	36,019,217	87,234,466.3	61.12	228.39	4.95	46.17	9.62
Unknown	118	118	517	23,918	26,267	69.2	0	1,942	4,133.5	60.76	202.69	4.38	46.26	0.00
<b>Statins</b>														
Female	2,464,485	2,464,485	10,490,314	490,630,328	485,522,985	1,413,281.3	719	37,105,494	90,743,258.2	66.42	199.08	4.26	46.77	5.09
Male	2,680,432	2,680,432	11,634,507	530,860,139	524,221,119	1,530,598.6	1,717	35,257,438	83,290,452.0	76.02	198.05	4.34	45.63	11.22
Unknown	150	150	561	28,322	29,443	82.0	0	1,921	4,014.8	78.08	188.81	3.74	50.48	0.00
<b>CK value <math>\geq</math> 0 U/L</b>														
<b>ACE Inhibitors</b>														
Female	1,897,193	1,897,193	9,182,333	429,580,785	463,581,596	1,151,560.0	66,723	37,751,823	94,666,761.3	50.25	226.43	4.84	46.78	579.41
Male	2,204,437	2,204,437	10,907,365	503,865,858	544,058,131	1,343,958.9	82,394	36,020,045	87,249,114.4	61.20	228.57	4.95	46.20	613.07
Unknown	118	118	517	23,918	26,267	61.9	8	1,942	4,133.5	60.76	202.69	4.38	46.26	1292.81
<b>Statins</b>														
Female	2,465,862	2,465,862	10,498,093	491,080,753	485,975,004	1,300,228.5	122,422	37,106,045	90,751,956.0	66.45	199.15	4.26	46.78	941.54
Male	2,683,232	2,683,232	11,651,891	531,951,891	525,302,846	1,410,038.8	129,024	35,258,357	83,304,521.1	76.10	198.25	4.34	45.65	915.04
Unknown	150	150	561	28,322	29,443	67.1	10	1,921	4,015.9	78.08	188.81	3.74	50.48	1490.45

**Table 4: Incident Angiotensin-Converting-Enzyme (ACE) Inhibitor or Statin Use and Subsequent Outpatient Rhabdomyolysis and/or Creatine Kinase (CK) Laboratory Values in the Sentinel Distributed Database (SDD) between January 1, 2006 and December 31, 2015, by Event Definition, Exposure, and Year**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied / Dispensing	New Episodes w/ Events / 10K Years at Risk
<b>Rhabdomyolysis International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code 728.88</b>														
<i>ACE Inhibitors</i>														
2006	231,626	231,626	1,405,189	82,396,525	90,237,849	231,884.2	101	16,112,618	9,013,006.3	14.38	355.73	6.07	58.64	4.36
2007	337,934	337,934	2,077,589	103,158,878	112,503,643	292,418.8	98	19,939,187	14,238,322.8	16.95	305.26	6.15	49.65	3.35
2008	509,249	509,249	2,884,520	131,014,730	142,635,511	373,412.5	200	29,718,989	20,034,298.9	17.14	257.27	5.66	45.42	5.36
2009	592,309	592,309	3,164,425	142,352,497	154,305,407	406,747.9	237	29,930,360	23,190,294.6	19.79	240.33	5.34	44.99	5.83
2010	523,440	523,440	2,712,683	124,339,784	134,145,845	355,124.0	209	28,179,425	21,950,407.7	18.58	237.54	5.18	45.84	5.89
2011	451,142	451,142	2,248,053	104,398,427	112,281,617	298,252.6	229	26,667,331	20,948,152.5	16.92	231.41	4.98	46.44	7.68
2012	431,223	431,223	2,055,020	93,993,301	100,498,661	269,007.8	208	27,671,047	21,139,610.8	15.58	217.97	4.77	45.74	7.73
2013	428,558	428,558	1,808,331	81,155,166	86,250,681	233,434.6	171	27,663,017	21,617,151.8	15.49	189.37	4.22	44.88	7.33
2014	436,560	436,560	1,434,089	59,329,674	62,787,868	172,455.0	146	29,173,623	21,915,478.5	14.96	135.90	3.28	41.37	8.47
2015	155,442	155,442	276,672	9,845,259	10,301,277	28,850.1	35	22,856,168	7,849,160.9	6.80	63.34	1.78	35.58	12.13
<i>Statins</i>														
2006	310,458	310,458	1,522,387	84,458,930	84,265,997	239,926.2	99	15,757,513	8,759,448.1	19.70	272.05	4.90	55.48	4.13
2007	452,631	452,631	2,295,510	109,869,320	107,182,040	315,307.7	102	19,452,194	13,787,620.1	23.27	242.73	5.07	47.86	3.23
2008	659,595	659,595	3,211,689	144,063,219	142,570,778	415,586.1	200	28,897,028	19,322,133.5	22.83	218.41	4.87	44.86	4.81
2009	735,238	735,238	3,464,699	154,875,625	153,771,093	447,205.8	210	28,972,370	22,267,837.3	25.38	210.65	4.71	44.70	4.70
2010	613,477	613,477	2,828,713	128,868,539	127,985,476	371,399.7	231	27,148,927	20,999,727.6	22.60	210.06	4.61	45.56	6.22
2011	544,286	544,286	2,412,783	111,816,286	110,464,707	321,872.9	192	25,633,913	19,986,658.0	21.23	205.44	4.43	46.34	5.97
2012	538,344	538,344	2,319,894	107,579,592	105,161,135	309,957.4	204	26,568,643	20,127,344.7	20.26	199.83	4.31	46.37	6.58
2013	539,146	539,146	2,085,701	95,092,538	94,119,347	275,289.0	182	26,521,317	20,554,548.2	20.33	176.38	3.87	45.59	6.61
2014	554,728	554,728	1,651,964	72,457,796	71,930,952	211,605.4	178	27,921,545	20,786,141.0	19.87	130.62	2.98	43.86	8.41
2015	197,164	197,164	332,042	12,436,944	12,322,024	36,557.9	37	21,737,758	7,446,266.6	9.07	63.08	1.68	37.46	10.12
<b>Rhabdomyolysis without CK value <math>\geq</math> 1,000 U/L within +/- 14 days</b>														
<i>ACE Inhibitors</i>														
2006	231,626	231,626	1,405,189	82,396,525	90,237,849	231,923.8	71	16,112,618	9,013,006.3	14.38	355.73	6.07	58.64	3.06
2007	337,934	337,934	2,077,589	103,158,878	112,503,643	292,451.2	78	19,939,187	14,238,322.8	16.95	305.26	6.15	49.65	2.67
2008	509,249	509,249	2,884,520	131,014,730	142,635,511	373,455.6	177	29,718,989	20,034,298.9	17.14	257.27	5.66	45.42	4.74
2009	592,309	592,309	3,164,425	142,352,497	154,305,407	406,761.7	215	29,930,360	23,190,294.6	19.79	240.33	5.34	44.99	5.29
2010	523,440	523,440	2,712,683	124,339,784	134,145,845	355,143.5	192	28,179,425	21,950,407.7	18.58	237.54	5.18	45.84	5.41
2011	451,142	451,142	2,248,053	104,398,427	112,281,617	298,265.5	216	26,667,331	20,948,152.5	16.92	231.41	4.98	46.44	7.24
2012	431,223	431,223	2,055,020	93,993,301	100,498,661	269,013.1	194	27,671,047	21,139,610.8	15.58	217.97	4.77	45.74	7.21
2013	428,558	428,558	1,808,331	81,155,166	86,250,681	233,438.6	157	27,663,017	21,617,151.8	15.49	189.37	4.22	44.88	6.73
2014	436,560	436,560	1,434,089	59,329,674	62,787,868	172,457.5	130	29,173,623	21,915,478.5	14.96	135.90	3.28	41.37	7.54
2015	155,442	155,442	276,672	9,845,259	10,301,277	28,851.0	30	22,856,168	7,849,160.9	6.80	63.34	1.78	35.58	10.40

<b>Statins</b>														
2006	310,458	310,458	1,522,387	84,458,930	84,265,997	239,936.9	73	15,757,513	8,759,448.1	19.70	272.05	4.90	55.48	3.04
2007	452,631	452,631	2,295,510	109,869,320	107,182,040	315,315.9	81	19,452,194	13,787,620.1	23.27	242.73	5.07	47.86	2.57
2008	659,595	659,595	3,211,689	144,063,219	142,570,778	415,591.4	179	28,897,028	19,322,133.5	22.83	218.41	4.87	44.86	4.31
2009	735,238	735,238	3,464,699	154,875,625	153,771,093	447,214.4	176	28,972,370	22,267,837.3	25.38	210.65	4.71	44.70	3.94
2010	613,477	613,477	2,828,713	128,868,539	127,985,476	371,411.6	201	27,148,927	20,999,727.6	22.60	210.06	4.61	45.56	5.41
2011	544,286	544,286	2,412,783	111,816,286	110,464,707	321,877.5	178	25,633,913	19,986,658.0	21.23	205.44	4.43	46.34	5.53
2012	538,344	538,344	2,319,894	107,579,592	105,161,135	309,970.6	173	26,568,643	20,127,344.7	20.26	199.83	4.31	46.37	5.58
2013	539,146	539,146	2,085,701	95,092,538	94,119,347	275,292.1	167	26,521,317	20,554,548.2	20.33	176.38	3.87	45.59	6.07
2014	554,728	554,728	1,651,964	72,457,796	71,930,952	211,608.1	159	27,921,545	20,786,141.0	19.87	130.62	2.98	43.86	7.51
2015	197,164	197,164	332,042	12,436,944	12,322,024	36,558.8	29	21,737,758	7,446,266.6	9.07	63.08	1.68	37.46	7.93
<b>Rhabdomyolysis and CK value <math>\geq</math> 0 U/L within +/- 14 days</b>														
<b>ACE Inhibitors</b>														
2006	231,623	231,623	1,405,172	82,395,525	90,237,319	231,923.6	56	16,112,617	9,013,005.7	14.38	355.73	6.07	58.64	2.41
2007	337,934	337,934	2,077,589	103,158,878	112,503,643	292,483.8	45	19,939,187	14,238,322.9	16.95	305.26	6.15	49.65	1.54
2008	509,248	509,248	2,884,513	131,014,030	142,634,811	373,506.1	66	29,718,987	20,034,298.8	17.14	257.27	5.66	45.42	1.77
2009	592,309	592,309	3,164,425	142,352,497	154,305,407	406,888.2	64	29,930,360	23,190,295.1	19.79	240.33	5.34	44.99	1.57
2010	523,439	523,439	2,712,678	124,339,634	134,145,695	355,222.4	61	28,179,427	21,950,408.2	18.58	237.54	5.18	45.84	1.72
2011	451,140	451,140	2,248,049	104,398,307	112,281,512	298,334.7	44	26,667,332	20,948,151.8	16.92	231.41	4.98	46.44	1.47
2012	431,220	431,220	2,055,011	93,992,851	100,498,121	269,097.8	47	27,671,051	21,139,611.9	15.58	217.97	4.77	45.74	1.75
2013	428,558	428,558	1,808,331	81,155,166	86,250,681	233,478.9	43	27,663,019	21,617,152.0	15.49	189.37	4.22	44.88	1.84
2014	436,561	436,561	1,434,090	59,329,704	62,787,948	172,484.3	31	29,173,626	21,915,479.4	14.96	135.90	3.28	41.37	1.80
2015	155,442	155,442	276,672	9,845,259	10,301,277	28,853.0	9	22,856,170	7,849,161.0	6.80	63.34	1.78	35.58	3.12
<b>Statins</b>														
2006	310,457	310,457	1,522,379	84,458,130	84,265,197	239,967.8	52	15,757,513	8,759,447.6	19.70	272.04	4.90	55.48	2.17
2007	452,630	452,630	2,295,509	109,869,230	107,181,950	315,346.1	44	19,452,194	13,787,619.5	23.27	242.74	5.07	47.86	1.40
2008	659,594	659,594	3,211,683	144,062,679	142,570,238	415,687.5	56	28,897,026	19,322,132.9	22.83	218.41	4.87	44.86	1.35
2009	735,237	735,237	3,464,698	154,875,535	153,771,003	447,256.4	68	28,972,370	22,267,837.1	25.38	210.65	4.71	44.70	1.52
2010	613,476	613,476	2,828,705	128,867,819	127,984,801	371,482.8	73	27,148,930	20,999,728.5	22.60	210.06	4.61	45.56	1.97
2011	544,286	544,286	2,412,783	111,816,286	110,464,707	321,930.6	57	25,633,913	19,986,657.4	21.23	205.44	4.43	46.34	1.77
2012	538,343	538,343	2,319,893	107,579,562	105,161,120	310,021.8	77	26,568,643	20,127,344.4	20.26	199.83	4.31	46.37	2.48
2013	539,147	539,147	2,085,702	95,092,628	94,119,437	275,321.2	46	26,521,317	20,554,547.2	20.33	176.38	3.87	45.59	1.67
2014	554,728	554,728	1,651,964	72,457,796	71,930,952	211,627.8	63	27,921,544	20,786,139.3	19.87	130.62	2.98	43.86	2.98
2015	197,164	197,164	332,042	12,436,944	12,322,024	36,559.9	15	21,737,756	7,446,266.0	9.07	63.08	1.68	37.46	4.10

**Rhabdomyolysis and CK value > 0 U/L and < 1,000 U/L within +/- 14 days**

<i>ACE Inhibitors</i>														
2006	231,623	231,623	1,405,172	82,395,525	90,237,319	231,942.5	48	16,112,617	9,013,005.7	14.38	355.73	6.07	58.64	2.07
2007	337,934	337,934	2,077,589	103,158,878	112,503,643	292,484.8	42	19,939,187	14,238,322.9	16.95	305.26	6.15	49.65	1.44
2008	509,248	509,248	2,884,513	131,014,030	142,634,811	373,515.6	59	29,718,987	20,034,298.8	17.14	257.27	5.66	45.42	1.58
2009	592,309	592,309	3,164,425	142,352,497	154,305,407	406,890.2	59	29,930,360	23,190,295.1	19.79	240.33	5.34	44.99	1.45
2010	523,439	523,439	2,712,678	124,339,634	134,145,695	355,232.1	52	28,179,427	21,950,408.2	18.58	237.54	5.18	45.84	1.46
2011	451,140	451,140	2,248,049	104,398,307	112,281,512	298,335.8	41	26,667,332	20,948,151.8	16.92	231.41	4.98	46.44	1.37
2012	431,220	431,220	2,055,011	93,992,851	100,498,121	269,100.0	37	27,671,051	21,139,611.9	15.58	217.97	4.77	45.74	1.37
2013	428,558	428,558	1,808,331	81,155,166	86,250,681	233,479.8	39	27,663,019	21,617,152.0	15.49	189.37	4.22	44.88	1.67
2014	436,561	436,561	1,434,090	59,329,704	62,787,948	172,486.3	19	29,173,626	21,915,479.4	14.96	135.90	3.28	41.37	1.10
2015	155,442	155,442	276,672	9,845,259	10,301,277	28,853.4	6	22,856,170	7,849,161.0	6.80	63.34	1.78	35.58	2.08

<i>Statins</i>														
2006	310,457	310,457	1,522,379	84,458,130	84,265,197	239,971.6	47	15,757,513	8,759,447.6	19.70	272.04	4.90	55.48	1.96
2007	452,630	452,630	2,295,509	109,869,230	107,181,950	315,349.1	35	19,452,194	13,787,619.5	23.27	242.74	5.07	47.86	1.11
2008	659,594	659,594	3,211,683	144,062,679	142,570,238	415,688.4	50	28,897,026	19,322,132.9	22.83	218.41	4.87	44.86	1.20
2009	735,237	735,237	3,464,698	154,875,535	153,771,003	447,258.2	62	28,972,370	22,267,837.1	25.38	210.65	4.71	44.70	1.39
2010	613,476	613,476	2,828,705	128,867,819	127,984,801	371,485.3	60	27,148,930	20,999,728.5	22.60	210.06	4.61	45.56	1.62
2011	544,286	544,286	2,412,783	111,816,286	110,464,707	321,932.4	50	25,633,913	19,986,657.4	21.23	205.44	4.43	46.34	1.55
2012	538,343	538,343	2,319,893	107,579,562	105,161,120	310,025.1	67	26,568,643	20,127,344.4	20.26	199.83	4.31	46.37	2.16
2013	539,147	539,147	2,085,702	95,092,628	94,119,437	275,322.9	37	26,521,317	20,554,547.2	20.33	176.38	3.87	45.59	1.34
2014	554,728	554,728	1,651,964	72,457,796	71,930,952	211,628.8	54	27,921,544	20,786,139.3	19.87	130.62	2.98	43.86	2.55
2015	197,164	197,164	332,042	12,436,944	12,322,024	36,560.3	12	21,737,756	7,446,266.0	9.07	63.08	1.68	37.46	3.28

**Rhabdomyolysis and CK value ≥ 1,000 U/L within +/- 14 days**

<i>ACE Inhibitors</i>														
2006	231,626	231,626	1,405,189	82,396,525	90,237,849	231,948.8	38	16,112,618	9,013,006.3	14.38	355.73	6.07	58.64	1.64
2007	337,934	337,934	2,077,589	103,158,878	112,503,643	292,525.6	26	19,939,187	14,238,322.8	16.95	305.26	6.15	49.65	0.89
2008	509,249	509,249	2,884,520	131,014,730	142,635,511	373,541.2	30	29,718,989	20,034,298.9	17.14	257.27	5.66	45.42	0.80
2009	592,309	592,309	3,164,425	142,352,497	154,305,407	406,916.7	30	29,930,360	23,190,294.6	19.79	240.33	5.34	44.99	0.74
2010	523,440	523,440	2,712,683	124,339,784	134,145,845	355,246.6	29	28,179,425	21,950,407.7	18.58	237.54	5.18	45.84	0.82
2011	451,142	451,142	2,248,053	104,398,427	112,281,617	298,355.0	23	26,667,331	20,948,152.5	16.92	231.41	4.98	46.44	0.77
2012	431,223	431,223	2,055,020	93,993,301	100,498,661	269,122.3	20	27,671,047	21,139,610.8	15.58	217.97	4.77	45.74	0.74
2013	428,558	428,558	1,808,331	81,155,166	86,250,681	233,489.8	14	27,663,017	21,617,151.8	15.49	189.37	4.22	44.88	0.60
2014	436,560	436,560	1,434,089	59,329,674	62,787,868	172,487.1	19	29,173,623	21,915,478.5	14.96	135.90	3.28	41.37	1.10
2015	155,442	155,442	276,672	9,845,259	10,301,277	28,853.6	5	22,856,168	7,849,160.9	6.80	63.34	1.78	35.58	1.73

<b>Statins</b>														
2006	310,458	310,458	1,522,387	84,458,930	84,265,997	239,984.2	34	15,757,513	8,759,448.1	19.70	272.05	4.90	55.48	1.42
2007	452,631	452,631	2,295,510	109,869,320	107,182,040	315,360.2	28	19,452,194	13,787,620.1	23.27	242.73	5.07	47.86	0.89
2008	659,595	659,595	3,211,689	144,063,219	142,570,778	415,706.9	25	28,897,028	19,322,133.5	22.83	218.41	4.87	44.86	0.60
2009	735,238	735,238	3,464,699	154,875,625	153,771,093	447,275.3	39	28,972,370	22,267,837.3	25.38	210.65	4.71	44.70	0.87
2010	613,477	613,477	2,828,713	128,868,539	127,985,476	371,494.7	40	27,148,927	20,999,727.6	22.60	210.06	4.61	45.56	1.08
2011	544,286	544,286	2,412,783	111,816,286	110,464,707	321,954.5	18	25,633,913	19,986,658.0	21.23	205.44	4.43	46.34	0.56
2012	538,344	538,344	2,319,894	107,579,592	105,161,135	310,039.3	38	26,568,643	20,127,344.7	20.26	199.83	4.31	46.37	1.23
2013	539,146	539,146	2,085,701	95,092,538	94,119,347	275,328.1	21	26,521,317	20,554,548.2	20.33	176.38	3.87	45.59	0.76
2014	554,728	554,728	1,651,964	72,457,796	71,930,952	211,637.5	21	27,921,545	20,786,141.0	19.87	130.62	2.98	43.86	0.99
2015	197,164	197,164	332,042	12,436,944	12,322,024	36,560.5	8	21,737,758	7,446,266.6	9.07	63.08	1.68	37.46	2.19
<b>CK value ≥ 1,000 U/L</b>														
<b>ACE Inhibitors</b>														
2006	231,626	231,626	1,405,189	82,396,525	90,237,849	231,460.4	467	16,112,618	9,013,006.3	14.38	355.73	6.07	58.64	20.18
2007	337,934	337,934	2,077,589	103,158,878	112,503,643	292,155.9	373	19,939,187	14,238,322.8	16.95	305.26	6.15	49.65	12.77
2008	509,249	509,249	2,884,520	131,014,730	142,635,511	373,280.8	288	29,718,989	20,034,298.9	17.14	257.27	5.66	45.42	7.72
2009	592,309	592,309	3,164,425	142,352,497	154,305,407	406,717.5	257	29,930,360	23,190,294.6	19.79	240.33	5.34	44.99	6.32
2010	523,440	523,440	2,712,683	124,339,784	134,145,845	355,063.5	227	28,179,425	21,950,407.7	18.58	237.54	5.18	45.84	6.39
2011	451,142	451,142	2,248,053	104,398,427	112,281,617	298,216.0	199	26,667,331	20,948,152.5	16.92	231.41	4.98	46.44	6.67
2012	431,223	431,223	2,055,020	93,993,301	100,498,661	269,027.8	166	27,671,047	21,139,610.8	15.58	217.97	4.77	45.74	6.17
2013	428,558	428,558	1,808,331	81,155,166	86,250,681	233,423.1	165	27,663,017	21,617,151.8	15.49	189.37	4.22	44.88	7.07
2014	436,560	436,560	1,434,089	59,329,674	62,787,868	172,454.8	112	29,173,623	21,915,478.5	14.96	135.90	3.28	41.37	6.49
2015	155,442	155,442	276,672	9,845,259	10,301,277	28,849.3	28	22,856,168	7,849,160.9	6.80	63.34	1.78	35.58	9.71
<b>Statins</b>														
2006	310,458	310,458	1,522,387	84,458,930	84,265,997	239,625.1	498	15,757,513	8,759,448.1	19.70	272.05	4.90	55.48	20.78
2007	452,631	452,631	2,295,510	109,869,320	107,182,040	315,117.0	384	19,452,194	13,787,620.1	23.27	242.73	5.07	47.86	12.19
2008	659,595	659,595	3,211,689	144,063,219	142,570,778	415,510.0	321	28,897,028	19,322,133.5	22.83	218.41	4.87	44.86	7.73
2009	735,238	735,238	3,464,699	154,875,625	153,771,093	447,073.2	314	28,972,370	22,267,837.3	25.38	210.65	4.71	44.70	7.02
2010	613,477	613,477	2,828,713	128,868,539	127,985,476	371,354.6	286	27,148,927	20,999,727.6	22.60	210.06	4.61	45.56	7.70
2011	544,286	544,286	2,412,783	111,816,286	110,464,707	321,846.0	226	25,633,913	19,986,658.0	21.23	205.44	4.43	46.34	7.02
2012	538,344	538,344	2,319,894	107,579,592	105,161,135	309,948.8	248	26,568,643	20,127,344.7	20.26	199.83	4.31	46.37	8.00
2013	539,146	539,146	2,085,701	95,092,538	94,119,347	275,238.4	204	26,521,317	20,554,548.2	20.33	176.38	3.87	45.59	7.41
2014	554,728	554,728	1,651,964	72,457,796	71,930,952	211,601.7	159	27,921,545	20,786,141.0	19.87	130.62	2.98	43.86	7.51
2015	197,164	197,164	332,042	12,436,944	12,322,024	36,554.4	50	21,737,758	7,446,266.6	9.07	63.08	1.68	37.46	13.68

**CK value  $\geq$  1,000 U/L without Rhabdomyolysis within +/- 14 days**

**ACE Inhibitors**

2006	231,626	231,626	1,405,189	82,396,525	90,237,849	231,509.1	435	16,112,618	9,013,006.3	14.38	355.73	6.07	58.64	18.79
2007	337,934	337,934	2,077,589	103,158,878	112,503,643	292,191.9	348	19,939,187	14,238,322.8	16.95	305.26	6.15	49.65	11.91
2008	509,249	509,249	2,884,520	131,014,730	142,635,511	373,319.6	261	29,718,989	20,034,298.9	17.14	257.27	5.66	45.42	6.99
2009	592,309	592,309	3,164,425	142,352,497	154,305,407	406,747.7	230	29,930,360	23,190,294.6	19.79	240.33	5.34	44.99	5.65
2010	523,440	523,440	2,712,683	124,339,784	134,145,845	355,087.1	199	28,179,425	21,950,407.7	18.58	237.54	5.18	45.84	5.60
2011	451,142	451,142	2,248,053	104,398,427	112,281,617	298,239.4	176	26,667,331	20,948,152.5	16.92	231.41	4.98	46.44	5.90
2012	431,223	431,223	2,055,020	93,993,301	100,498,661	269,033.2	148	27,671,047	21,139,610.8	15.58	217.97	4.77	45.74	5.50
2013	428,558	428,558	1,808,331	81,155,166	86,250,681	233,427.0	153	27,663,017	21,617,151.8	15.49	189.37	4.22	44.88	6.55
2014	436,560	436,560	1,434,089	59,329,674	62,787,868	172,458.4	95	29,173,623	21,915,478.5	14.96	135.90	3.28	41.37	5.51
2015	155,442	155,442	276,672	9,845,259	10,301,277	28,850.2	23	22,856,168	7,849,160.9	6.80	63.34	1.78	35.58	7.97

**Statins**

2006	310,458	310,458	1,522,387	84,458,930	84,265,997	239,643.4	467	15,757,513	8,759,448.1	19.70	272.05	4.90	55.48	19.49
2007	452,631	452,631	2,295,510	109,869,320	107,182,040	315,131.0	358	19,452,194	13,787,620.1	23.27	242.73	5.07	47.86	11.36
2008	659,595	659,595	3,211,689	144,063,219	142,570,778	415,518.0	298	28,897,028	19,322,133.5	22.83	218.41	4.87	44.86	7.17
2009	735,238	735,238	3,464,699	154,875,625	153,771,093	447,082.8	275	28,972,370	22,267,837.3	25.38	210.65	4.71	44.70	6.15
2010	613,477	613,477	2,828,713	128,868,539	127,985,476	371,368.8	249	27,148,927	20,999,727.6	22.60	210.06	4.61	45.56	6.70
2011	544,286	544,286	2,412,783	111,816,286	110,464,707	321,851.7	208	25,633,913	19,986,658.0	21.23	205.44	4.43	46.34	6.46
2012	538,344	538,344	2,319,894	107,579,592	105,161,135	309,963.4	213	26,568,643	20,127,344.7	20.26	199.83	4.31	46.37	6.87
2013	539,146	539,146	2,085,701	95,092,538	94,119,347	275,242.8	186	26,521,317	20,554,548.2	20.33	176.38	3.87	45.59	6.76
2014	554,728	554,728	1,651,964	72,457,796	71,930,952	211,604.5	139	27,921,545	20,786,141.0	19.87	130.62	2.98	43.86	6.57
2015	197,164	197,164	332,042	12,436,944	12,322,024	36,555.3	43	21,737,758	7,446,266.6	9.07	63.08	1.68	37.46	11.76

**CK value  $\geq$  0 U/L**

**ACE Inhibitors**

2006	232,199	232,199	1,408,655	82,656,082	90,555,788	193,057.1	25,370	16,112,900	9,014,382.1	14.41	355.97	6.07	58.68	1314.12
2007	338,452	338,452	2,080,965	103,401,808	112,786,477	262,123.2	21,638	19,939,633	14,240,215.5	16.97	305.51	6.15	49.69	825.49
2008	509,746	509,746	2,887,734	131,231,306	142,879,171	348,192.5	19,565	29,719,245	20,036,717.0	17.15	257.44	5.67	45.44	561.90
2009	592,750	592,750	3,166,866	142,511,750	154,505,462	385,056.0	18,959	29,930,389	23,192,931.4	19.80	240.42	5.34	45.00	492.37
2010	523,832	523,832	2,715,115	124,484,833	134,310,390	337,363.4	16,714	28,179,320	21,952,934.9	18.59	237.64	5.18	45.85	495.43
2011	451,585	451,585	2,250,406	104,538,459	112,437,379	285,155.5	13,904	26,667,210	20,950,853.6	16.93	231.49	4.98	46.45	487.59
2012	431,655	431,655	2,057,676	94,128,306	100,650,357	259,774.7	11,828	27,670,897	21,142,484.2	15.60	218.06	4.77	45.74	455.32
2013	428,946	428,946	1,810,292	81,260,214	86,359,545	226,997.0	10,693	27,662,843	21,620,280.1	15.51	189.44	4.22	44.89	471.06
2014	436,965	436,965	1,435,489	59,398,380	62,864,038	169,306.2	8,558	29,173,529	21,918,842.0	14.98	135.93	3.29	41.38	505.47
2015	155,618	155,618	277,017	9,859,423	10,317,387	28,555.3	1,896	22,856,953	7,850,368.6	6.81	63.36	1.78	35.59	663.98



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**Statins**

2006	311,006	311,006	1,526,057	84,720,974	84,538,792	194,394.6	36,144	15,757,836	8,760,667.6	19.74	272.41	4.91	55.52	1859.31
2007	453,144	453,144	2,298,953	110,115,736	107,424,134	277,105.9	33,217	19,452,689	13,789,280.1	23.29	243.00	5.07	47.90	1198.71
2008	660,073	660,073	3,214,943	144,272,754	142,773,916	380,660.6	32,813	28,897,461	19,324,346.2	22.84	218.57	4.87	44.88	862.00
2009	735,681	735,681	3,467,465	155,049,618	153,946,159	413,595.6	34,124	28,972,706	22,270,292.3	25.39	210.76	4.71	44.72	825.06
2010	613,833	613,833	2,831,084	129,006,665	128,121,853	345,374.5	28,169	27,149,136	21,002,118.8	22.61	210.17	4.61	45.57	815.61
2011	544,669	544,669	2,415,261	111,964,436	110,607,730	301,364.8	24,207	25,634,129	19,989,224.3	21.25	205.56	4.43	46.36	803.25
2012	538,774	538,774	2,322,681	107,721,784	105,294,288	292,903.3	22,603	26,568,907	20,130,104.2	20.28	199.94	4.31	46.38	771.69
2013	539,537	539,537	2,087,828	95,208,979	94,237,602	263,234.5	20,204	26,521,580	20,557,616.2	20.34	176.46	3.87	45.60	767.53
2014	555,169	555,169	1,653,830	72,546,600	72,023,233	205,701.6	16,283	27,921,920	20,789,407.1	19.88	130.67	2.98	43.87	791.58
2015	197,358	197,358	332,443	12,453,420	12,339,586	35,998.9	3,692	21,738,851	7,447,436.3	9.08	63.10	1.68	37.46	1025.59

**Appendix A. Dates of Available Data for Each Data Partner up to Request Send Date (February 19, 2016)**

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<b>DP ID</b>	<b>Start Date</b>	<b>End Date</b>
DP0001	1/1/2006	7/31/2014
DP0002	1/1/2006	4/30/2015
DP0003	1/1/2006	10/31/2014
DP0004	1/1/2006	6/30/2015
DP0005	1/1/2006	6/30/2012
DP0006	1/1/2006	7/31/2015
DP0007	1/1/2006	5/31/2015
DP0008	1/1/2006	6/30/2015
DP0009	1/1/2006	4/30/2015
DP0010	1/1/2006	7/31/2015
DP0011	1/1/2006	7/31/2015

## Appendix B. Generic Drug Names used for Exposures in this Request

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### Generic Name

#### ACE Inhibitors

AMLODIPINE BESYLATE/BENAZEPRIL HCL  
BENAZEPRIL HCL  
BENAZEPRIL HCL/HYDROCHLOROTHIAZIDE  
CAPTOPRIL  
CAPTOPRIL/HYDROCHLOROTHIAZIDE  
ENALAPRIL MALEATE  
ENALAPRIL MALEATE/FELODIPINE  
ENALAPRIL MALEATE/HYDROCHLOROTHIAZIDE  
ENALAPRILAT DIHYDRATE  
FOSINOPRIL SODIUM  
FOSINOPRIL SODIUM/HYDROCHLOROTHIAZIDE  
LISINOPRIL  
LISINOPRIL/DIETARY SUPPLEMENT, COMB.10  
LISINOPRIL/HYDROCHLOROTHIAZIDE  
MOEXIPRIL HCL  
MOEXIPRIL HCL/HYDROCHLOROTHIAZIDE  
PERINDOPRIL ARGININE/AMLODIPINE BESYLATE  
PERINDOPRIL ERBUMINE  
QUINAPRIL HCL  
QUINAPRIL HCL/HYDROCHLOROTHIAZIDE  
RAMIPRIL  
TRANDOLAPRIL  
TRANDOLAPRIL/VERAPAMIL HCL

#### Statins

AMLODIPINE BESYLATE/ATORVASTATIN CALCIUM  
ATORVASTATIN CALCIUM  
EZETIMIBE/ATORVASTATIN CALCIUM  
EZETIMIBE/SIMVASTATIN  
FLUVASTATIN SODIUM  
LOVASTATIN  
NIACIN/SIMVASTATIN  
PITAVASTATIN CALCIUM  
PRAVASTATIN SODIUM  
ROSUVASTATIN CALCIUM  
SIMVASTATIN  
SITAGLIPTIN PHOSPHATE/SIMVASTATIN

**Appendix C. Specifications for Request ID: cder\_mpl1r\_wp001\_nsdp\_v02**

This request was executed using the Cohort Identification and Descriptive Analysis (CIDA) tool to investigate rhabdomyolysis events following new use of statins or angiotensin-converting enzyme (ACE) inhibitors in the Sentinel Distributed Database (SDD). This request also utilizes creatine kinase (CK) to select the cohort and identify events.

**Enrollment Gap:** 45 Days  
**Age Groups:** <22, 22- <45, 45-<65, 65+ years  
**Query Period:** January 1, 2006 - December 31, 2015  
**Coverage Requirement:** Medical and Drug Coverage  
**Pre-Exposure Enrollment Requirement:** 183 days  
**Laboratory Date Algorithm:** Lab Date, Order Date, Result Date

Scenario	Drug/Exposure									Event/Outcome								
	Incident exposure	Incident w/ respect to:	Washout (days)	Cohort Definition	Episode Gap	Exposure Extension Period	Minimum Days Supplied	Minimum Episode Duration	Episode Truncation by Evidence of Death	Event	Care Setting	Time Window	Event Date	Incident w/ respect to:	Incident Care Setting	Blackout Period (days)	Washout (days)	
1	Statins	Statins	183	01	10	10	1	1	No	Rhabdomyolysis	Inpatient (IP)	N/A	N/A	Rhabdomyolysis, or CK value ≥ 1,000 U/L*	IP	0	183	
2	Statins	Statins	183	01	10	10	1	1	No	Rhabdomyolysis WITHOUT CK value ≥ 1,000 U/L*	IP	+/- 14 days	Diagnosis (DX) date	Rhabdomyolysis, or CK value ≥ 1,000 U/L*	IP	0	183	
3	Statins	Statins	183	01	10	10	1	1	No	Rhabdomyolysis AND CK value ≥ 0 U/L*	IP	+/- 14 days	First occurrence	Rhabdomyolysis, or CK value ≥ 1,000 U/L*	IP	0	183	
4	Statins	Statins	183	01	10	10	1	1	No	Rhabdomyolysis AND CK value > 0 and < 1,000 U/L*	IP	+/- 14 days	First occurrence	Rhabdomyolysis, or CK value ≥ 1,000 U/L*	IP	0	183	
5	Statins	Statins	183	01	10	10	1	1	No	Rhabdomyolysis AND CK value ≥ 1,000 U/L*	IP	+/- 14 days	First occurrence	Rhabdomyolysis, or CK value ≥ 1,000 U/L*	IP	0	183	
6	Statins	Statins	183	01	10	10	1	1	No	CK value ≥ 1,000 U/L*	Any	N/A	N/A	Rhabdomyolysis, or CK value ≥ 1,000 U/L*	IP	0	183	
7	Statins	Statins	183	01	10	10	1	1	No	CK value ≥ 1,000 U/L* WITHOUT Rhabdomyolysis	IP	+/- 14 days	Lab date	Rhabdomyolysis, or CK value ≥ 1,000 U/L*	IP	0	183	
8	Statins	Statins	183	01	10	10	1	1	No	CK value ≥ 0 U/L*	Any	N/A	N/A	N/A	N/A	0	0	
9	ACE Inhibitors	ACE Inhibitors	183	01	10	10	1	1	No	Rhabdomyolysis	IP	N/A	N/A	Rhabdomyolysis, or CK value ≥ 1,000 U/L*	IP	0	183	
10	ACE Inhibitors	ACE Inhibitors	183	01	10	10	1	1	No	Rhabdomyolysis WITHOUT CK value ≥ 1,000 U/L*	IP	+/- 14 days	DX date	Rhabdomyolysis, or CK value ≥ 1,000 U/L*	IP	0	183	
11	ACE Inhibitors	ACE Inhibitors	183	01	10	10	1	1	No	Rhabdomyolysis AND CK value ≥ 0 U/L*	IP	+/- 14 days	First occurrence	Rhabdomyolysis, or CK value ≥ 1,000 U/L*	IP	0	183	
12	ACE Inhibitors	ACE Inhibitors	183	01	10	10	1	1	No	Rhabdomyolysis AND CK value > 0 and < 1,000 U/L*	IP	+/- 14 days	First occurrence	Rhabdomyolysis, or CK value ≥ 1,000 U/L*	IP	0	183	
13	ACE Inhibitors	ACE Inhibitors	183	01	10	10	1	1	No	Rhabdomyolysis AND CK value ≥ 1,000 U/L*	IP	+/- 14 days	First occurrence	Rhabdomyolysis, or CK value ≥ 1,000 U/L*	IP	0	183	
14	ACE Inhibitors	ACE Inhibitors	183	01	10	10	1	1	No	CK value ≥ 1,000 U/L*	Any	N/A	N/A	Rhabdomyolysis, or CK value ≥ 1,000 U/L*	IP	0	183	
15	ACE Inhibitors	ACE Inhibitors	183	01	10	10	1	1	No	CK value ≥ 1,000 U/L* WITHOUT Rhabdomyolysis	IP	+/- 14 days	Lab date	Rhabdomyolysis, or CK value ≥ 1,000 U/L*	IP	0	183	
16	ACE Inhibitors	ACE Inhibitors	183	01	10	10	1	1	No	CK value ≥ 0 U/L*	Any	N/A	N/A	N/A	N/A	0	0	

\*Creatine kinase (CK) laboratory results in this request will include values where the result unit is either U/L or UNKNOWN.