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_mpl2r_wp016

Request ID: cder_mpl2r_wp016

Request Description: In this request, we assessed the risk of angioedema associated with sacubitril/valsartan (SV) compared to angiotensin-converting enzyme inhibitors (ACEI) or to angiotensin II receptor blockers (ARBs, excluding SV) among heart failure patients in the Sentinel Distributed Database (SDD).

Sentinel Modular Program Tool: Cohort Identification and Descriptive Analysis (CIDA) and Propensity Score Analysis (PSA) tools, version 9.7.0

Data Source: The study period spanned from July 7, 2015 to February 29, 2020. We distributed the analytic package to seven Data Partners (DP) on November 13, 2020. This report contains aggregated data from five Data Partners for which the propensity score estimation models converged across all comparisons. See Appendix A for a list of the latest dates of available data for each DP included in this report.

Study Design: We identified individuals with incident use of SV, ACEI, and ARBs who were 18 years or older with a history of heart failure and evaluated the occurrence of angioedema and serious angioedema during exposure episodes. We then conducted a PSA comparing the SV users to the ACEI or ARB users, matching and stratifying on propensity score. This is a Type 2 analysis using the Propensity Score Analysis module in the Query Request Package (QRP) documentation.

Exposure and Comparator: We defined exposures of interest as new use of SV, ACEI, and ARBs. The exposure drugs were defined using National Drug Codes (NDCs). For a list of generic and brand names of medical products used to define the exposure and comparator drugs, please see Appendix B.

Outcomes of Interest: We defined our main outcome of interest, angioedema, as an angioedema diagnosis code recorded in any diagnostic position of an inpatient, emergency department, or outpatient encounter. We defined our secondary outcome of interest, serious angioedema, as an angioedema diagnosis recorded in any diagnostic position of an inpatient or emergency department encounter with evidence of an intensive care unit admission, intubation, tracheostomy, or laryngoscopy occurring within two days of the hospital admission or emergency department visit. We defined our outcomes using International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM), International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), Current Procedural Terminology, Fourth Edition (CPT-4), and Healthcare Common Procedure Coding System, Level II (HCPCS). For a list of codes used to define outcomes, please see Appendix C.

Cohort Eligibility Criteria: We required patients 18 years or older to be enrolled in plans with both medical and drug coverage for at least 183 days before index dispensing, during which gaps in coverage of up to 45 days were allowed and treated as continuous enrollment. New use was defined as no use of SV, ACEI, or ARBs in the 183 days preceding the index dispensing. We included patients with evidence of heart failure in the 183 days preceding and including index date. We excluded patients from the cohort if they had evidence of a dispensing for the other two exposures on their index date. Incidence, inclusion, and exclusion criteria were defined using NDCs, ICD-9-CM, and ICD-10-CM. For a list of generic and brand names of medical products and specific codes used to define cohort eligibility, please see Appendices D and E.

Follow-up: We determined follow-up time based on the length of the exposure episodes and censored upon prespecified criteria. We created exposure episodes using outpatient pharmacy dispensing data. We bridged together exposure episodes less than 14 days apart and added 14 days at the end of each exposure episodes to create continuous treatment episodes. Sensitivity analyses shortened the episode gap and episode extension to 7 days. Follow-up began on the day of exposure initiation and continued until the earliest of any of the following: 1) outcome occurrence; 2) requester-defined censoring criteria -- initiation of any of the other two study drugs or after 365 days of continuous exposure; 3) disenrollment; 4) recorded death; 5) end of exposure episode; 6) end of query period; or 7) end of available data. Only the first valid exposure episode that occurred during the study period was included per patient.

Baseline Covariates: Please refer to Appendices F, G, and I for a list of covariates, codes, and evaluation windows used to defined covariates.

Overview for Request cder_mpl2r_wp016
Propensity Score Estimation: For each comparison, we fit a logistic regression model to estimate the propensity score (PS) based on potential confounders outlined in Appendix J. The matching ratio for the PS was 1:1 and the matching caliper was 0.05. Patients in the exposed and comparator cohorts were nearest neighbor matched without replacement, meaning that each comparator patient was matched one time, at most, to an exposed patient. We also used PS stratification (deciles) for our main analyses comparing SV to ACEI and ARBs and risk of angioedema. For each comparison, we used risk set-based approach to estimate the adjusted hazard ratio and 95% confidence intervals for the unadjusted analyses, unconditional and conditional matched analyses, and PS stratified analyses. Subgroup analyses for effect estimation included angioedema diagnosis in 183 days prior to index date and separately, in entire enrollment history prior to index date; serious allergies diagnosis in the 183 days prior to index date; sex; age group; race; *and follow-up time.* ***See Appendices H and I for the specifications of parameters used in the analyses for this request.*** **Limitations:** As with all observational studies, this evaluation was limited in its ability to control for all sources of potential bias. Algorithms used to define exposures, outcomes, inclusion and exclusion criteria, and covariates are imperfect and may be misclassified. Therefore, data should be interpreted with this limitation in mind. **Notes:** Please contact the Sentinel Operations Center (info@sentinelsystem.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel's routine querying modules, please refer to the documentation (https://dev.sentinelsystem.org/projects/SENTINEL/repos/sentinel-routine-queryingtooldocumentation/browse).

Sentinel

Table of Contents

Table of Contents

Table of Contents

Table of Contents

Sentinel

Table of Contents

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

Glossary of Terms for Analyses Using Propensity Score Analysis (PSA) Tool*

Covariate - requester defined binary variable to include in the propensity score estimation model (e.g., diabetes, heart failure, etc.) during requester-defined lookback period. Requester may also choose to add any of the following categorical, continuous, or count

1. Age (continuous)
2. Sex
3. Time period (i.e., monitoring period for sequential analyses)
4. Year of exposure
5. Comorbidity score
6. Medical utilization – number of inpatient stays
7. Medical utilization – number of institutional stays
8. Medical utilization – number of emergency department visits
9. Medical utilization – number of outpatient visits
10. Health care utilization – number of other ambulatory encounters (e.g., telemedicine, email consults)
11. Drug utilization – number of dispensings
12. Drug utilization – number of unique generics dispensed
13. Drug Utilization – number of unique drug classes dispensed

Covariate Evaluation Window - specified number of days relative to index date to evaluate the occurrence of covariates of interest. Note: members are required to have continuous enrollment during the covariate evaluation window, regardless of the value

Individual Level Data Return - program may return individual-level, de-identified datasets to the Sentinel Operations Center (SOC). While the datasets contain a single row per patient for each specified analysis, patient identifiers such as a patient ID are not included in the output. Individual-level datasets are returned to the SOC, aggregated, and used to calculate effect estimates via Cox

Mahalanobis Distance - provides a measure of balance across all variables while accounting for their correlation.

Matching Caliper - maximum allowed difference in propensity scores between treatment and control patients. Requester may select any caliper (e.g., 0.01, 0.025, and 0.05).

Matching Ratio - patients in exposed and comparator groups are nearest neighbor matched by a 1:1 or 1:n (up to 10) matching

Matched Conditional and Unconditional Analysis - in a conditional matched analysis, a Cox model, stratified by Data Partner site and matched set, is run on the matched population. This can be done for both the both 1:1 and 1:n matched cohorts. In an unconditional analysis, a Cox model, stratified by Data Partner site only, is run on the matched population. This can be done for the

Propensity Score Stratification - option to stratify propensity scores based on requester-defined percentiles in the unmatched population. In a stratified analysis, a Cox model, stratified by Data Partner site, is run on the stratified population. Note that all

PSM Tool - performs effect estimation by comparing exposure propensity-score matched parallel new user cohorts. Propensity score estimation and matching are conducted within each Sentinel Data Partner site via distributed programming code; data are

Risk-set Level Data Return - alternative to the patient-level data return approach. In this approach, the PSM tool will produce de-identified, risk-set level datasets instead of or in addition to individual-level output. Whereas each observation in the patient-level datasets represents one patient in the cohort, each observation in the risk set dataset represents one event. Risk sets are created at the Data Partner site, returned to the SOC, aggregated, and used to calculate effect estimates via case-centered logistic regression.

Subgroup Analysis - may be conducted using any requester-defined covariates. Subgroup analyses may be performed in the

Zero Cell Correction - indicator for whether to screen variables with a zero correction added to each cell in the confounder/outcome 2x2 table. Recommended when the number of exposed outcomes is fewer than 150.

*all terms may not be used in this report

Table 1a. Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Unadjusted, Aggregated)

	Medical Product				Covariate Balance	
	SV (14-day gap)		ACEI (14-day gap)			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	41,998	100.0%	695,012	100.0%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age, years	71.6	11.8	72.7	12.5	-1.108	-0.091
Age	**Number**	**Percent**	**Number**	**Percent**		
18-44 years	*1,538*	*3.7%*	*21,594*	*3.1%*	*0.555*	*0.031*
45-54 years	*2,863*	*6.8%*	*45,064*	*6.5%*	*0.333*	*0.013*
55-64 years	*5,807*	*13.8%*	*97,267*	*14.0%*	*-0.168*	*-0.005*
≥65 years	*31,790*	*75.7%*	*531,087*	*76.4%*	*-0.720*	*-0.017*
Sex						
Female	14,867	35.4%	341,886	49.2%	-13.792	-0.282
Male	27,131	64.6%	353,126	50.8%	13.792	0.282
Race						
American Indian or Alaska Native	132	0.3%	4,529	0.7%	-0.337	-0.049
Asian	519	1.2%	7,874	1.1%	0.103	0.010
Black or African American	5,566	13.3%	92,129	13.3%	-0.003	-0.000
Native Hawaiian or Other Pacific Islander	46	0.1%	741	0.1%	0.003	0.001
Unknown	7,029	16.7%	99,645	14.3%	2.399	0.066
White	28,706	68.4%	490,094	70.5%	-2.165	-0.047
Hispanic Origin	*708*	*1.7%*	*15,586*	*2.2%*	*-0.557*	*-0.040*
Year						
2015	430	1.0%	87,092	12.5%	-11.507	-0.470
2016	4,087	9.7%	172,883	24.9%	-15.143	-0.409
2017	8,846	21.1%	156,612	22.5%	-1.471	-0.036
2018	11,912	28.4%	143,025	20.6%	7.784	0.182
2019	16,392	39.0%	133,649	19.2%	19.801	0.447
2020	331	5.8%	1,751	2.4%	3.366	0.170
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[3]	5.6	2.8	5.8	3.0	-0.259	-0.089
	Number	**Percent**	**Number**	**Percent**		
Ambulatory allergies or allergy treatment	*20,540*	*48.9%*	*320,744*	*46.1%*	*2.758*	*0.055*
Ambulatory allergies or treatment and not serious allergies	16,919	40.3%	253,012	36.4%	3.881	0.080
Angioedema (-183, -1)	57	0.1%	864	0.1%	0.011	0.003
Angioedema (ever, -1)	*571*	*1.4%*	*7,320*	*1.1%*	*0.306*	*0.028*
Diabetes	19,570	46.6%	326,116	46.9%	-0.325	-0.007
Ischemic heart disease	31,758	75.6%	433,085	62.3%	13.305	0.291
Renal disorders	18,574	44.2%	289,803	41.7%	2.528	0.051
Serious allergies	5,684	13.5%	110,980	16.0%	-2.434	-0.069

Table 1a. Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Unadjusted, Aggregated)

	Medical Product				Covariate Balance	
	SV (14-day gap)		ACEI (14-day gap)			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	33,728	80.3%	458,232	65.9%	14.377	0.329
Everolimus	12	0.0%	183	0.0%	0.002	0.001
Nonsteroidal anti-inflammatory drugs (NSAIDs)	4,213	10.0%	88,980	12.8%	-2.771	-0.087
Sirolimus	*****	*****	208	0.0%	-0.006	-0.004
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	18.2	17.0	17.3	19.7	0.886	0.048
Mean number of emergency room encounters	0.6	1.3	0.9	1.8	-0.205	-0.129
Mean number of inpatient hospital encounters	0.8	1.1	1.0	1.2	-0.212	-0.190
Mean number of non-acute institutional encounters	0.3	0.9	0.4	1.1	-0.163	-0.168
Mean number of other ambulatory encounters	9.2	14.1	12.8	18.0	-3.641	-0.226
Mean number of filled prescriptions	*26.5*	*20.5*	*26.9*	*23.0*	*-0.349*	*-0.016*
Mean number of generics	*11.6*	*5.4*	*11.5*	*5.7*	*0.106*	*0.019*
Mean number of unique drug classes	11.0	4.9	10.8	5.0	0.195	0.039

[1]Covariates in italics were not included in the propensity score logistic regression model

[2]Covariates in blue show a standardized difference greater than 0.1

[3]The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1b. Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Adjusted, Aggregated), Fixed Ratio 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	SV (14-day gap)		ACEI (14-day gap)			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	41,998	100.0%	41,998	6.0%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age, years	71.6	11.8	71.6	12.1	0.033	0.003
Age	**Number**	**Percent**	**Number**	**Percent**		
18-44 years	*1,538*	*3.7%*	*1,462*	*3.5%*	*0.181*	*0.010*
45-54 years	*2,863*	*6.8%*	*2,925*	*7.0%*	*-0.148*	*-0.006*
55-64 years	*5,807*	*13.8%*	*6,460*	*15.4%*	*-1.555*	*-0.045*
≥65 years	*31,790*	*75.7%*	*31,151*	*74.2%*	*1.522*	*0.038*
Sex						
Female	14,867	35.4%	15,072	35.9%	-0.488	-0.010
Male	27,131	64.6%	26,926	64.1%	0.488	0.010
Race						
American Indian or Alaska Native	132	0.3%	132	0.3%	0.000	0.000
Asian	519	1.2%	536	1.3%	-0.040	-0.004
Black or African American	5,566	13.3%	5,557	13.2%	0.021	0.001
Native Hawaiian or Other Pacific Islander	46	0.1%	41	0.1%	0.012	0.004
Unknown	7,029	16.7%	7,058	16.8%	-0.069	-0.003
White	28,706	68.4%	28,674	68.3%	0.076	0.002
Hispanic Origin	*708*	*1.7%*	*843*	*2.0%*	*-0.321*	*-0.024*
Year						
2015	430	1.0%	378	0.9%	0.124	0.013
2016	4,087	9.7%	4,104	9.8%	-0.040	-0.001
2017	8,846	21.1%	8,931	21.3%	-0.202	-0.005
2018	11,912	28.4%	11,867	28.3%	0.107	0.002
2019	16,392	39.0%	16,366	39.0%	0.062	0.001
2020	331	5.8%	352	6.1%	-0.367	-0.016
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[3]	5.6	2.8	5.6	2.8	0.006	0.002
	Number	**Percent**	**Number**	**Percent**		
Ambulatory allergies or allergy treatment	*20,540*	*48.9%*	*20,437*	*48.7%*	*0.245*	*0.005*
Ambulatory allergies or treatment and not serious allergies	16,919	40.3%	16,914	40.3%	0.012	0.000
Angioedema (-183, -1)	57	0.1%	53	0.1%	0.010	0.003
Angioedema (ever, -1)	*571*	*1.4%*	*448*	*1.1%*	*0.293*	*0.027*
Diabetes	19,570	46.6%	19,715	46.9%	-0.345	-0.007
Ischemic heart disease	31,758	75.6%	31,645	75.3%	0.269	0.006
Renal disorders	18,574	44.2%	18,577	44.2%	-0.007	-0.000
Serious allergies	5,684	13.5%	5,702	13.6%	-0.043	-0.001

Table 1b. Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Adjusted, Aggregated), Fixed Ratio 1:1, Caliper: 0.05

Characteristic[1,2]	Medical Product				Covariate Balance	
	SV (14-day gap)		ACEI (14-day gap)		Absolute Difference	Standardized Difference
	Number	Percent	Number	Percent		
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	33,728	80.3%	33,786	80.4%	-0.138	-0.003
Everolimus	12	0.0%	13	0.0%	-0.002	-0.001
Nonsteroidal anti-inflammatory drugs (NSAIDs)	4,213	10.0%	4,192	10.0%	0.050	0.002
Sirolimus	*****	*****	*****	*****	0.000	0.000
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	18.2	17.0	18.2	21.5	-0.011	-0.001
Mean number of emergency room encounters	0.6	1.3	0.6	1.1	0.002	0.002
Mean number of inpatient hospital encounters	0.8	1.1	0.8	0.9	0.002	0.002
Mean number of non-acute institutional encounters	0.3	0.9	0.3	0.8	-0.001	-0.002
Mean number of other ambulatory encounters	9.2	14.1	9.2	12.8	-0.024	-0.002
Mean number of filled prescriptions	*26.5*	*20.5*	*26.7*	*22.3*	*-0.208*	*-0.010*
Mean number of generics	*11.6*	*5.4*	*11.7*	*5.5*	*-0.035*	*-0.006*
Mean number of unique drug classes	11.0	4.9	11.0	4.9	0.014	0.003

[1]Covariates in italics were not included in the propensity score logistic regression model

[2]Covariates in blue show a standardized difference greater than 0.1

[3]The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1c. Weighted Baseline Characteristics of Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Propensity Score (PS) Stratified, Aggregated), Percentiles: 10

	Medical Product				Covariate Balance	
	SV (14-day gap)		ACEI (14-day gap)			
Characteristic[1,2,3]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	41,998	100.0%	695,012	100.0%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age, years	72.3	12.2	72.7	12.5	-0.418	-0.034
Age	**Number**	**Percent**	**Number**	**Percent**		
18-44 years	*1,456*	*3.5%*	*21,633*	*3.1%*	*0.355*	*0.020*
45-54 years	*2,752*	*6.6%*	*45,109*	*6.5%*	*0.062*	*0.003*
55-64 years	*5,690*	*13.5%*	*97,451*	*14.0%*	*-0.473*	*-0.014*
≥65 years	*32,100*	*76.4%*	*530,819*	*76.4%*	*0.057*	*0.001*
Sex						
Female	19,800	47.1%	336,959	48.5%	-1.338	-0.027
Male	22,198	52.9%	358,053	51.5%	1.338	0.027
Race						
American Indian or Alaska Native	235	0.6%	4,407	0.6%	-0.075	-0.010
Asian	489	1.2%	7,914	1.1%	0.025	0.002
Black or African American	5,426	12.9%	92,228	13.3%	-0.351	-0.010
Native Hawaiian or Other Pacific Islander	34	0.1%	744	0.1%	-0.026	-0.009
Unknown	7,013	16.7%	99,598	14.3%	2.369	0.110
White	28,802	68.6%	490,120	70.5%	-1.941	-0.050
Hispanic Origin	*703*	*1.7%*	*15,517*	*2.2%*	*-0.558*	*-0.040*
Year						
2015	4,956	11.8%	82,533	11.9%	-0.074	-0.002
2016	9,386	22.3%	166,944	24.0%	-1.672	-0.040
2017	9,299	22.1%	156,252	22.5%	-0.339	-0.008
2018	9,003	21.4%	146,432	21.1%	0.368	0.009
2019	9,192	21.9%	140,943	20.3%	1.607	0.039
2020	162	2.8%	1,909	2.6%	0.199	0.012
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[4]	5.9	3.1	5.8	3.0	0.103	0.034
	Number	**Percent**	**Number**	**Percent**		
Ambulatory allergies or allergy treatment	*20,161*	*48.0%*	*321,762*	*46.3%*	*1.709*	*0.034*
Ambulatory allergies or treatment and not serious allergies	15,900	37.9%	254,456	36.6%	1.246	0.026
Angioedema (-183, -1)	56	0.1%	866	0.1%	0.008	0.002
Angioedema (ever, -1)	*532*	*1.3%*	*7,325*	*1.1%*	*0.214*	*0.020*
Diabetes	19,849	47.3%	326,148	46.9%	0.334	0.007
Ischemic heart disease	27,212	64.8%	438,289	63.1%	1.731	0.036
Renal disorders	18,387	43.8%	290,929	41.9%	1.921	0.039
Serious allergies	6,765	16.1%	110,244	15.9%	0.245	0.007

Table 1c. Weighted Baseline Characteristics of Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Propensity Score (PS) Stratified, Aggregated), Percentiles: 10

	Medical Product				Covariate Balance	
	SV (14-day gap)		ACEI (14-day gap)			
Characteristic[1,2,3]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	29,007	69.1%	463,884	66.7%	2.322	0.050
Everolimus	*****	*****	184	0.0%	-0.008	-0.005
Nonsteroidal anti-inflammatory drugs (NSAIDs)	5,321	12.7%	87,959	12.7%	0.013	0.000
Sirolimus	16	0.0%	205	0.0%	0.008	0.004
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	18.6	16.7	17.4	19.8	1.218	0.067
Mean number of emergency room encounters	1.0	2.9	0.8	1.8	0.181	0.076
Mean number of inpatient hospital encounters	1.1	1.7	1.0	1.1	0.121	0.084
Mean number of non-acute institutional encounters	0.4	1.2	0.4	1.0	0.022	0.019
Mean number of other ambulatory encounters	13.2	20.4	12.6	17.8	0.598	0.031
Mean number of filled prescriptions	*27.6*	*22.1*	*26.9*	*23.0*	*0.685*	*0.030*
Mean number of generics	*11.7*	*5.9*	*11.5*	*5.7*	*0.223*	*0.039*
Mean number of unique drug classes	11.0	5.3	10.8	5.0	0.256	0.050

[1]Covariates in italics were not included in the propensity score logistic regression model

[2]Covariates in blue show a standardized difference greater than 0.1

[3]Weighted patient characteristics tables facilitate the assessment of covariate balance after PS stratification. Treated/control patients are weighted by the proportion of the total patient population included in their PS stratum
divided by the proportion of the total treated/control patient population included in their PS stratum.

[4]The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

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Table 1d. Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Unadjusted, Aggregated)

	Medical Product				Covariate Balance	
	SV (14-day gap)		ARBs (14-day gap)			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	43,777	100.0%	337,157	100.0%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age, years	71.5	11.9	73.8	12.0	-2.285	-0.191
Age	**Number**	**Percent**	**Number**	**Percent**		
18-44 years	*1,634*	*3.7%*	*8,500*	*2.5%*	*1.211*	*0.070*
45-54 years	*3,068*	*7.0%*	*18,297*	*5.4%*	*1.581*	*0.066*
55-64 years	*6,120*	*14.0%*	*40,556*	*12.0%*	*1.951*	*0.058*
≥65 years	*32,955*	*75.3%*	*269,804*	*80.0%*	*-4.744*	*-0.114*
Sex						
Female	15,466	35.3%	187,905	55.7%	-20.403	-0.419
Male	28,311	64.7%	149,252	44.3%	20.403	0.419
Race						
American Indian or Alaska Native	143	0.3%	1,947	0.6%	-0.251	-0.037
Asian	511	1.2%	7,817	2.3%	-1.151	-0.088
Black or African American	5,853	13.4%	55,815	16.6%	-3.185	-0.089
Native Hawaiian or Other Pacific Islander	46	0.1%	478	0.1%	-0.037	-0.010
Unknown	7,289	16.7%	47,812	14.2%	2.469	0.068
White	29,935	68.4%	223,288	66.2%	2.154	0.046
Hispanic Origin	*751*	*1.7%*	*9,038*	*2.7%*	*-0.965*	*-0.066*
Year						
2015	430	1.0%	32,231	9.6%	-8.577	-0.391
2016	4,168	9.5%	70,705	21.0%	-11.450	-0.323
2017	9,173	21.0%	73,808	21.9%	-0.937	-0.023
2018	12,488	28.5%	81,684	24.2%	4.299	0.098
2019	17,167	39.2%	77,624	23.0%	16.192	0.355
2020	351	5.9%	1,105	3.2%	2.670	0.128
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[3]	5.6	2.8	5.8	3.0	-0.171	-0.059
	Number	**Percent**	**Number**	**Percent**		
Ambulatory allergies or allergy treatment	*21,349*	*48.8%*	*169,542*	*50.3%*	*-1.518*	*-0.030*
Ambulatory allergies or treatment and not serious allergies	17,590	40.2%	134,478	39.9%	0.295	0.006
Angioedema (-183, -1)	60	0.1%	825	0.2%	-0.108	-0.025
Angioedema (ever, -1)	*599*	*1.4%*	*7,359*	*2.2%*	*-0.814*	*-0.062*
Diabetes	20,372	46.5%	173,558	51.5%	-4.941	-0.099
Ischemic heart disease	33,124	75.7%	203,999	60.5%	15.160	0.330
Renal disorders	19,390	44.3%	154,663	45.9%	-1.580	-0.032
Serious allergies	5,930	13.5%	54,432	16.1%	-2.598	-0.073

Table 1d. Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Unadjusted, Aggregated)

Characteristic[1,2]	Medical Product				Covariate Balance	
	SV (14-day gap)		ARBs (14-day gap)			
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	35,208	80.4%	222,934	66.1%	14.304	0.328
Everolimus	12	0.0%	98	0.0%	-0.002	-0.001
Nonsteroidal anti-inflammatory drugs (NSAIDs)	4,405	10.1%	44,187	13.1%	-3.043	-0.095
Sirolimus	*****	*****	142	0.0%	-0.022	-0.012
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	18.2	17.1	20.4	22.5	-2.205	-0.110
Mean number of emergency room encounters	0.7	1.4	0.8	1.7	-0.114	-0.075
Mean number of inpatient hospital encounters	0.8	1.1	0.8	1.1	-0.047	-0.042
Mean number of non-acute institutional encounters	0.3	0.9	0.4	1.0	-0.112	-0.116
Mean number of other ambulatory encounters	9.2	14.0	11.7	17.4	-2.490	-0.157
Mean number of filled prescriptions	*26.6*	*20.7*	*27.8*	*22.3*	*-1.120*	*-0.052*
Mean number of generics	*11.6*	*5.5*	*12.0*	*5.8*	*-0.342*	*-0.061*
Mean number of unique drug classes	11.0	4.9	11.2	5.1	-0.221	-0.044

[1]Covariates in italics were not included in the propensity score logistic regression model

[2]Covariates in blue show a standardized difference greater than 0.1

[3]The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

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Table 1e. Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Adjusted, Aggregated), Fixed Ratio 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	SV (14-day gap)		ARBs (14-day gap)			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	43,755	99.9%	43,755	13.0%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age, years	71.5	11.9	71.6	11.9	-0.033	-0.003
Age	**Number**	**Percent**	**Number**	**Percent**		
18-44 years	*1,623*	*3.7%*	*1,517*	*3.5%*	*0.242*	*0.013*
45-54 years	*3,059*	*7.0%*	*3,067*	*7.0%*	*-0.018*	*-0.001*
55-64 years	*6,118*	*14.0%*	*6,380*	*14.6%*	*-0.599*	*-0.018*
≥65 years	*32,955*	*75.3%*	*32,791*	*74.9%*	*0.375*	*0.009*
Sex						
Female	15,466	35.3%	15,554	35.5%	-0.201	-0.004
Male	28,289	64.7%	28,201	64.5%	0.201	0.004
Race						
American Indian or Alaska Native	143	0.3%	155	0.4%	-0.027	-0.005
Asian	511	1.2%	506	1.2%	0.011	0.001
Black or African American	5,852	13.4%	5,880	13.4%	-0.064	-0.002
Native Hawaiian or Other Pacific Islander	46	0.1%	35	0.1%	0.025	0.008
Unknown	7,271	16.6%	7,265	16.6%	0.014	0.001
White	29,932	68.4%	29,914	68.4%	0.041	0.001
Hispanic Origin	*751*	*1.7%*	*833*	*1.9%*	*-0.187*	*-0.014*
Year						
2015	430	1.0%	400	0.9%	0.069	0.007
2016	4,168	9.5%	4,044	9.2%	0.283	0.010
2017	9,173	21.0%	9,222	21.1%	-0.112	-0.003
2018	12,486	28.5%	12,664	28.9%	-0.407	-0.009
2019	17,148	39.2%	17,038	38.9%	0.251	0.005
2020	350	5.9%	387	6.5%	-0.625	-0.026
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[3]	5.6	2.8	5.6	2.9	-0.030	-0.011
	Number	**Percent**	**Number**	**Percent**		
Ambulatory allergies or allergy treatment	*21,340*	*48.8%*	*21,523*	*49.2%*	*-0.418*	*-0.008*
Ambulatory allergies or treatment and not serious allergies	17,582	40.2%	17,679	40.4%	-0.222	-0.005
Angioedema (-183, -1)	60	0.1%	58	0.1%	0.005	0.001
Angioedema (ever, -1)	*598*	*1.4%*	*916*	*2.1%*	*-0.727*	*-0.056*
Diabetes	20,371	46.6%	20,282	46.4%	0.203	0.004
Ischemic heart disease	33,103	75.7%	33,062	75.6%	0.094	0.002
Renal disorders	19,388	44.3%	19,531	44.6%	-0.327	-0.007
Serious allergies	5,928	13.5%	5,967	13.6%	-0.089	-0.003

Table 1e. Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Adjusted, Aggregated), Fixed Ratio 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	SV (14-day gap)		ARBs (14-day gap)			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	35,186	80.4%	35,179	80.4%	0.016	0.000
Everolimus	12	0.0%	16	0.0%	-0.009	-0.005
Nonsteroidal anti-inflammatory drugs (NSAIDs)	4,405	10.1%	4,394	10.0%	0.025	0.001
Sirolimus	*****	*****	*****	*****	0.000	0.000
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	18.2	17.1	18.3	19.0	-0.087	-0.005
Mean number of emergency room encounters	0.7	1.4	0.7	1.3	0.007	0.005
Mean number of inpatient hospital encounters	0.8	1.1	0.8	1.1	-0.015	-0.014
Mean number of non-acute institutional encounters	0.3	0.9	0.3	0.9	-0.008	-0.010
Mean number of other ambulatory encounters	9.2	14.0	9.4	13.8	-0.153	-0.011
Mean number of filled prescriptions	*26.6*	*20.7*	*26.2*	*20.5*	*0.441*	*0.021*
Mean number of generics	*11.6*	*5.5*	*11.7*	*5.5*	*-0.085*	*-0.016*
Mean number of unique drug classes	11.0	4.9	11.0	4.8	-0.025	-0.005

[1]Covariates in italics were not included in the propensity score logistic regression model

[2]Covariates in blue show a standardized difference greater than 0.1

[3]The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

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Table 1f. Weighted Baseline Characteristics of Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Propensity Score (PS) Stratified, Aggregated), Percentiles: 10

	Medical Product				Covariate Balance	
	SV (14-day gap)		ARBs (14-day gap)			
Characteristic[1,2,3]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	43,777	100.0%	337,157	100.0%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age, years	73.2	12.0	73.6	12.0	-0.382	-0.032
Age	**Number**	**Percent**	**Number**	**Percent**		
18-44 years	*1,249*	*2.9%*	*8,753*	*2.6%*	*0.258*	*0.016*
45-54 years	*2,559*	*5.8%*	*18,681*	*5.5%*	*0.306*	*0.013*
55-64 years	*5,585*	*12.8%*	*41,057*	*12.2%*	*0.579*	*0.018*
≥65 years	*34,384*	*78.5%*	*268,666*	*79.7%*	*-1.143*	*-0.030*
Sex						
Female	22,862	52.2%	180,403	53.5%	-1.282	-0.026
Male	20,915	47.8%	156,754	46.5%	1.282	0.026
Race						
American Indian or Alaska Native	201	0.5%	1,862	0.6%	-0.092	-0.013
Asian	887	2.0%	7,405	2.2%	-0.170	-0.012
Black or African American	6,822	15.6%	54,823	16.3%	-0.677	-0.019
Native Hawaiian or Other Pacific Islander	46	0.1%	466	0.1%	-0.032	-0.009
Unknown	7,504	17.1%	47,484	14.1%	3.058	0.134
White	28,316	64.7%	225,116	66.8%	-2.086	-0.050
Hispanic Origin	*944*	*2.2%*	*8,771*	*2.6%*	*-0.446*	*-0.029*
Year						
2015	3,661	8.4%	28,920	8.6%	-0.214	-0.008
2016	8,426	19.2%	66,279	19.7%	-0.410	-0.010
2017	9,453	21.6%	73,686	21.9%	-0.262	-0.006
2018	10,758	24.6%	83,656	24.8%	-0.237	-0.005
2019	11,261	25.7%	83,387	24.7%	0.991	0.023
2020	217	3.7%	1,230	3.6%	0.054	0.003
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[4]	5.7	2.9	5.8	3.0	-0.010	-0.003
	Number	**Percent**	**Number**	**Percent**		
Ambulatory allergies or allergy treatment	*22,289*	*50.9%*	*169,231*	*50.2%*	*0.722*	*0.014*
Ambulatory allergies or treatment and not serious allergies	17,968	41.0%	134,696	40.0%	1.093	0.022
Angioedema (-183, -1)	134	0.3%	784	0.2%	0.074	0.014
Angioedema (ever, -1)	*675*	*1.5%*	*7,308*	*2.2%*	*-0.626*	*-0.046*
Diabetes	21,885	50.0%	172,051	51.0%	-1.037	-0.021
Ischemic heart disease	27,492	62.8%	209,958	62.3%	0.526	0.011
Renal disorders	20,094	45.9%	154,462	45.8%	0.088	0.002
Serious allergies	6,724	15.4%	53,664	15.9%	-0.556	-0.015

Table 1f. Weighted Baseline Characteristics of Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Propensity Score (PS) Stratified, Aggregated), Percentiles: 10

	Medical Product				Covariate Balance	
	SV (14-day gap)		ARBs (14-day gap)			
Characteristic[1,2,3]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	30,349	69.3%	228,471	67.8%	1.563	0.034
Everolimus	*****	*****	97	0.0%	-0.009	-0.006
Nonsteroidal anti-inflammatory drugs (NSAIDs)	5,657	12.9%	43,061	12.8%	0.151	0.005
Sirolimus	12	0.0%	133	0.0%	-0.012	-0.006
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	20.2	20.3	20.2	22.2	0.017	0.001
Mean number of emergency room encounters	0.8	1.9	0.8	1.6	0.029	0.016
Mean number of inpatient hospital encounters	0.8	1.2	0.8	1.1	-0.007	-0.006
Mean number of non-acute institutional encounters	0.4	1.1	0.4	1.0	-0.005	-0.004
Mean number of other ambulatory encounters	11.2	17.6	11.5	17.1	-0.317	-0.018
Mean number of filled prescriptions	*28.6*	*22.8*	*27.6*	*22.2*	*0.984*	*0.044*
Mean number of generics	*12.0*	*5.8*	*12.0*	*5.8*	*0.043*	*0.007*
Mean number of unique drug classes	11.3	5.2	11.2	5.1	0.106	0.020

[1]Covariates in italics were not included in the propensity score logistic regression model

[2]Covariates in blue show a standardized difference greater than 0.1

[3]Weighted patient characteristics tables facilitate the assessment of covariate balance after PS stratification. Treated/control patients are weighted by the proportion of the total patient population included in their PS stratum
divided by the proportion of the total treated/control patient population included in their PS stratum.

[4]The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

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Table 1g. Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 7-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Unadjusted, Aggregated), Fixed Ratio 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	SV (7-day gap)		ACEI (7-day gap)			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	41,998	100.0%	695,012	100.0%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age, years	71.6	11.8	72.7	12.5	-1.108	-0.091
Age	**Number**	**Percent**	**Number**	**Percent**		
18-44 years	*1,538*	*3.7%*	*21,594*	*3.1%*	*0.555*	*0.031*
45-54 years	*2,863*	*6.8%*	*45,064*	*6.5%*	*0.333*	*0.013*
55-64 years	*5,807*	*13.8%*	*97,267*	*14.0%*	*-0.168*	*-0.005*
≥65 years	*31,790*	*75.7%*	*531,087*	*76.4%*	*-0.720*	*-0.017*
Sex						
Female)	14,867	35.4%	341,886	49.2%	-13.792	-0.282
Male	27,131	64.6%	353,126	50.8%	13.792	0.282
Race						
American Indian or Alaska Native	132	0.3%	4,529	0.7%	-0.337	-0.049
Asian	519	1.2%	7,874	1.1%	0.103	0.010
Black or African American	5,566	13.3%	92,129	13.3%	-0.003	-0.000
Native Hawaiian or Other Pacific Islander	46	0.1%	741	0.1%	0.003	0.001
Unknown	7,029	16.7%	99,645	14.3%	2.399	0.066
White	28,706	68.4%	490,094	70.5%	-2.165	-0.047
Hispanic Origin	*708*	*1.7%*	*15,586*	*2.2%*	*-0.557*	*-0.040*
Year						
2015	430	1.0%	87,092	12.5%	-11.507	-0.470
2016	4,087	9.7%	172,883	24.9%	-15.143	-0.409
2017	8,846	21.1%	156,612	22.5%	-1.471	-0.036
2018	11,912	28.4%	143,025	20.6%	7.784	0.182
2019	16,392	39.0%	133,649	19.2%	19.801	0.447
2020	331	5.8%	1,751	2.4%	3.366	0.170
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[3]	5.6	2.8	5.8	3.0	-0.259	-0.089
	Number	**Percent**	**Number**	**Percent**		
Ambulatory allergies or allergy treatment	*20,540*	*48.9%*	*320,744*	*46.1%*	*2.758*	*0.055*
Ambulatory allergies or treatment and not serious allergies	16,919	40.3%	253,012	36.4%	3.881	0.080
Angioedema (-183, -1)	57	0.1%	864	0.1%	0.011	0.003
Angioedema (ever, -1)	*571*	*1.4%*	*7,320*	*1.1%*	*0.306*	*0.028*
Diabetes	19,570	46.6%	326,116	46.9%	-0.325	-0.007
Ischemic heart disease	31,758	75.6%	433,085	62.3%	13.305	0.291
Renal disorders	18,574	44.2%	289,803	41.7%	2.528	0.051
Serious allergies	5,684	13.5%	110,980	16.0%	-2.434	-0.069

Table 1g. Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 7-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Unadjusted, Aggregated), Fixed Ratio 1:1, Caliper: 0.05

Characteristic[1,2]	Medical Product				Covariate Balance	
	SV (7-day gap)		ACEI (7-day gap)			
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	33,728	80.3%	458,232	65.9%	14.377	0.329
Everolimus	12	0.0%	183	0.0%	0.002	0.001
Nonsteroidal anti-inflammatory drugs (NSAIDs)	4,213	10.0%	88,980	12.8%	-2.771	-0.087
Sirolimus	*****	*****	208	0.0%	-0.006	-0.004
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	18.2	17.0	17.3	19.7	0.886	0.048
Mean number of emergency room encounters	0.6	1.3	0.9	1.8	-0.205	-0.129
Mean number of inpatient hospital encounters	0.8	1.1	1.0	1.2	-0.212	-0.190
Mean number of non-acute institutional encounters	0.3	0.9	0.4	1.1	-0.163	-0.168
Mean number of other ambulatory encounters	9.2	14.1	12.8	18.0	-3.641	-0.226
Mean number of filled prescriptions	*26.5*	*20.5*	*26.9*	*23.0*	*-0.349*	*-0.016*
Mean number of generics	*11.6*	*5.4*	*11.5*	*5.7*	*0.106*	*0.019*
Mean number of unique drug classes	11.0	4.9	10.8	5.0	0.195	0.039

[1]Covariates in italics were not included in the propensity score logistic regression model

[2]Covariates in blue show a standardized difference greater than 0.1

[3]The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

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Table 1h. Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 7-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Adjusted, Aggregated), Fixed Ratio 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	SV (7-day gap)		ACEI (7-day gap)			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	41,998	100.0%	41,998	6.0%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age, years	71.6	11.8	71.6	12.1	0.033	0.003
Age	**Number**	**Percent**	**Number**	**Percent**		
18-44 years	*1,538*	*3.7%*	*1,462*	*3.5%*	*0.181*	*0.010*
45-54 years	*2,863*	*6.8%*	*2,925*	*7.0%*	*-0.148*	*-0.006*
55-64 years	*5,807*	*13.8%*	*6,460*	*15.4%*	*-1.555*	*-0.045*
≥65 years	*31,790*	*75.7%*	*31,151*	*74.2%*	*1.522*	*0.038*
Sex						
Female	14,867	35.4%	15,072	35.9%	-0.488	-0.010
Male	27,131	64.6%	26,926	64.1%	0.488	0.010
Race						
American Indian or Alaska Native	132	0.3%	132	0.3%	0.000	0.000
Asian	519	1.2%	536	1.3%	-0.040	-0.004
Black or African American	5,566	13.3%	5,557	13.2%	0.021	0.001
Native Hawaiian or Other Pacific Islander	46	0.1%	41	0.1%	0.012	0.004
Unknown	7,029	16.7%	7,058	16.8%	-0.069	-0.003
White	28,706	68.4%	28,674	68.3%	0.076	0.002
Hispanic Origin	*708*	*1.7%*	*843*	*2.0%*	*-0.321*	*-0.024*
Year						
2015	430	1.0%	378	0.9%	0.124	0.013
2016	4,087	9.7%	4,104	9.8%	-0.040	-0.001
2017	8,846	21.1%	8,931	21.3%	-0.202	-0.005
2018	11,912	28.4%	11,867	28.3%	0.107	0.002
2019	16,392	39.0%	16,366	39.0%	0.062	0.001
2020	331	5.8%	352	6.1%	-0.367	-0.016
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[3]	5.6	2.8	5.6	2.8	0.006	0.002
	Number	**Percent**	**Number**	**Percent**		
Ambulatory allergies or allergy treatment	*20,540*	*48.9%*	*20,437*	*48.7%*	*0.245*	*0.005*
Ambulatory allergies or treatment and not serious allergies	16,919	40.3%	16,914	40.3%	0.012	0.000
Angioedema (-183, -1)	57	0.1%	53	0.1%	0.010	0.003
Angioedema (ever, -1)	*571*	*1.4%*	*448*	*1.1%*	*0.293*	*0.027*
Diabetes	19,570	46.6%	19,715	46.9%	-0.345	-0.007
Ischemic heart disease	31,758	75.6%	31,645	75.3%	0.269	0.006
Renal disorders	18,574	44.2%	18,577	44.2%	-0.007	-0.000
Serious allergies	5,684	13.5%	5,702	13.6%	-0.043	-0.001

Table 1h. Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 7-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Adjusted, Aggregated), Fixed Ratio 1:1, Caliper: 0.05

Characteristic[1,2]	Medical Product				Covariate Balance	
	SV (7-day gap)		ACEI (7-day gap)			
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	33,728	80.3%	33,786	80.4%	-0.138	-0.003
Everolimus	12	0.0%	13	0.0%	-0.002	-0.001
Nonsteroidal anti-inflammatory drugs (NSAIDs)	4,213	10.0%	4,192	10.0%	0.050	0.002
Sirolimus	*****	*****	*****	*****	0.000	0.000
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	18.2	17.0	18.2	21.5	-0.011	-0.001
Mean number of emergency room encounters	0.6	1.3	0.6	1.1	0.002	0.002
Mean number of inpatient hospital encounters	0.8	1.1	0.8	0.9	0.002	0.002
Mean number of non-acute institutional encounters	0.3	0.9	0.3	0.8	-0.001	-0.002
Mean number of other ambulatory encounters	9.2	14.1	9.2	12.8	-0.024	-0.002
Mean number of filled prescriptions	*26.5*	*20.5*	*26.7*	*22.3*	*-0.208*	*-0.010*
Mean number of generics	*11.6*	*5.4*	*11.7*	*5.5*	*-0.035*	*-0.006*
Mean number of unique drug classes	11.0	4.9	11.0	4.9	0.014	0.003

[1]Covariates in italics were not included in the propensity score logistic regression model

[2]Covariates in blue show a standardized difference greater than 0.1

[3]The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

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Table 1i. Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 7-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Unadjusted, Aggregated), Fixed Ratio 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	SV (7-day gap)		ARBs (7-day gap)			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	43,777	100.0%	337,157	100.0%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age, years	71.5	11.9	73.8	12.0	-2.285	-0.191
Age	**Number**	**Percent**	**Number**	**Percent**		
18-44 years	*1,634*	*3.7%*	*8,500*	*2.5%*	*1.211*	*0.070*
45-54 years	*3,068*	*7.0%*	*18,297*	*5.4%*	*1.581*	*0.066*
55-64 years	*6,120*	*14.0%*	*40,556*	*12.0%*	*1.951*	*0.058*
≥65 years	*32,955*	*75.3%*	*269,804*	*80.0%*	*-4.744*	*-0.114*
Sex						
Female	15,466	35.3%	187,905	55.7%	-20.403	-0.419
Male	28,311	64.7%	149,252	44.3%	20.403	0.419
Race						
American Indian or Alaska Native	143	0.3%	1,947	0.6%	-0.251	-0.037
Asian	511	1.2%	7,817	2.3%	-1.151	-0.088
Black or African American	5,853	13.4%	55,815	16.6%	-3.185	-0.089
Native Hawaiian or Other Pacific Islander	46	0.1%	478	0.1%	-0.037	-0.010
Unknown	7,289	16.7%	47,812	14.2%	2.469	0.068
White	29,935	68.4%	223,288	66.2%	2.154	0.046
Hispanic Origin	*751*	*1.7%*	*9,038*	*2.7%*	*-0.965*	*-0.066*
Year						
2015	430	1.0%	32,231	9.6%	-8.577	-0.391
2016	4,168	9.5%	70,705	21.0%	-11.450	-0.323
2017	9,173	21.0%	73,808	21.9%	-0.937	-0.023
2018	12,488	28.5%	81,684	24.2%	4.299	0.098
2019	17,167	39.2%	77,624	23.0%	16.192	0.355
2020	351	5.9%	1,105	3.2%	2.670	0.128
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[3]	5.6	2.8	5.8	3.0	-0.171	-0.059
	Number	**Percent**	**Number**	**Percent**		
Ambulatory allergies or allergy treatment	*21,349*	*48.8%*	*169,542*	*50.3%*	*-1.518*	*-0.030*
Ambulatory allergies or treatment and not serious allergies	17,590	40.2%	134,478	39.9%	0.295	0.006
Angioedema (-183, -1)	60	0.1%	825	0.2%	-0.108	-0.025
Angioedema (ever, -1)	*599*	*1.4%*	*7,359*	*2.2%*	*-0.814*	*-0.062*
Diabetes	20,372	46.5%	173,558	51.5%	-4.941	-0.099
Ischemic heart disease	33,124	75.7%	203,999	60.5%	15.160	0.330
Renal disorders	19,390	44.3%	154,663	45.9%	-1.580	-0.032
Serious allergies	5,930	13.5%	54,432	16.1%	-2.598	-0.073

Table 1i. Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 7-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Unadjusted, Aggregated), Fixed Ratio 1:1, Caliper: 0.05

Characteristic[1,2]	Medical Product				Covariate Balance	
	SV (7-day gap)		ARBs (7-day gap)			
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	35,208	80.4%	222,934	66.1%	14.304	0.328
Everolimus	12	0.0%	98	0.0%	-0.002	-0.001
Nonsteroidal anti-inflammatory drugs (NSAIDs)	4,405	10.1%	44,187	13.1%	-3.043	-0.095
Sirolimus	*****	*****	142	0.0%	-0.022	-0.012
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	18.2	17.1	20.4	22.5	-2.205	-0.110
Mean number of emergency room encounters	0.7	1.4	0.8	1.7	-0.114	-0.075
Mean number of inpatient hospital encounters	0.8	1.1	0.8	1.1	-0.047	-0.042
Mean number of non-acute institutional encounters	0.3	0.9	0.4	1.0	-0.112	-0.116
Mean number of other ambulatory encounters	9.2	14.0	11.7	17.4	-2.490	-0.157
Mean number of filled prescriptions	*26.6*	*20.7*	*27.8*	*22.3*	*-1.120*	*-0.052*
Mean number of generics	*11.6*	*5.5*	*12.0*	*5.8*	*-0.342*	*-0.061*
Mean number of unique drug classes	11.0	4.9	11.2	5.1	-0.221	-0.044

[1]Covariates in italics were not included in the propensity score logistic regression model

[2]Covariates in blue show a standardized difference greater than 0.1

[3]The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

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Table 1j. Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 7-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Adjusted, Aggregated), Fixed Ratio 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	SV (7-day gap)		ARBs (7-day gap)			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	43,755	99.9%	43,755	13.0%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age, years	71.5	11.9	71.6	11.9	-0.033	-0.003
Age	**Number**	**Percent**	**Number**	**Percent**		
18-44 years	*1,623*	*3.7%*	*1,517*	*3.5%*	*0.242*	*0.013*
45-54 years	*3,059*	*7.0%*	*3,067*	*7.0%*	*-0.018*	*-0.001*
55-64 years	*6,118*	*14.0%*	*6,380*	*14.6%*	*-0.599*	*-0.018*
≥65 years	*32,955*	*75.3%*	*32,791*	*74.9%*	*0.375*	*0.009*
Sex						
Female	15,466	35.3%	15,554	35.5%	-0.201	-0.004
Male	28,289	64.7%	28,201	64.5%	0.201	0.004
Race						
American Indian or Alaska Native	143	0.3%	155	0.4%	-0.027	-0.005
Asian	511	1.2%	506	1.2%	0.011	0.001
Black or African American	5,852	13.4%	5,880	13.4%	-0.064	-0.002
Native Hawaiian or Other Pacific Islander	46	0.1%	35	0.1%	0.025	0.008
Unknown	7,271	16.6%	7,265	16.6%	0.014	0.001
White	29,932	68.4%	29,914	68.4%	0.041	0.001
Hispanic Origin	*751*	*1.7%*	*833*	*1.9%*	*-0.187*	*-0.014*
Year						
2015	430	1.0%	400	0.9%	0.069	0.007
2016	4,168	9.5%	4,044	9.2%	0.283	0.010
2017	9,173	21.0%	9,222	21.1%	-0.112	-0.003
2018	12,486	28.5%	12,664	28.9%	-0.407	-0.009
2019	17,148	39.2%	17,038	38.9%	0.251	0.005
2020	350	5.9%	387	6.5%	-0.625	-0.026
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[3]	5.6	2.8	5.6	2.9	-0.030	-0.011
	Number	**Percent**	**Number**	**Percent**		
Ambulatory allergies or allergy treatment	*21,340*	*48.8%*	*21,523*	*49.2%*	*-0.418*	*-0.008*
Ambulatory allergies or treatment and not serious allergies	17,582	40.2%	17,679	40.4%	-0.222	-0.005
Angioedema (-183, -1)	60	0.1%	58	0.1%	0.005	0.001
Angioedema (ever, -1)	*598*	*1.4%*	*916*	*2.1%*	*-0.727*	*-0.056*
Diabetes	20,371	46.6%	20,282	46.4%	0.203	0.004
Ischemic heart disease	33,103	75.7%	33,062	75.6%	0.094	0.002
Renal disorders	19,388	44.3%	19,531	44.6%	-0.327	-0.007
Serious allergies	5,928	13.5%	5,967	13.6%	-0.089	-0.003

Table 1j. Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 7-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Adjusted, Aggregated), Fixed Ratio 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	SV (7-day gap)		ARBs (7-day gap)			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	35,186	80.4%	35,179	80.4%	0.016	0.000
Everolimus	12	0.0%	16	0.0%	-0.009	-0.005
Nonsteroidal anti-inflammatory drugs (NSAIDs)	4,405	10.1%	4,394	10.0%	0.025	0.001
Sirolimus	*****	*****	*****	*****	0.000	0.000
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	18.2	17.1	18.3	19.0	-0.087	-0.005
Mean number of emergency room encounters	0.7	1.4	0.7	1.3	0.007	0.005
Mean number of inpatient hospital encounters	0.8	1.1	0.8	1.1	-0.015	-0.014
Mean number of non-acute institutional encounters	0.3	0.9	0.3	0.9	-0.008	-0.010
Mean number of other ambulatory encounters	9.2	14.0	9.4	13.8	-0.153	-0.011
Mean number of filled prescriptions	*26.6*	*20.7*	*26.2*	*20.5*	*0.441*	*0.021*
Mean number of generics	*11.6*	*5.5*	*11.7*	*5.5*	*-0.085*	*-0.016*
Mean number of unique drug classes	11.0	4.9	11.0	4.8	-0.025	-0.005

[1]Covariates in italics were not included in the propensity score logistic regression model

[2]Covariates in blue show a standardized difference greater than 0.1

[3]The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 2. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Site-Adjusted Analysis											
SV	41,998	*****	*****	*****	*****	1.33	*****	-5.4	*****	0.19 (0.12, 0.29)	<0.001
ACEI	695,012	*****	*****	*****	*****	6.73	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	41,998	*****	*****	*****	*****	1.59	*****	-9.07	*****	0.15 (0.08, 0.26)	<0.001
ACEI	41,998	*****	*****	*****	*****	10.66	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	41,998	*****	*****	*****	*****	1.33	*****	-5.84	*****	0.18 (0.11, 0.29)	<0.001
ACEI	41,998	*****	*****	*****	*****	7.17	*****				
Propensity Score Adjusted Stratified Analysis; Percentiles= 10[1]											
SV	41,998	*****	*****	*****	*****	1.33	*****	-5.4	*****	0.18 (0.12, 0.29)	<0.001
ACEI	695,012	*****	*****	*****	*****	6.73	*****				

[1]Conditional analysis accounts for informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 3. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	41,998	*****	*****	*****	*****	1.33	*****	-5.4	*****	0.19 (0.12, 0.29)	<0.001
ACEI (14-day gap)	695,012	*****	*****	*****	*****	6.73	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	41,998	*****	*****	*****	*****	1.59	*****	-9.07	*****	0.15 (0.08, 0.26)	<0.001
ACEI (14-day gap)	41,998	*****	*****	*****	*****	10.66	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	41,998	*****	*****	*****	*****	1.33	*****	-5.84	*****	0.18 (0.11, 0.29)	<0.001
ACEI (14-day gap)	41,998	*****	*****	*****	*****	7.17	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	41,998	*****	*****	*****	*****	0.9	*****	-14.43	*****	0.06 (0.02, 0.18)	<0.001
ACEI (14-day gap)	695,012	*****	*****	*****	*****	15.33	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	41,998	*****	*****	*****	*****	0.94	*****	-17.83	*****	0.05 (0.02, 0.16)	<0.001
ACEI (14-day gap)	41,998	*****	*****	*****	*****	18.76	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	41,998	*****	*****	*****	*****	0.9	*****	-17.22	*****	0.05 (0.02, 0.16)	<0.001
ACEI (14-day gap)	41,998	*****	*****	*****	*****	18.12	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	38,241	*****	*****	*****	*****	1.55	*****	-4.49	*****	0.26 (0.10, 0.69)	0.007
ACEI (14-day gap)	638,495	*****	*****	*****	*****	6.05	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	34,662	*****	*****	*****	*****	1.95	*****	-3.89	*****	0.33 (0.11, 1.03)	0.057
ACEI (14-day gap)	34,662	*****	*****	*****	*****	5.84	*****				

Table 3. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	38,241	*****	*****	*****	*****	1.55	*****	-3.29	*****	0.32 (0.10, 0.98)	0.047
ACEI (14-day gap)	38,053	*****	*****	*****	*****	4.84	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	25,273	*****	*****	*****	*****	2.11	*****	-3.67	*****	0.37 (0.14, 0.99)	0.047
ACEI (14-day gap)	463,109	*****	*****	*****	*****	5.78	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	16,757	*****	*****	*****	*****	3.4	*****	-0.85	*****	0.80 (0.21, 2.98)	0.739
ACEI (14-day gap)	16,757	*****	*****	*****	*****	4.25	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	25,273	*****	*****	*****	*****	2.11	*****	-3.05	*****	0.41 (0.13, 1.29)	0.128
ACEI (14-day gap)	27,895	*****	*****	*****	*****	5.16	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	20,547	*****	*****	*****	*****	1.66	*****	-2.73	*****	0.38 (0.17, 0.85)	0.019
ACEI (14-day gap)	397,838	*****	*****	*****	*****	4.39	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	11,738	*****	*****	*****	*****	1.94	*****	-5.18	*****	0.27 (0.08, 0.98)	0.046
ACEI (14-day gap)	11,738	*****	*****	*****	*****	7.12	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	20,547	*****	*****	*****	*****	1.66	*****	-2.81	*****	0.37 (0.15, 0.92)	0.033
ACEI (14-day gap)	23,945	*****	*****	*****	*****	4.47	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	11,098	*****	*****	*****	*****	0.93	*****	-3.19	*****	0.23 (0.06, 0.91)	0.037
ACEI (14-day gap)	235,612	*****	*****	*****	*****	4.12	*****				

Table 3. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	3,606	*****	*****	*****	*****	0	*****	-6.97	*****	-	-
ACEI (14-day gap)	3,606	*****	*****	*****	*****	6.97	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	11,098	*****	*****	*****	*****	0.93	*****	-4.34	*****	0.18 (0.04, 0.80)	0.024
ACEI (14-day gap)	13,550	*****	*****	*****	*****	5.28	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	6,937	*****	*****	*****	*****	0.68	*****	-2.87	*****	0.19 (0.03, 1.33)	0.094
ACEI (14-day gap)	164,817	*****	*****	*****	*****	3.54	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,512	*****	*****	*****	*****	0	*****	-7.46	*****	-	-
ACEI (14-day gap)	1,512	*****	*****	*****	*****	7.46	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	6,937	*****	*****	*****	*****	0.68	*****	-1.48	*****	0.33 (0.04, 2.97)	0.323
ACEI (14-day gap)	8,796	*****	*****	*****	*****	2.16	*****				

[1]Conditional analysis accounts for informative events and person-time.

[2]Data presented by a dash are unable to be calculated. This table may not use all data representations.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 4. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1)

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No Angioedema (-183, -1)											
Site-Adjusted Analysis											
SV	41,941	*****	*****	*****	*****	1.07	*****	-5.41	*****	0.15 (0.09, 0.25)	<0.001
ACEI	694,148	*****	*****	*****	*****	6.47	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	41,930	*****	*****	*****	*****	1.14	*****	-9.43	*****	0.11 (0.06, 0.21)	<0.001
ACEI	41,930	*****	*****	*****	*****	10.56	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	41,930	*****	*****	*****	*****	1.07	*****	-5.99	*****	0.15 (0.09, 0.24)	<0.001
ACEI	41,930	*****	*****	*****	*****	7.06	*****				
Angioedema (-183, -1)											
Site-Adjusted Analysis											
SV	57	*****	*****	*****	*****	193.8	*****	-74.4	*****	0.75 (0.27, 2.07)	0.584
ACEI	864	*****	*****	*****	*****	268.2	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	42	*****	*****	*****	*****	355.03	*****	118.34	*****	1.50 (0.25, 8.98)	0.657
ACEI	42	*****	*****	*****	*****	236.69	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	42	*****	*****	*****	*****	195.82	*****	81.21	*****	1.97 (0.33, 11.91)	0.46
ACEI	42	*****	*****	*****	*****	114.61	*****				

[1]Conditional analysis accounts for informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 5. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1) and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
No Angioedema (-183, -1)											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	41,941	*****	*****	*****	*****	1.07	*****	-5.41	*****	0.15 (0.09, 0.25)	<0.001
ACEI (14-day gap)	694,148	*****	*****	*****	*****	6.47	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	41,930	*****	*****	*****	*****	1.14	*****	-9.43	*****	0.11 (0.06, 0.21)	<0.001
ACEI (14-day gap)	41,930	*****	*****	*****	*****	10.56	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	41,930	*****	*****	*****	*****	1.07	*****	-5.99	*****	0.15 (0.09, 0.24)	<0.001
ACEI (14-day gap)	41,930	*****	*****	*****	*****	7.06	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	41,941	*****	*****	*****	*****	0.3	*****	-14.16	*****	0.02 (0.00, 0.15)	<0.001
ACEI (14-day gap)	694,148	*****	*****	*****	*****	14.46	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	41,930	*****	*****	*****	*****	0.31	*****	-18.17	*****	0.02 (0.00, 0.12)	<0.001
ACEI (14-day gap)	41,930	*****	*****	*****	*****	18.48	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	41,930	*****	*****	*****	*****	0.3	*****	-17.55	*****	0.02 (0.00, 0.12)	<0.001
ACEI (14-day gap)	41,930	*****	*****	*****	*****	17.85	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	38,191	*****	*****	*****	*****	1.55	*****	-4.19	*****	0.27 (0.10, 0.73)	0.01
ACEI (14-day gap)	637,749	*****	*****	*****	*****	5.74	*****				

Table 5. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1) and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	34,610	*****	*****	*****	*****	1.95	*****	-3.9	*****	0.33 (0.11, 1.03)	0.057
ACEI (14-day gap)	34,610	*****	*****	*****	*****	5.84	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	38,182	*****	*****	*****	*****	1.55	*****	-3.3	*****	0.32 (0.10, 0.98)	0.047
ACEI (14-day gap)	37,993	*****	*****	*****	*****	4.85	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	25,238	*****	*****	*****	*****	1.58	*****	-4.06	*****	0.28 (0.09, 0.88)	0.03
ACEI (14-day gap)	462,621	*****	*****	*****	*****	5.65	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	16,735	*****	*****	*****	*****	2.55	*****	-1.7	*****	0.60 (0.14, 2.51)	0.484
ACEI (14-day gap)	16,735	*****	*****	*****	*****	4.25	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	25,233	*****	*****	*****	*****	1.58	*****	-3.58	*****	0.31 (0.09, 1.10)	0.07
ACEI (14-day gap)	27,852	*****	*****	*****	*****	5.16	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	20,519	*****	*****	*****	*****	1.39	*****	-2.94	*****	0.32 (0.13, 0.78)	0.012
ACEI (14-day gap)	397,439	*****	*****	*****	*****	4.32	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	11,721	*****	*****	*****	*****	1.3	*****	-5.84	*****	0.18 (0.04, 0.82)	0.027
ACEI (14-day gap)	11,721	*****	*****	*****	*****	7.13	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	20,515	*****	*****	*****	*****	1.39	*****	-3.09	*****	0.31 (0.11, 0.82)	0.018
ACEI (14-day gap)	23,905	*****	*****	*****	*****	4.48	*****				

Table 5. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1) and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	11,083	*****	*****	*****	*****	0.93	*****	-3.15	*****	0.23 (0.06, 0.92)	0.038
ACEI (14-day gap)	235,412	*****	*****	*****	*****	4.08	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	3,599	*****	*****	*****	*****	0	*****	-6.98	*****	-	-
ACEI (14-day gap)	3,599	*****	*****	*****	*****	6.98	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	11,082	*****	*****	*****	*****	0.93	*****	-3.97	*****	0.20 (0.04, 0.87)	0.032
ACEI (14-day gap)	13,529	*****	*****	*****	*****	4.91	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	6,928	*****	*****	*****	*****	0.68	*****	-2.78	*****	0.19 (0.03, 1.36)	0.099
ACEI (14-day gap)	164,674	*****	*****	*****	*****	3.46	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,509	*****	*****	*****	*****	0	*****	-7.45	*****	-	-
ACEI (14-day gap)	1,509	*****	*****	*****	*****	7.45	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	6,927	*****	*****	*****	*****	0.68	*****	-1.49	*****	0.33 (0.04, 2.97)	0.323
ACEI (14-day gap)	8,783	*****	*****	*****	*****	2.17	*****				
Angioedema (-183, -1)											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	57	*****	*****	*****	*****	193.8	*****	-74.4	*****	0.75 (0.27, 2.07)	0.584
ACEI (14-day gap)	864	*****	*****	*****	*****	268.2	*****				

Table 5. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1) and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	42	*****	*****	*****	*****	355.03	*****	118.34	*****	1.50 (0.25, 8.98)	0.657
ACEI (14-day gap)	42	*****	*****	*****	*****	236.69	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	42	*****	*****	*****	*****	195.82	*****	81.21	*****	1.97 (0.33, 11.91)	0.46
ACEI (14-day gap)	42	*****	*****	*****	*****	114.61	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	453	*****	*****	*****	*****	301.66	*****	-146.73	*****	0.57 (0.14, 2.34)	0.432
ACEI (14-day gap)	8,744	*****	*****	*****	*****	448.39	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	630	*****	*****	*****	*****	40	*****	0	*****	1.00 (0.06, 15.99)	1
ACEI (14-day gap)	630	*****	*****	*****	*****	40	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	4,023	*****	*****	*****	*****	6.84	*****	1.71	*****	1.04 (0.07, 16.67)	0.976
ACEI (14-day gap)	5,300	*****	*****	*****	*****	5.12	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	50	*****	*****	*****	*****	0	*****	-276.46	*****	-	-
ACEI (14-day gap)	749	*****	*****	*****	*****	276.46	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	95	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	95	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	371	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	536	*****	*****	*****	*****	0	*****				

Table 5. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1) and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	35	*****	*****	*****	*****	387.6	*****	253.22	*****	3.57 (0.42, 30.57)	0.245
ACEI (14-day gap)	497	*****	*****	*****	*****	134.37	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	91	*****	*****	*****	*****	162.07	*****	162.07	*****	-	-
ACEI (14-day gap)	91	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	360	*****	*****	*****	*****	34.19	*****	34.19	*****	-	-
ACEI (14-day gap)	524	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	28	*****	*****	*****	*****	190.84	*****	117.12	*****	2.92 (0.33, 25.76)	0.335
ACEI (14-day gap)	408	*****	*****	*****	*****	73.72	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	70	*****	*****	*****	*****	242.13	*****	242.13	*****	-	-
ACEI (14-day gap)	70	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	352	*****	*****	*****	*****	63.49	*****	63.49	*****	-	-
ACEI (14-day gap)	521	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	18	*****	*****	*****	*****	0	*****	-48.23	*****	-	-
ACEI (14-day gap)	202	*****	*****	*****	*****	48.23	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	*****	*****	*****	*****	*****	0	*****	-662.25	*****	-	-
ACEI (14-day gap)	*****	*****	*****	*****	*****	662.25	*****				

Table 5. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1) and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	14	*****	*****	*****	*****	0	*****	-306.75	*****	-	-
ACEI (14-day gap)	15	*****	*****	*****	*****	306.75	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	12	*****	*****	*****	*****	0	*****	-94.4	*****	-	-
ACEI (14-day gap)	145	*****	*****	*****	*****	94.4	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	11	*****	*****	*****	*****	0	*****				

[1]Conditional analysis accounts for informative events and person-time.

[2]Data presented by a dash are unable to be calculated. This table may not use all data representations.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 6. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (ever, -1)

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No Angioedema (ever, -1)											
Site-Adjusted Analysis											
SV	41,427	*****	*****	*****	*****	1.01	*****	-4.86	*****	0.16 (0.10, 0.27)	<0.001
ACEI	687,692	*****	*****	*****	*****	5.87	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	41,416	*****	*****	*****	*****	1.04	*****	-8.4	*****	0.11 (0.06, 0.22)	<0.001
ACEI	41,416	*****	*****	*****	*****	9.43	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	41,416	*****	*****	*****	*****	1.01	*****	-5.41	*****	0.15 (0.09, 0.26)	<0.001
ACEI	41,416	*****	*****	*****	*****	6.43	*****				
Angioedema (ever, -1)											
Site-Adjusted Analysis											
SV	571	*****	*****	*****	*****	24.05	*****	-73.01	*****	0.24 (0.10, 0.59)	0.002
ACEI	7,320	*****	*****	*****	*****	97.06	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	437	*****	*****	*****	*****	47.03	*****	-58.79	*****	0.44 (0.14, 1.44)	0.177
ACEI	437	*****	*****	*****	*****	105.82	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	437	*****	*****	*****	*****	31.92	*****	-50.6	*****	0.38 (0.14, 1.07)	0.067
ACEI	437	*****	*****	*****	*****	82.51	*****				

[1]Conditional analysis accounts for informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 7. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Serious Allergies

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No Serious Allergies											
Site-Adjusted Analysis											
SV	36,314	*****	*****	*****	*****	1.14	*****	-5.33	*****	0.17 (0.10, 0.27)	<0.001
ACEI	584,032	*****	*****	*****	*****	6.47	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	36,159	*****	*****	*****	*****	1.42	*****	-8.91	*****	0.14 (0.07, 0.26)	<0.001
ACEI	36,159	*****	*****	*****	*****	10.34	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	36,159	*****	*****	*****	*****	1.14	*****	-5.77	*****	0.16 (0.09, 0.27)	<0.001
ACEI	36,159	*****	*****	*****	*****	6.92	*****				
Serious Allergies											
Site-Adjusted Analysis											
SV	5,684	*****	*****	*****	*****	2.67	*****	-5.62	*****	0.31 (0.13, 0.75)	0.009
ACEI	110,980	*****	*****	*****	*****	8.29	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	5,545	*****	*****	*****	*****	1.92	*****	-8.65	*****	0.18 (0.04, 0.82)	0.027
ACEI	5,545	*****	*****	*****	*****	10.58	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	5,545	*****	*****	*****	*****	2.73	*****	-6.64	*****	0.29 (0.11, 0.79)	0.015
ACEI	5,545	*****	*****	*****	*****	9.37	*****				

[1]Conditional analysis accounts for informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 8. Effect Estimates for Risk of Angioedema Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI) 14-Day Gap in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Sex and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Sex: Male											
Overall											
Site-Adjusted Analysis											
SV (14-Day Gap)	27,131	*****	*****	*****	*****	0.93	*****	-5.05	*****	0.14 (0.07, 0.28)	<0.001
ACEI (14-Day Gap)	353,126	*****	*****	*****	*****	5.98	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	26,865	*****	*****	*****	*****	1.23	*****	-9.13	*****	0.12 (0.05, 0.26)	<0.001
ACEI (14-Day Gap)	26,865	*****	*****	*****	*****	10.36	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	26,865	*****	*****	*****	*****	0.94	*****	-6.13	*****	0.13 (0.06, 0.25)	<0.001
ACEI (14-Day Gap)	26,865	*****	*****	*****	*****	7.06	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	27,131	*****	*****	*****	*****	0.46	*****	-14.14	*****	0.03 (0.00, 0.23)	<0.001
ACEI (14-Day Gap)	353,126	*****	*****	*****	*****	14.6	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	26,865	*****	*****	*****	*****	0.49	*****	-20.49	*****	0.02 (0.00, 0.17)	<0.001
ACEI (14-Day Gap)	26,865	*****	*****	*****	*****	20.97	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	26,865	*****	*****	*****	*****	0.47	*****	-19.81	*****	0.02 (0.00, 0.17)	<0.001
ACEI (14-Day Gap)	26,865	*****	*****	*****	*****	20.28	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	24,802	*****	*****	*****	*****	1.8	*****	-3.8	*****	0.32 (0.10, 1.01)	0.052
ACEI (14-Day Gap)	325,651	*****	*****	*****	*****	5.59	*****				

Table 8. Effect Estimates for Risk of Angioedema Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI) 14-Day Gap in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Sex and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	22,346	*****	*****	*****	*****	2.26	*****	-1.51	*****	0.60 (0.14, 2.51)	0.484
ACEI (14-Day Gap)	22,346	*****	*****	*****	*****	3.76	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	24,557	*****	*****	*****	*****	1.81	*****	-2.24	*****	0.45 (0.12, 1.72)	0.241
ACEI (14-Day Gap)	24,423	*****	*****	*****	*****	4.05	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	16,352	*****	*****	*****	*****	0.81	*****	-3.92	*****	0.17 (0.02, 1.25)	0.082
ACEI (14-Day Gap)	236,828	*****	*****	*****	*****	4.74	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	10,859	*****	*****	*****	*****	1.31	*****	-3.92	*****	0.25 (0.03, 2.24)	0.215
ACEI (14-Day Gap)	10,859	*****	*****	*****	*****	5.23	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	16,184	*****	*****	*****	*****	0.82	*****	-5.7	*****	0.13 (0.02, 1.00)	0.05
ACEI (14-Day Gap)	18,020	*****	*****	*****	*****	6.52	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	13,315	*****	*****	*****	*****	0.86	*****	-2.64	*****	0.25 (0.06, 1.00)	0.05
ACEI (14-Day Gap)	203,967	*****	*****	*****	*****	3.5	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	7,652	*****	*****	*****	*****	2.01	*****	0	*****	1.00 (0.14, 7.10)	1
ACEI (14-Day Gap)	7,652	*****	*****	*****	*****	2.01	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	13,180	*****	*****	*****	*****	0.87	*****	-2.05	*****	0.30 (0.06, 1.39)	0.123
ACEI (14-Day Gap)	15,521	*****	*****	*****	*****	2.92	*****				
181 - 270 Days											
Site-Adjusted Analysis											

Table 8. Effect Estimates for Risk of Angioedema Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI) 14-Day Gap in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Sex and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
SV (14-Day Gap)	7,179	*****	*****	*****	*****	0.72	*****	-2.68	*****	0.21 (0.03, 1.51)	0.121
ACEI (14-Day Gap)	120,304	*****	*****	*****	*****	3.4	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	2,354	*****	*****	*****	*****	0	*****	-10.56	*****	-	-
ACEI (14-Day Gap)	2,354	*****	*****	*****	*****	10.56	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	7,102	*****	*****	*****	*****	0.73	*****	-4.48	*****	0.14 (0.02, 1.14)	0.067
ACEI (14-Day Gap)	8,784	*****	*****	*****	*****	5.21	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	4,493	*****	*****	*****	*****	1.06	*****	-1.85	*****	0.35 (0.05, 2.52)	0.295
ACEI (14-Day Gap)	84,166	*****	*****	*****	*****	2.91	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	1,015	*****	*****	*****	*****	0	*****	-5.59	*****	-	-
ACEI (14-Day Gap)	1,015	*****	*****	*****	*****	5.59	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	4,445	*****	*****	*****	*****	1.07	*****	0.23	*****	1.32 (0.08, 21.08)	0.845
ACEI (14-Day Gap)	5,717	*****	*****	*****	*****	0.83	*****				
Sex: Female											
Overall											
Site-Adjusted Analysis											
SV (14-Day Gap)	14,867	*****	*****	*****	*****	2.07	*****	-5.45	*****	0.26 (0.14, 0.47)	<0.001
ACEI (14-Day Gap)	341,886	*****	*****	*****	*****	7.52	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	14,820	*****	*****	*****	*****	1.62	*****	-8.42	*****	0.16 (0.06, 0.41)	<0.001
ACEI (14-Day Gap)	14,820	*****	*****	*****	*****	10.04	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	14,820	*****	*****	*****	*****	2.07	*****	-5.25	*****	0.28 (0.14, 0.54)	<0.001

Table 8. Effect Estimates for Risk of Angioedema Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI) 14-Day Gap in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Sex and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
ACEI (14-Day Gap)	14,820	*****	*****	*****	*****	7.32	*****	[illegible]		[illegible]	[illegible]
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	14,867	*****	*****	*****	*****	1.7	*****	-14.39	*****	0.11 (0.03, 0.42)	0.001
ACEI (14-Day Gap)	341,886	*****	*****	*****	*****	16.09	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	14,820	*****	*****	*****	*****	0.89	*****	-14.23	*****	0.06 (0.01, 0.44)	0.006
ACEI (14-Day Gap)	14,820	*****	*****	*****	*****	15.12	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	14,820	*****	*****	*****	*****	1.71	*****	-12.86	*****	0.12 (0.03, 0.51)	0.004
ACEI (14-Day Gap)	14,820	*****	*****	*****	*****	14.57	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	13,439	*****	*****	*****	*****	1.1	*****	-5.42	*****	0.17 (0.02, 1.22)	0.078
ACEI (14-Day Gap)	312,844	*****	*****	*****	*****	6.52	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	12,080	*****	*****	*****	*****	0	*****	-6.99	*****	-	-
ACEI (14-Day Gap)	12,080	*****	*****	*****	*****	6.99	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	13,397	*****	*****	*****	*****	1.1	*****	-5.29	*****	0.17 (0.02, 1.45)	0.106
ACEI (14-Day Gap)	13,360	*****	*****	*****	*****	6.4	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	8,921	*****	*****	*****	*****	4.49	*****	-2.39	*****	0.65 (0.21, 2.03)	0.456
ACEI (14-Day Gap)	226,281	*****	*****	*****	*****	6.88	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	5,806	*****	*****	*****	*****	7.38	*****	4.92	*****	3.00 (0.31, 28.84)	0.341
ACEI (14-Day Gap)	5,806	*****	*****	*****	*****	2.46	*****				

Table 8. Effect Estimates for Risk of Angioedema Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI) 14-Day Gap in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Sex and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	8,894	*****	*****	*****	*****	4.5	*****	1.79	*****	1.69 (0.28, 10.10)	0.567
ACEI (14-Day Gap)	9,686	*****	*****	*****	*****	2.71	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	7,232	*****	*****	*****	*****	3.12	*****	-2.19	*****	0.58 (0.21, 1.55)	0.277
ACEI (14-Day Gap)	193,871	*****	*****	*****	*****	5.31	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	4,049	*****	*****	*****	*****	0	*****	-12.91	*****	-	-
ACEI (14-Day Gap)	4,049	*****	*****	*****	*****	12.91	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	7,208	*****	*****	*****	*****	3.13	*****	-4.31	*****	0.42 (0.13, 1.31)	0.134
ACEI (14-Day Gap)	8,263	*****	*****	*****	*****	7.45	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	3,919	*****	*****	*****	*****	1.32	*****	-3.54	*****	0.28 (0.04, 1.97)	0.199
ACEI (14-Day Gap)	115,308	*****	*****	*****	*****	4.86	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	1,256	*****	*****	*****	*****	4.98	*****	0	*****	1.00 (0.06, 15.99)	1
ACEI (14-Day Gap)	1,256	*****	*****	*****	*****	4.98	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	3,911	*****	*****	*****	*****	1.32	*****	-3.06	*****	0.31 (0.03, 2.74)	0.289
ACEI (14-Day Gap)	4,690	*****	*****	*****	*****	4.38	*****				

Table 8. Effect Estimates for Risk of Angioedema Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI) 14-Day Gap in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Sex and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	2,444	*****	*****	*****	*****	0	*****	-4.21	*****	-	-
ACEI (14-Day Gap)	80,651	*****	*****	*****	*****	4.21	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	538	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-Day Gap)	538	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	2,441	*****	*****	*****	*****	0	*****	-4.69	*****	-	-
ACEI (14-Day Gap)	3,036	*****	*****	*****	*****	4.69	*****				

[1]Conditional analysis accounts for informative events and person-time.

[2]Data presented by a dash are unable to be calculated. This table may not use all data representations.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 9. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Age Group

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Age Group: 18-44 years											
Site-Adjusted Analysis											
SV	1,538	*****	*****	*****	*****	1.95	*****	-7.2	*****	0.23 (0.03, 1.65)	0.143
ACEI	21,594	*****	*****	*****	*****	9.15	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	1,408	*****	*****	*****	*****	3.99	*****	0	*****	1.00 (0.06, 15.99)	1
ACEI	1,408	*****	*****	*****	*****	3.99	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	1,408	*****	*****	*****	*****	2.11	*****	-2.13	*****	0.53 (0.05, 5.85)	0.601
ACEI	1,408	*****	*****	*****	*****	4.24	*****				
Age Group: 45-54 years											
Site-Adjusted Analysis											
SV	2,863	*****	*****	*****	*****	1.01	*****	-9.27	*****	0.10 (0.01, 0.69)	0.02
ACEI	45,064	*****	*****	*****	*****	10.28	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	2,789	*****	*****	*****	*****	0	*****	-20.26	*****	-	-
ACEI	2,789	*****	*****	*****	*****	20.26	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	2,789	*****	*****	*****	*****	1.04	*****	-11.43	*****	0.08 (0.01, 0.62)	0.015
ACEI	2,789	*****	*****	*****	*****	12.47	*****				
Age Group: 55-64 years											
Site-Adjusted Analysis											
SV	5,807	*****	*****	*****	*****	1.97	*****	-6.94	*****	0.22 (0.08, 0.59)	0.003
ACEI	97,267	*****	*****	*****	*****	8.91	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	5,692	*****	*****	*****	*****	2.64	*****	-10.55	*****	0.20 (0.06, 0.69)	0.011
ACEI	5,692	*****	*****	*****	*****	13.19	*****				

Table 9. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Age Group

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	5,692	*****	*****	*****	*****	2.01	*****	-7.62	*****	0.21 (0.07, 0.62)	0.004
ACEI	5,692	*****	*****	*****	*****	9.63	*****				
Age Group: ≥65 years											
Site-Adjusted Analysis											
SV	31,790	*****	*****	*****	*****	1.22	*****	-4.81	*****	0.19 (0.11, 0.32)	<0.001
ACEI	531,087	*****	*****	*****	*****	6.03	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	31,082	*****	*****	*****	*****	1.5	*****	-8.09	*****	0.16 (0.08, 0.30)	<0.001
ACEI	31,082	*****	*****	*****	*****	9.59	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	31,082	*****	*****	*****	*****	1.24	*****	-5.16	*****	0.18 (0.10, 0.33)	<0.001
ACEI	31,082	*****	*****	*****	*****	6.4	*****				

[1]Conditional analysis accounts for informative events and person-time.

[2]Data presented by a dash are unable to be calculated. This table may not use all data representations.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 10. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Age Group: 18-44											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	1,538	*****	*****	*****	*****	1.95	*****	-7.2	*****	0.23 (0.03, 1.65)	0.143
ACEI (14-day gap)	21,594	*****	*****	*****	*****	9.15	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,408	*****	*****	*****	*****	3.99	*****	0	*****	1.00 (0.06, 15.99)	1
ACEI (14-day gap)	1,408	*****	*****	*****	*****	3.99	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	1,408	*****	*****	*****	*****	2.11	*****	-2.13	*****	0.53 (0.05, 5.85)	0.601
ACEI (14-day gap)	1,408	*****	*****	*****	*****	4.24	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	1,538	*****	*****	*****	*****	0	*****	-18.03	*****	-	-
ACEI (14-day gap)	21,594	*****	*****	*****	*****	18.03	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,396	*****	*****	*****	*****	0	*****	-9.47	*****	-	-
ACEI (14-day gap)	1,396	*****	*****	*****	*****	9.47	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	1,406	*****	*****	*****	*****	0	*****	-9.06	*****	-	-
ACEI (14-day gap)	1,469	*****	*****	*****	*****	9.06	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	1,414	*****	*****	*****	*****	0	*****	-8.33	*****	-	-
ACEI (14-day gap)	20,001	*****	*****	*****	*****	8.33	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,158	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	1,158	*****	*****	*****	*****	0	*****				

Table 10. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	1,293	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	1,256	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	891	*****	*****	*****	*****	0	*****	-7.41	*****	-	-
ACEI (14-day gap)	12,616	*****	*****	*****	*****	7.41	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	485	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	485	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	824	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	817	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	673	*****	*****	*****	*****	8.49	*****	2.65	*****	1.82 (0.23, 14.38)	0.571
ACEI (14-day gap)	10,173	*****	*****	*****	*****	5.84	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	294	*****	*****	*****	*****	28.34	*****	28.34	*****	-	-
ACEI (14-day gap)	294	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	624	*****	*****	*****	*****	9.12	*****	0.13	*****	1.10 (0.07, 17.82)	0.947
ACEI (14-day gap)	659	*****	*****	*****	*****	8.99	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	362	*****	*****	*****	*****	0	*****	-7.89	*****	-	-
ACEI (14-day gap)	5,186	*****	*****	*****	*****	7.89	*****				

Table 10. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	71	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	71	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	338	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	335	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	214	*****	*****	*****	*****	0	*****	-1.38	*****	-	-
ACEI (14-day gap)	3,345	*****	*****	*****	*****	1.38	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	26	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	26	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	205	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	202	*****	*****	*****	*****	0	*****				
Age Group: 45-54											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	2,863	*****	*****	*****	*****	1.01	*****	-9.27	*****	0.10 (0.01, 0.69)	0.02
ACEI (14-day gap)	45,064	*****	*****	*****	*****	10.28	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	2,789	*****	*****	*****	*****	0	*****	-20.26	*****	-	-
ACEI (14-day gap)	2,789	*****	*****	*****	*****	20.26	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	2,789	*****	*****	*****	*****	1.04	*****	-11.43	*****	0.08 (0.01, 0.62)	0.015
ACEI (14-day gap)	2,789	*****	*****	*****	*****	12.47	*****				

Table 10. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	2,863	*****	*****	*****	*****	0	*****	-23.69	*****	-	-
ACEI (14-day gap)	45,064	*****	*****	*****	*****	23.69	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	2,789	*****	*****	*****	*****	0	*****	-28.18	*****	-	-
ACEI (14-day gap)	2,789	*****	*****	*****	*****	28.18	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	2,789	*****	*****	*****	*****	0	*****	-27.3	*****	-	-
ACEI (14-day gap)	2,789	*****	*****	*****	*****	27.3	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	2,623	*****	*****	*****	*****	0	*****	-9.2	*****	-	-
ACEI (14-day gap)	41,772	*****	*****	*****	*****	9.2	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	2,337	*****	*****	*****	*****	0	*****	-22.42	*****	-	-
ACEI (14-day gap)	2,337	*****	*****	*****	*****	22.42	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	2,566	*****	*****	*****	*****	0	*****	-22.88	*****	-	-
ACEI (14-day gap)	2,531	*****	*****	*****	*****	22.88	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	1,674	*****	*****	*****	*****	0	*****	-9.51	*****	-	-
ACEI (14-day gap)	27,866	*****	*****	*****	*****	9.51	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,024	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	1,024	*****	*****	*****	*****	0	*****				

Table 10. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	1,630	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	1,771	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	1,324	*****	*****	*****	*****	0	*****	-5.25	*****	-	-
ACEI (14-day gap)	22,994	*****	*****	*****	*****	5.25	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	663	*****	*****	*****	*****	0	*****	-11.49	*****	-	-
ACEI (14-day gap)	663	*****	*****	*****	*****	11.49	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	1,291	*****	*****	*****	*****	0	*****	-7.87	*****	-	-
ACEI (14-day gap)	1,459	*****	*****	*****	*****	7.87	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	706	*****	*****	*****	*****	7.31	*****	2.89	*****	1.82 (0.23, 14.29)	0.569
ACEI (14-day gap)	12,537	*****	*****	*****	*****	4.42	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	194	*****	*****	*****	*****	0	*****	-32.92	*****	-	-
ACEI (14-day gap)	194	*****	*****	*****	*****	32.92	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	691	*****	*****	*****	*****	7.46	*****	1	*****	1.18 (0.07, 19.00)	0.906
ACEI (14-day gap)	789	*****	*****	*****	*****	6.45	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	449	*****	*****	*****	*****	0	*****	-5.47	*****	-	-
ACEI (14-day gap)	8,412	*****	*****	*****	*****	5.47	*****				

Table 10. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	82	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	82	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	444	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	514	*****	*****	*****	*****	0	*****				
Age Group: 55-64											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	5,807	*****	*****	*****	*****	1.97	*****	-6.94	*****	0.22 (0.08, 0.59)	0.003
ACEI (14-day gap)	97,267	*****	*****	*****	*****	8.91	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	5,692	*****	*****	*****	*****	2.64	*****	-10.55	*****	0.20 (0.06, 0.69)	0.011
ACEI (14-day gap)	5,692	*****	*****	*****	*****	13.19	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	5,692	*****	*****	*****	*****	2.01	*****	-7.62	*****	0.21 (0.07, 0.62)	0.004
ACEI (14-day gap)	5,692	*****	*****	*****	*****	9.63	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	5,807	*****	*****	*****	*****	2.18	*****	-15.01	*****	0.13 (0.02, 0.92)	0.041
ACEI (14-day gap)	97,267	*****	*****	*****	*****	17.19	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	5,692	*****	*****	*****	*****	2.31	*****	-20.8	*****	0.10 (0.01, 0.78)	0.028
ACEI (14-day gap)	5,692	*****	*****	*****	*****	23.11	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	5,692	*****	*****	*****	*****	2.22	*****	-20.05	*****	0.10 (0.01, 0.78)	0.028
ACEI (14-day gap)	5,692	*****	*****	*****	*****	22.27	*****				

Table 10. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	5,279	*****	*****	*****	*****	0	*****	-7.74	*****	-	-
ACEI (14-day gap)	89,870	*****	*****	*****	*****	7.74	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	4,725	*****	*****	*****	*****	0	*****	-7.29	*****	-	-
ACEI (14-day gap)	4,725	*****	*****	*****	*****	7.29	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	5,177	*****	*****	*****	*****	0	*****	-5.54	*****	-	-
ACEI (14-day gap)	5,184	*****	*****	*****	*****	5.54	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	3,449	*****	*****	*****	*****	7.76	*****	0.43	*****	1.16 (0.28, 4.81)	0.843
ACEI (14-day gap)	62,809	*****	*****	*****	*****	7.33	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	2,151	*****	*****	*****	*****	13.46	*****	6.73	*****	2.00 (0.18, 22.06)	0.571
ACEI (14-day gap)	2,151	*****	*****	*****	*****	6.73	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	3,385	*****	*****	*****	*****	7.91	*****	0.79	*****	1.16 (0.16, 8.24)	0.882
ACEI (14-day gap)	3,696	*****	*****	*****	*****	7.12	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	2,776	*****	*****	*****	*****	2.07	*****	-4.32	*****	0.33 (0.05, 2.42)	0.278
ACEI (14-day gap)	52,867	*****	*****	*****	*****	6.39	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,452	*****	*****	*****	*****	0	*****	-10.65	*****	-	-
ACEI (14-day gap)	1,452	*****	*****	*****	*****	10.65	*****				

Table 10. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	2,728	*****	*****	*****	*****	2.11	*****	-3.39	*****	0.39 (0.04, 3.81)	0.422
ACEI (14-day gap)	3,127	*****	*****	*****	*****	5.5	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	1,462	*****	*****	*****	*****	0	*****	-6.55	*****	-	-
ACEI (14-day gap)	29,794	*****	*****	*****	*****	6.55	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	414	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	414	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	1,431	*****	*****	*****	*****	0	*****	-9.19	*****	-	-
ACEI (14-day gap)	1,689	*****	*****	*****	*****	9.19	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	919	*****	*****	*****	*****	0	*****	-6.32	*****	-	-
ACEI (14-day gap)	20,223	*****	*****	*****	*****	6.32	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	173	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	173	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	898	*****	*****	*****	*****	0	*****	-4.57	*****	-	-
ACEI (14-day gap)	1,058	*****	*****	*****	*****	4.57	*****				
Age Group: 65+											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	31,790	*****	*****	*****	*****	1.22	*****	-4.81	*****	0.19 (0.11, 0.32)	<0.001
ACEI (14-day gap)	531,087	*****	*****	*****	*****	6.03	*****				

Table 10. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	31,082	*****	*****	*****	*****	1.5	*****	-8.09	*****	0.16 (0.08, 0.30)	<0.001
ACEI (14-day gap)	31,082	*****	*****	*****	*****	9.59	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	31,082	*****	*****	*****	*****	1.24	*****	-5.16	*****	0.18 (0.10, 0.33)	<0.001
ACEI (14-day gap)	31,082	*****	*****	*****	*****	6.4	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	31,790	*****	*****	*****	*****	0.79	*****	-13.38	*****	0.06 (0.01, 0.22)	<0.001
ACEI (14-day gap)	531,087	*****	*****	*****	*****	14.17	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	30,993	*****	*****	*****	*****	0.84	*****	-16.47	*****	0.05 (0.01, 0.20)	<0.001
ACEI (14-day gap)	30,993	*****	*****	*****	*****	17.32	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	31,034	*****	*****	*****	*****	0.81	*****	-15.92	*****	0.05 (0.01, 0.20)	<0.001
ACEI (14-day gap)	31,041	*****	*****	*****	*****	16.73	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	28,925	*****	*****	*****	*****	2.04	*****	-3.35	*****	0.38 (0.14, 1.02)	0.055
ACEI (14-day gap)	486,852	*****	*****	*****	*****	5.4	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	25,639	*****	*****	*****	*****	2.6	*****	-1.95	*****	0.57 (0.17, 1.95)	0.372
ACEI (14-day gap)	25,639	*****	*****	*****	*****	4.56	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	28,289	*****	*****	*****	*****	2.09	*****	-1.41	*****	0.60 (0.17, 2.04)	0.411
ACEI (14-day gap)	28,148	*****	*****	*****	*****	3.5	*****				

Table 10. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	19,259	*****	*****	*****	*****	1.38	*****	-3.79	*****	0.27 (0.07, 1.08)	0.064
ACEI (14-day gap)	359,818	*****	*****	*****	*****	5.17	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	12,705	*****	*****	*****	*****	2.23	*****	-2.23	*****	0.50 (0.09, 2.73)	0.423
ACEI (14-day gap)	12,705	*****	*****	*****	*****	4.45	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	18,847	*****	*****	*****	*****	1.41	*****	-4.18	*****	0.25 (0.05, 1.16)	0.077
ACEI (14-day gap)	20,968	*****	*****	*****	*****	5.59	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	15,774	*****	*****	*****	*****	1.44	*****	-2.51	*****	0.37 (0.14, 0.99)	0.047
ACEI (14-day gap)	311,804	*****	*****	*****	*****	3.96	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	9,047	*****	*****	*****	*****	1.66	*****	-4.99	*****	0.25 (0.05, 1.18)	0.08
ACEI (14-day gap)	9,047	*****	*****	*****	*****	6.66	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	15,448	*****	*****	*****	*****	1.47	*****	-2.23	*****	0.40 (0.13, 1.23)	0.108
ACEI (14-day gap)	18,166	*****	*****	*****	*****	3.7	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	8,568	*****	*****	*****	*****	0.6	*****	-3.02	*****	0.17 (0.02, 1.20)	0.075
ACEI (14-day gap)	188,096	*****	*****	*****	*****	3.62	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	2,837	*****	*****	*****	*****	0	*****	-6.61	*****	-	-
ACEI (14-day gap)	2,837	*****	*****	*****	*****	6.61	*****				

Table 10. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	8,387	*****	*****	*****	*****	0.62	*****	-4.25	*****	0.13 (0.02, 0.99)	0.049
ACEI (14-day gap)	10,439	*****	*****	*****	*****	4.87	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	5,355	*****	*****	*****	*****	0.87	*****	-2.19	*****	0.29 (0.04, 2.05)	0.212
ACEI (14-day gap)	132,840	*****	*****	*****	*****	3.06	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,212	*****	*****	*****	*****	0	*****	-4.52	*****	-	-
ACEI (14-day gap)	1,212	*****	*****	*****	*****	4.52	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	5,241	*****	*****	*****	*****	0.89	*****	-1.18	*****	0.43 (0.04, 4.15)	0.467
ACEI (14-day gap)	6,850	*****	*****	*****	*****	2.08	*****				

[1]Conditional analysis accounts for informative events and person-time.

[2]Data presented by a dash are unable to be calculated. This table may not use all data representations.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 11. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Race

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Race: Unknown											
Site-Adjusted Analysis											
SV	7,029	*****	*****	*****	*****	0.77	*****	-6	*****	0.11 (0.03, 0.44)	0.002
ACEI	99,645	*****	*****	*****	*****	6.76	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	6,992	*****	*****	*****	*****	0	*****	-8.33	*****	-	-
ACEI	6,992	*****	*****	*****	*****	8.33	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	6,992	*****	*****	*****	*****	0.77	*****	-6.48	*****	0.11 (0.03, 0.47)	0.003
ACEI	6,992	*****	*****	*****	*****	7.25	*****				
Race: American Indian											
Site-Adjusted Analysis											
SV	132	*****	*****	*****	*****	0	*****	-2.38	*****	-	-
ACEI	4,529	*****	*****	*****	*****	2.38	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	123	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI	123	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	123	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI	123	*****	*****	*****	*****	0	*****				
Race: Asian											
Site-Adjusted Analysis											
SV	519	*****	*****	*****	*****	0	*****	-2.63	*****	-	-
ACEI	7,874	*****	*****	*****	*****	2.63	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	495	*****	*****	*****	*****	0	*****	-10.49	*****	-	-
ACEI	495	*****	*****	*****	*****	10.49	*****				

Table 11. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Race

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	495	*****	*****	*****	*****	0	*****	-5.6	*****	-	-
ACEI	495	*****	*****	*****	*****	5.6	*****				
Race: Black											
Site-Adjusted Analysis											
SV	5,566	*****	*****	*****	*****	4.18	*****	-18.39	*****	0.17 (0.08, 0.36)	<0.001
ACEI	92,129	*****	*****	*****	*****	22.57	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	5,479	*****	*****	*****	*****	4.08	*****	-30.58	*****	0.12 (0.04, 0.33)	<0.001
ACEI	5,479	*****	*****	*****	*****	34.66	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	5,479	*****	*****	*****	*****	4.25	*****	-20.53	*****	0.16 (0.07, 0.36)	<0.001
ACEI	5,479	*****	*****	*****	*****	24.79	*****				
Race: Pacific Islander											
Site-Adjusted Analysis											
SV	46	*****	*****	*****	*****	0	*****	-14.36	*****	-	-
ACEI	741	*****	*****	*****	*****	14.36	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	39	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI	39	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	39	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI	39	*****	*****	*****	*****	0	*****				
Race: White											
Site-Adjusted Analysis											
SV	28,706	*****	*****	*****	*****	1.05	*****	-3.29	*****	0.23 (0.13, 0.41)	<0.001
ACEI	490,094	*****	*****	*****	*****	4.34	*****				

Table 11. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Race

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	28,638	*****	*****	*****	*****	1.43	*****	-4.94	*****	0.23 (0.11, 0.46)	<0.001
ACEI	28,638	*****	*****	*****	*****	6.37	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	28,638	*****	*****	*****	*****	1.05	*****	-3.28	*****	0.23 (0.12, 0.44)	<0.001
ACEI	28,638	*****	*****	*****	*****	4.33	*****				

[1]Conditional analysis accounts for informative events and person-time.

[2]Data presented by a dash are unable to be calculated. This table may not use all data representations.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 12. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Race: Unknown											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	7,029	*****	*****	*****	*****	0.77	*****	-6	*****	0.11 (0.03, 0.44)	0.002
ACEI (14-day gap)	99,645	*****	*****	*****	*****	6.76	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	6,992	*****	*****	*****	*****	0	*****	-8.33	*****	-	-
ACEI (14-day gap)	6,992	*****	*****	*****	*****	8.33	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	6,992	*****	*****	*****	*****	0.77	*****	-6.48	*****	0.11 (0.03, 0.47)	0.003
ACEI (14-day gap)	6,992	*****	*****	*****	*****	7.25	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	7,029	*****	*****	*****	*****	0	*****	-15.99	*****	-	-
ACEI (14-day gap)	99,645	*****	*****	*****	*****	15.99	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	6,992	*****	*****	*****	*****	0	*****	-20.99	*****	-	-
ACEI (14-day gap)	6,992	*****	*****	*****	*****	20.99	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	6,992	*****	*****	*****	*****	0	*****	-20.15	*****	-	-
ACEI (14-day gap)	6,992	*****	*****	*****	*****	20.15	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	6,335	*****	*****	*****	*****	0	*****	-5.05	*****	-	-
ACEI (14-day gap)	91,186	*****	*****	*****	*****	5.05	*****				

Table 12. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	5,635	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	5,635	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	6,307	*****	*****	*****	*****	0	*****	-2.31	*****	-	-
ACEI (14-day gap)	6,232	*****	*****	*****	*****	2.31	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	4,314	*****	*****	*****	*****	3.09	*****	-2.23	*****	0.59 (0.08, 4.37)	0.608
ACEI (14-day gap)	64,654	*****	*****	*****	*****	5.32	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	2,742	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	2,742	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	4,296	*****	*****	*****	*****	3.1	*****	0.11	*****	1.06 (0.07, 16.95)	0.967
ACEI (14-day gap)	4,422	*****	*****	*****	*****	3	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	3,500	*****	*****	*****	*****	1.57	*****	-2.93	*****	0.35 (0.05, 2.55)	0.3
ACEI (14-day gap)	53,831	*****	*****	*****	*****	4.5	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,845	*****	*****	*****	*****	0	*****	-3.91	*****	-	-
ACEI (14-day gap)	1,845	*****	*****	*****	*****	3.91	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	3,487	*****	*****	*****	*****	1.57	*****	-4.51	*****	0.26 (0.03, 2.32)	0.227
ACEI (14-day gap)	3,656	*****	*****	*****	*****	6.09	*****				

Table 12. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	1,996	*****	*****	*****	*****	0	*****	-3.81	*****	-	-
ACEI (14-day gap)	31,204	*****	*****	*****	*****	3.81	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	584	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	584	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	1,990	*****	*****	*****	*****	0	*****	-5.12	*****	-	-
ACEI (14-day gap)	2,022	*****	*****	*****	*****	5.12	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	1,269	*****	*****	*****	*****	0	*****	-3.8	*****	-	-
ACEI (14-day gap)	21,471	*****	*****	*****	*****	3.8	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	253	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	253	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	1,264	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	1,259	*****	*****	*****	*****	0	*****				
Race: American Indian											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	132	*****	*****	*****	*****	0	*****	-2.38	*****	-	-
ACEI (14-day gap)	4,529	*****	*****	*****	*****	2.38	*****				

Table 12. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	123	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	123	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	123	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	123	*****	*****	*****	*****	0	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	192	*****	*****	*****	*****	0	*****	-5.35	*****	-	-
ACEI (14-day gap)	5,667	*****	*****	*****	*****	5.35	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	125	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	125	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	193	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	214	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	117	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	4,188	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	101	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	101	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	179	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	204	*****	*****	*****	*****	0	*****				

Table 12. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	73	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	2,743	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	49	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	49	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	72	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	79	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	59	*****	*****	*****	*****	0	*****	-5	*****	-	-
ACEI (14-day gap)	2,256	*****	*****	*****	*****	5	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	33	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	33	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	59	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	65	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	30	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	1,258	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	*****	*****	*****	*****	*****	0	*****				

Table 12. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	31	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	37	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	17	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	838	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	18	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	25	*****	*****	*****	*****	0	*****				
Race: Asian											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	519	*****	*****	*****	*****	0	*****	-2.63	*****	-	-
ACEI (14-day gap)	7,874	*****	*****	*****	*****	2.63	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	495	*****	*****	*****	*****	0	*****	-10.49	*****	-	-
ACEI (14-day gap)	495	*****	*****	*****	*****	10.49	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	495	*****	*****	*****	*****	0	*****	-5.6	*****	-	-
ACEI (14-day gap)	495	*****	*****	*****	*****	5.6	*****				

Table 12. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	519	*****	*****	*****	*****	0	*****	-4.83	*****	-	-
ACEI (14-day gap)	7,874	*****	*****	*****	*****	4.83	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	479	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	479	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	488	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	485	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	479	*****	*****	*****	*****	0	*****	-6.01	*****	-	-
ACEI (14-day gap)	7,151	*****	*****	*****	*****	6.01	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	417	*****	*****	*****	*****	0	*****	-36.79	*****	-	-
ACEI (14-day gap)	417	*****	*****	*****	*****	36.79	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	458	*****	*****	*****	*****	0	*****	-30.83	*****	-	-
ACEI (14-day gap)	449	*****	*****	*****	*****	30.83	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	326	*****	*****	*****	*****	0	*****	-5.15	*****	-	-
ACEI (14-day gap)	5,094	*****	*****	*****	*****	5.15	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	217	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	217	*****	*****	*****	*****	0	*****				

Table 12. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	320	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	327	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	249	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	4,335	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	125	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	125	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	240	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	261	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	131	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	2,369	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	31	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	31	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	127	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	130	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	82	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	1,547	*****	*****	*****	*****	0	*****				

Table 12. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	12	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	12	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	82	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	88	*****	*****	*****	*****	0	*****				
Race: Black											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	5,566	*****	*****	*****	*****	4.18	*****	-18.39	*****	0.17 (0.08, 0.36)	<0.001
ACEI (14-day gap)	92,129	*****	*****	*****	*****	22.57	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	5,479	*****	*****	*****	*****	4.08	*****	-30.58	*****	0.12 (0.04, 0.33)	<0.001
ACEI (14-day gap)	5,479	*****	*****	*****	*****	34.66	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	5,479	*****	*****	*****	*****	4.25	*****	-20.53	*****	0.16 (0.07, 0.36)	<0.001
ACEI (14-day gap)	5,479	*****	*****	*****	*****	24.79	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	5,566	*****	*****	*****	*****	2.27	*****	-46.47	*****	0.05 (0.01, 0.33)	0.002
ACEI (14-day gap)	92,129	*****	*****	*****	*****	48.74	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	5,479	*****	*****	*****	*****	2.39	*****	-59.79	*****	0.04 (0.01, 0.28)	0.001
ACEI (14-day gap)	5,479	*****	*****	*****	*****	62.18	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	5,479	*****	*****	*****	*****	2.3	*****	-57.76	*****	0.04 (0.01, 0.28)	0.001
ACEI (14-day gap)	5,479	*****	*****	*****	*****	60.06	*****				

Table 12. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	5,059	*****	*****	*****	*****	3.08	*****	-14.89	*****	0.17 (0.02, 1.21)	0.076
ACEI (14-day gap)	84,701	*****	*****	*****	*****	17.97	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	4,542	*****	*****	*****	*****	3.95	*****	-15.82	*****	0.20 (0.02, 1.71)	0.142
ACEI (14-day gap)	4,542	*****	*****	*****	*****	19.77	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	4,982	*****	*****	*****	*****	3.13	*****	-11.52	*****	0.22 (0.03, 1.85)	0.161
ACEI (14-day gap)	4,995	*****	*****	*****	*****	14.65	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	2,977	*****	*****	*****	*****	4.58	*****	-14.1	*****	0.25 (0.03, 1.79)	0.167
ACEI (14-day gap)	56,538	*****	*****	*****	*****	18.67	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,834	*****	*****	*****	*****	0	*****	-15.97	*****	-	-
ACEI (14-day gap)	1,834	*****	*****	*****	*****	15.97	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	2,927	*****	*****	*****	*****	4.66	*****	-6.85	*****	0.40 (0.04, 3.85)	0.428
ACEI (14-day gap)	3,425	*****	*****	*****	*****	11.5	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	2,268	*****	*****	*****	*****	5.54	*****	-9.05	*****	0.38 (0.09, 1.54)	0.176
ACEI (14-day gap)	47,224	*****	*****	*****	*****	14.6	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,181	*****	*****	*****	*****	7.74	*****	0	*****	1.00 (0.06, 15.99)	1
ACEI (14-day gap)	1,181	*****	*****	*****	*****	7.74	*****				

Table 12. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	2,231	*****	*****	*****	*****	5.64	*****	-11.42	*****	0.33 (0.07, 1.55)	0.16
ACEI (14-day gap)	2,902	*****	*****	*****	*****	17.06	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	1,029	*****	*****	*****	*****	10.3	*****	-1.85	*****	0.83 (0.20, 3.41)	0.799
ACEI (14-day gap)	24,192	*****	*****	*****	*****	12.15	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	253	*****	*****	*****	*****	25.37	*****	25.37	*****	-	-
ACEI (14-day gap)	253	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	1,012	*****	*****	*****	*****	10.47	*****	-8.6	*****	0.54 (0.10, 2.76)	0.455
ACEI (14-day gap)	1,401	*****	*****	*****	*****	19.06	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	631	*****	*****	*****	*****	0	*****	-11.59	*****	-	-
ACEI (14-day gap)	15,675	*****	*****	*****	*****	11.59	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	106	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	106	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	623	*****	*****	*****	*****	0	*****	-5.85	*****	-	-
ACEI (14-day gap)	831	*****	*****	*****	*****	5.85	*****				

Table 12. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Race: Pacific Islander											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	46	*****	*****	*****	*****	0	*****	-14.36	*****	-	-
ACEI (14-day gap)	741	*****	*****	*****	*****	14.36	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	39	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	39	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	39	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	39	*****	*****	*****	*****	0	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	66	*****	*****	*****	*****	0	*****	-33.11	*****	-	-
ACEI (14-day gap)	1,001	*****	*****	*****	*****	33.11	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	39	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	39	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	63	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	106	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	43	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	652	*****	*****	*****	*****	0	*****				

Table 12. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	32	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	32	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	37	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	32	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	28	*****	*****	*****	*****	0	*****	-26.53	*****	-	-
ACEI (14-day gap)	490	*****	*****	*****	*****	26.53	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	17	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	17	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	25	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	27	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	24	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	424	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	11	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	11	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	21	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	21	*****	*****	*****	*****	0	*****				

Table 12. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	14	*****	*****	*****	*****	0	*****	-24.49	*****	-	-
ACEI (14-day gap)	208	*****	*****	*****	*****	24.49	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	12	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	*****	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	138	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI (14-day gap)	*****	*****	*****	*****	*****	0	*****				
Race: White											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	28,706	*****	*****	*****	*****	1.05	*****	-3.29	*****	0.23 (0.13, 0.41)	<0.001
ACEI (14-day gap)	490,094	*****	*****	*****	*****	4.34	*****				

Table 12. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	28,638	*****	*****	*****	*****	1.43	*****	-4.94	*****	0.23 (0.11, 0.46)	<0.001
ACEI (14-day gap)	28,638	*****	*****	*****	*****	6.37	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	28,638	*****	*****	*****	*****	1.05	*****	-3.28	*****	0.23 (0.12, 0.44)	<0.001
ACEI (14-day gap)	28,638	*****	*****	*****	*****	4.33	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	28,706	*****	*****	*****	*****	0.88	*****	-8.27	*****	0.10 (0.02, 0.39)	<0.001
ACEI (14-day gap)	490,094	*****	*****	*****	*****	9.15	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	28,638	*****	*****	*****	*****	0.91	*****	-9.14	*****	0.09 (0.02, 0.39)	0.001
ACEI (14-day gap)	28,638	*****	*****	*****	*****	10.05	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	28,638	*****	*****	*****	*****	0.88	*****	-8.84	*****	0.09 (0.02, 0.39)	0.001
ACEI (14-day gap)	28,638	*****	*****	*****	*****	9.72	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	26,209	*****	*****	*****	*****	1.69	*****	-2.48	*****	0.41 (0.13, 1.28)	0.125
ACEI (14-day gap)	450,620	*****	*****	*****	*****	4.16	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	23,776	*****	*****	*****	*****	2.1	*****	-1.4	*****	0.60 (0.14, 2.51)	0.484
ACEI (14-day gap)	23,776	*****	*****	*****	*****	3.5	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	26,150	*****	*****	*****	*****	1.69	*****	-1.54	*****	0.52 (0.13, 2.08)	0.357
ACEI (14-day gap)	26,026	*****	*****	*****	*****	3.24	*****				

Table 12. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	17,556	*****	*****	*****	*****	1.51	*****	-2.23	*****	0.40 (0.10, 1.63)	0.203
ACEI (14-day gap)	333,594	*****	*****	*****	*****	3.74	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	11,888	*****	*****	*****	*****	2.37	*****	0	*****	1.00 (0.14, 7.10)	1
ACEI (14-day gap)	11,888	*****	*****	*****	*****	2.37	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	17,513	*****	*****	*****	*****	1.51	*****	-3.16	*****	0.32 (0.07, 1.54)	0.156
ACEI (14-day gap)	19,475	*****	*****	*****	*****	4.68	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	14,448	*****	*****	*****	*****	1.18	*****	-1.75	*****	0.41 (0.13, 1.27)	0.121
ACEI (14-day gap)	289,770	*****	*****	*****	*****	2.92	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	8,587	*****	*****	*****	*****	1.74	*****	-4.34	*****	0.29 (0.06, 1.38)	0.118
ACEI (14-day gap)	8,587	*****	*****	*****	*****	6.08	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	14,411	*****	*****	*****	*****	1.18	*****	-1.12	*****	0.51 (0.13, 1.96)	0.324
ACEI (14-day gap)	16,921	*****	*****	*****	*****	2.3	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	7,898	*****	*****	*****	*****	0	*****	-3.19	*****	-	-
ACEI (14-day gap)	176,393	*****	*****	*****	*****	3.19	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	2,800	*****	*****	*****	*****	0	*****	-6.69	*****	-	-
ACEI (14-day gap)	2,800	*****	*****	*****	*****	6.69	*****				

Table 12. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	7,872	*****	*****	*****	*****	0	*****	-3.58	*****	-	-
ACEI (14-day gap)	9,890	*****	*****	*****	*****	3.58	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	4,930	*****	*****	*****	*****	0.96	*****	-1.64	*****	0.37 (0.05, 2.65)	0.321
ACEI (14-day gap)	125,154	*****	*****	*****	*****	2.59	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,178	*****	*****	*****	*****	0	*****	-4.62	*****	-	-
ACEI (14-day gap)	1,178	*****	*****	*****	*****	4.62	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	4,916	*****	*****	*****	*****	0.96	*****	-1.2	*****	0.44 (0.05, 4.25)	0.479
ACEI (14-day gap)	6,552	*****	*****	*****	*****	2.16	*****				

[1]Conditional analysis accounts for informative events and person-time.

[2]Data presented by a dash are unable to be calculated. This table may not use all data representations.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 13. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Site-Adjusted Analysis											
SV	43,777	*****	*****	*****	*****	1.35	*****	-1.67	*****	0.42 (0.27, 0.65)	<0.001
ARBs	337,157	*****	*****	*****	*****	3.01	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	43,755	*****	*****	*****	*****	1.36	*****	-0.84	*****	0.62 (0.31, 1.24)	0.174
ARBs	43,755	*****	*****	*****	*****	2.2	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	43,755	*****	*****	*****	*****	1.35	*****	-0.87	*****	0.59 (0.35, 1.01)	0.053
ARBs	43,755	*****	*****	*****	*****	2.21	*****				
Propensity Score Adjusted Stratified Analysis; Percentiles= 10[1]											
SV	43,777	*****	*****	*****	*****	1.35	*****	-1.67	*****	0.50 (0.32, 0.79)	0.003
ARBs	337,157	*****	*****	*****	*****	3.01	*****				

[1]Conditional analysis accounts for informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 14. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	43,777	*****	*****	*****	*****	1.35	*****	-1.67	*****	0.42 (0.27, 0.65)	<0.001
ARBs (14-day gap)	337,157	*****	*****	*****	*****	3.01	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	43,755	*****	*****	*****	*****	1.36	*****	-0.84	*****	0.62 (0.31, 1.24)	0.174
ARBs (14-day gap)	43,755	*****	*****	*****	*****	2.2	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	43,755	*****	*****	*****	*****	1.35	*****	-0.87	*****	0.59 (0.35, 1.01)	0.053
ARBs (14-day gap)	43,755	*****	*****	*****	*****	2.21	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	43,777	*****	*****	*****	*****	1.15	*****	-4.81	*****	0.20 (0.07, 0.53)	0.001
ARBs (14-day gap)	337,157	*****	*****	*****	*****	5.96	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	43,755	*****	*****	*****	*****	1.19	*****	-2.38	*****	0.33 (0.11, 1.03)	0.057
ARBs (14-day gap)	43,755	*****	*****	*****	*****	3.57	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	43,755	*****	*****	*****	*****	1.15	*****	-2.29	*****	0.33 (0.11, 1.04)	0.058
ARBs (14-day gap)	43,755	*****	*****	*****	*****	3.45	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	39,842	*****	*****	*****	*****	1.49	*****	-1.92	*****	0.45 (0.16, 1.22)	0.116
ARBs (14-day gap)	316,299	*****	*****	*****	*****	3.42	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	36,865	*****	*****	*****	*****	1.35	*****	0	*****	1.00 (0.20, 4.95)	1
ARBs (14-day gap)	36,865	*****	*****	*****	*****	1.35	*****				

Table 14. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	39,822	*****	*****	*****	*****	1.49	*****	-1.25	*****	0.55 (0.17, 1.84)	0.333
ARBs (14-day gap)	40,510	*****	*****	*****	*****	2.74	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	26,195	*****	*****	*****	*****	2.04	*****	-0.77	*****	0.77 (0.28, 2.11)	0.606
ARBs (14-day gap)	243,513	*****	*****	*****	*****	2.81	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	18,508	*****	*****	*****	*****	3.07	*****	0	*****	1.00 (0.25, 4.00)	1
ARBs (14-day gap)	18,508	*****	*****	*****	*****	3.07	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	26,181	*****	*****	*****	*****	2.04	*****	-0.06	*****	0.99 (0.26, 3.67)	0.982
ARBs (14-day gap)	30,964	*****	*****	*****	*****	2.1	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	21,286	*****	*****	*****	*****	1.61	*****	-0.64	*****	0.70 (0.31, 1.61)	0.406
ARBs (14-day gap)	214,289	*****	*****	*****	*****	2.25	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	13,070	*****	*****	*****	*****	1.17	*****	0	*****	1.00 (0.14, 7.10)	1
ARBs (14-day gap)	13,070	*****	*****	*****	*****	1.17	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	21,278	*****	*****	*****	*****	1.61	*****	-0.47	*****	0.77 (0.28, 2.13)	0.62
ARBs (14-day gap)	26,917	*****	*****	*****	*****	2.08	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	11,464	*****	*****	*****	*****	0.9	*****	-1.17	*****	0.44 (0.11, 1.80)	0.252
ARBs (14-day gap)	130,098	*****	*****	*****	*****	2.07	*****				

Table 14. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	4,037	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	4,037	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	11,461	*****	*****	*****	*****	0.9	*****	-0.7	*****	0.58 (0.11, 3.00)	0.518
ARBs (14-day gap)	15,621	*****	*****	*****	*****	1.6	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	7,161	*****	*****	*****	*****	0.66	*****	-0.9	*****	0.43 (0.06, 3.19)	0.412
ARBs (14-day gap)	92,668	*****	*****	*****	*****	1.56	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,737	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	1,737	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	7,159	*****	*****	*****	*****	0.66	*****	-0.23	*****	0.78 (0.07, 8.60)	0.839
ARBs (14-day gap)	10,561	*****	*****	*****	*****	0.89	*****				

[1]Conditional analysis accounts for informative events and person-time.

[2]Data presented by a dash are unable to be calculated. This table may not use all data representations.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 15. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1)

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No Angioedema (-183, -1)											
Site-Adjusted Analysis											
SV	43,717	*****	*****	*****	*****	1.09	*****	-1.34	*****	0.43 (0.27, 0.70)	<0.001
ARBs	336,332	*****	*****	*****	*****	2.43	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	43,685	*****	*****	*****	*****	1.05	*****	-0.94	*****	0.53 (0.24, 1.13)	0.1
ARBs	43,685	*****	*****	*****	*****	1.99	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	43,685	*****	*****	*****	*****	1.09	*****	-0.91	*****	0.53 (0.30, 0.95)	0.032
ARBs	43,685	*****	*****	*****	*****	2.01	*****				
Angioedema (-183, -1)											
Site-Adjusted Analysis											
SV	60	*****	*****	*****	*****	174.67	*****	-96.96	*****	0.58 (0.21, 1.59)	0.29
ARBs	825	*****	*****	*****	*****	271.63	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	48	*****	*****	*****	*****	215.52	*****	-107.76	*****	0.67 (0.11, 3.99)	0.657
ARBs	48	*****	*****	*****	*****	323.28	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	48	*****	*****	*****	*****	209.86	*****	35.34	*****	1.36 (0.30, 6.09)	0.686
ARBs	48	*****	*****	*****	*****	174.52	*****				

[1]Conditional analysis accounts for informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 16. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1) and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
No Angioedema (-183, -1)											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	43,717	*****	*****	*****	*****	1.09	*****	-1.34	*****	0.43 (0.27, 0.70)	<0.001
ARBs (14-day gap)	336,332	*****	*****	*****	*****	2.43	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	43,685	*****	*****	*****	*****	1.05	*****	-0.94	*****	0.53 (0.24, 1.13)	0.1
ARBs (14-day gap)	43,685	*****	*****	*****	*****	1.99	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	43,685	*****	*****	*****	*****	1.09	*****	-0.91	*****	0.53 (0.30, 0.95)	0.032
ARBs (14-day gap)	43,685	*****	*****	*****	*****	2.01	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	43,717	*****	*****	*****	*****	0.58	*****	-3.51	*****	0.14 (0.04, 0.58)	0.007
ARBs (14-day gap)	336,332	*****	*****	*****	*****	4.08	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	43,685	*****	*****	*****	*****	0.6	*****	-2.38	*****	0.20 (0.04, 0.91)	0.038
ARBs (14-day gap)	43,685	*****	*****	*****	*****	2.98	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	43,685	*****	*****	*****	*****	0.58	*****	-2.3	*****	0.20 (0.04, 0.91)	0.038
ARBs (14-day gap)	43,685	*****	*****	*****	*****	2.88	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	39,788	*****	*****	*****	*****	1.49	*****	-1.49	*****	0.51 (0.19, 1.41)	0.194
ARBs (14-day gap)	315,576	*****	*****	*****	*****	2.98	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	36,810	*****	*****	*****	*****	1.35	*****	0	*****	1.00 (0.20, 4.95)	1
ARBs (14-day gap)	36,810	*****	*****	*****	*****	1.35	*****				

Table 16. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1) and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	39,758	*****	*****	*****	*****	1.5	*****	-1.25	*****	0.55 (0.17, 1.84)	0.333
ARBs (14-day gap)	40,450	*****	*****	*****	*****	2.75	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	26,157	*****	*****	*****	*****	1.53	*****	-0.7	*****	0.72 (0.22, 2.33)	0.586
ARBs (14-day gap)	242,996	*****	*****	*****	*****	2.23	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	18,487	*****	*****	*****	*****	2.3	*****	-0.77	*****	0.75 (0.17, 3.35)	0.706
ARBs (14-day gap)	18,487	*****	*****	*****	*****	3.07	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	26,139	*****	*****	*****	*****	1.53	*****	-0.15	*****	0.91 (0.20, 4.09)	0.907
ARBs (14-day gap)	30,921	*****	*****	*****	*****	1.68	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	21,255	*****	*****	*****	*****	1.34	*****	-0.66	*****	0.67 (0.27, 1.65)	0.382
ARBs (14-day gap)	213,845	*****	*****	*****	*****	2	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	13,057	*****	*****	*****	*****	1.17	*****	0	*****	1.00 (0.14, 7.10)	1
ARBs (14-day gap)	13,057	*****	*****	*****	*****	1.17	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	21,245	*****	*****	*****	*****	1.34	*****	-0.74	*****	0.64 (0.22, 1.89)	0.422
ARBs (14-day gap)	26,883	*****	*****	*****	*****	2.08	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	11,447	*****	*****	*****	*****	0.9	*****	-0.94	*****	0.49 (0.12, 2.01)	0.319
ARBs (14-day gap)	129,815	*****	*****	*****	*****	1.85	*****				

Table 16. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1) and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	4,033	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	4,033	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	11,442	*****	*****	*****	*****	0.9	*****	-0.38	*****	0.72 (0.13, 3.92)	0.701
ARBs (14-day gap)	15,602	*****	*****	*****	*****	1.28	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	7,150	*****	*****	*****	*****	0.66	*****	-0.75	*****	0.48 (0.07, 3.57)	0.477
ARBs (14-day gap)	92,474	*****	*****	*****	*****	1.41	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,736	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	1,736	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	7,147	*****	*****	*****	*****	0.66	*****	-0.23	*****	0.78 (0.07, 8.61)	0.84
ARBs (14-day gap)	10,551	*****	*****	*****	*****	0.89	*****				
Angioedema (-183, -1)											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	60	*****	*****	*****	*****	174.67	*****	-96.96	*****	0.58 (0.21, 1.59)	0.29
ARBs (14-day gap)	825	*****	*****	*****	*****	271.63	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	48	*****	*****	*****	*****	215.52	*****	-107.76	*****	0.67 (0.11, 3.99)	0.657
ARBs (14-day gap)	48	*****	*****	*****	*****	323.28	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	48	*****	*****	*****	*****	209.86	*****	35.34	*****	1.36 (0.30, 6.09)	0.686
ARBs (14-day gap)	48	*****	*****	*****	*****	174.52	*****				

Table 16. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1) and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	681	*****	*****	*****	*****	49.13	*****	-86.01	*****	0.49 (0.12, 2.01)	0.322
ARBs (14-day gap)	5,694	*****	*****	*****	*****	135.14	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	785	*****	*****	*****	*****	90.29	*****	0	*****	1.00 (0.14, 7.10)	1
ARBs (14-day gap)	785	*****	*****	*****	*****	90.29	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	4,532	*****	*****	*****	*****	16.52	*****	5.15	*****	1.01 (0.14, 7.15)	0.995
ARBs (14-day gap)	6,990	*****	*****	*****	*****	11.37	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	54	*****	*****	*****	*****	0	*****	-195.01	*****	-	-
ARBs (14-day gap)	725	*****	*****	*****	*****	195.01	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	98	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	98	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	455	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	519	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	38	*****	*****	*****	*****	354.61	*****	78.57	*****	1.41 (0.18, 10.92)	0.743
ARBs (14-day gap)	522	*****	*****	*****	*****	276.04	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	23	*****	*****	*****	*****	0	*****	-666.67	*****	-	-
ARBs (14-day gap)	23	*****	*****	*****	*****	666.67	*****				

Table 16. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1) and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	32	*****	*****	*****	*****	420.17	*****	35.55	*****	1.14 (0.07, 18.31)	0.924
ARBs (14-day gap)	34	*****	*****	*****	*****	384.62	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	31	*****	*****	*****	*****	173.31	*****	54.52	*****	1.48 (0.19, 11.65)	0.711
ARBs (14-day gap)	449	*****	*****	*****	*****	118.79	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	14	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	14	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	26	*****	*****	*****	*****	191.2	*****	191.2	*****	-	-
ARBs (14-day gap)	29	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	19	*****	*****	*****	*****	0	*****	-106.5	*****	-	-
ARBs (14-day gap)	285	*****	*****	*****	*****	106.5	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	18	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	15	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	12	*****	*****	*****	*****	0	*****	-67.2	*****	-	-
ARBs (14-day gap)	197	*****	*****	*****	*****	67.2	*****				

Table 16. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1) and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	11	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	*****	*****	*****	*****	*****	0	*****				

[1]Conditional analysis accounts for informative events and person-time.

[2]Data presented by a dash are unable to be calculated. This table may not use all data representations.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 17. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (ever, -1)

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No Angioedema (ever, -1)											
Site-Adjusted Analysis											
SV	43,178	*****	*****	*****	*****	0.98	*****	-1.05	*****	0.46 (0.28, 0.78)	0.004
ARBs	329,798	*****	*****	*****	*****	2.03	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	42,832	*****	*****	*****	*****	0.96	*****	-0.75	*****	0.56 (0.25, 1.27)	0.167
ARBs	42,832	*****	*****	*****	*****	1.71	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	42,832	*****	*****	*****	*****	0.98	*****	-0.74	*****	0.56 (0.30, 1.04)	0.066
ARBs	42,832	*****	*****	*****	*****	1.72	*****				
Angioedema (ever, -1)											
Site-Adjusted Analysis											
SV	599	*****	*****	*****	*****	27.13	*****	-20.81	*****	0.51 (0.22, 1.15)	0.104
ARBs	7,359	*****	*****	*****	*****	47.94	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	591	*****	*****	*****	*****	36.79	*****	0	*****	1.00 (0.29, 3.45)	1
ARBs	591	*****	*****	*****	*****	36.79	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	591	*****	*****	*****	*****	27.53	*****	-2.77	*****	0.85 (0.30, 2.47)	0.772
ARBs	591	*****	*****	*****	*****	30.3	*****				

[1]Conditional analysis accounts for informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 18. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Serious Allergies

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No Serious Allergies											
Site-Adjusted Analysis											
SV	37,847	*****	*****	*****	*****	1.17	*****	-1.41	*****	0.43 (0.26, 0.71)	<0.001
ARBs	282,725	*****	*****	*****	*****	2.59	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	37,637	*****	*****	*****	*****	1.07	*****	-0.72	*****	0.60 (0.26, 1.37)	0.226
ARBs	37,637	*****	*****	*****	*****	1.79	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	37,637	*****	*****	*****	*****	1.18	*****	-0.94	*****	0.54 (0.30, 0.99)	0.045
ARBs	37,637	*****	*****	*****	*****	2.12	*****				
Serious Allergies											
Site-Adjusted Analysis											
SV	5,930	*****	*****	*****	*****	2.56	*****	-2.93	*****	0.43 (0.18, 1.06)	0.068
ARBs	54,432	*****	*****	*****	*****	5.5	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	5,774	*****	*****	*****	*****	2.65	*****	-1.77	*****	0.60 (0.14, 2.51)	0.484
ARBs	5,774	*****	*****	*****	*****	4.42	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	5,774	*****	*****	*****	*****	2.64	*****	-0.41	*****	0.86 (0.27, 2.73)	0.801
ARBs	5,774	*****	*****	*****	*****	3.05	*****				

[1]Conditional analysis accounts for informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 19. Effect Estimates for Risk of Angioedema Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARB) 14-Day Gap in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Sex and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Sex: Male											
Overall											
Site-Adjusted Analysis											
SV (14-Day Gap)	28,311	*****	*****	*****	*****	0.99	*****	-1.9	*****	0.33 (0.17, 0.62)	<0.001
ARB (14-Day Gap)	149,252	*****	*****	*****	*****	2.9	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	27,999	*****	*****	*****	*****	0.82	*****	-1.48	*****	0.36 (0.13, 0.99)	0.048
ARB (14-Day Gap)	27,999	*****	*****	*****	*****	2.3	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	27,999	*****	*****	*****	*****	1.01	*****	-1.74	*****	0.36 (0.18, 0.73)	0.005
ARB (14-Day Gap)	27,999	*****	*****	*****	*****	2.74	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	28,311	*****	*****	*****	*****	0.89	*****	-4.13	*****	0.18 (0.04, 0.73)	0.016
ARB (14-Day Gap)	149,252	*****	*****	*****	*****	5.02	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	27,999	*****	*****	*****	*****	0.93	*****	-3.25	*****	0.22 (0.05, 1.03)	0.054
ARB (14-Day Gap)	27,999	*****	*****	*****	*****	4.18	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	27,999	*****	*****	*****	*****	0.9	*****	-3.14	*****	0.22 (0.05, 1.03)	0.055
ARB (14-Day Gap)	27,999	*****	*****	*****	*****	4.04	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	25,869	*****	*****	*****	*****	1.73	*****	-1.15	*****	0.62 (0.19, 2.03)	0.427
ARB (14-Day Gap)	139,781	*****	*****	*****	*****	2.88	*****				

Table 19. Effect Estimates for Risk of Angioedema Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARB) 14-Day Gap in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Sex and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	23,643	*****	*****	*****	*****	1.41	*****	1.41	*****	-	-
ARB (14-Day Gap)	23,643	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	25,578	*****	*****	*****	*****	1.75	*****	-0.94	*****	0.66 (0.16, 2.76)	0.569
ARB (14-Day Gap)	25,890	*****	*****	*****	*****	2.69	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	16,938	*****	*****	*****	*****	0.79	*****	-1.62	*****	0.34 (0.05, 2.54)	0.294
ARB (14-Day Gap)	107,343	*****	*****	*****	*****	2.41	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	11,771	*****	*****	*****	*****	1.2	*****	-1.2	*****	0.50 (0.05, 5.51)	0.571
ARB (14-Day Gap)	11,771	*****	*****	*****	*****	2.41	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	16,736	*****	*****	*****	*****	0.8	*****	-1.18	*****	0.40 (0.04, 3.87)	0.431
ARB (14-Day Gap)	19,728	*****	*****	*****	*****	1.98	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	13,783	*****	*****	*****	*****	0.83	*****	-1.93	*****	0.29 (0.07, 1.21)	0.09
ARB (14-Day Gap)	94,209	*****	*****	*****	*****	2.76	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	8,328	*****	*****	*****	*****	0	*****	-2.79	*****	-	-
ARB (14-Day Gap)	8,328	*****	*****	*****	*****	2.79	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	13,619	*****	*****	*****	*****	0.84	*****	-2.44	*****	0.26 (0.06, 1.19)	0.083
ARB (14-Day Gap)	17,120	*****	*****	*****	*****	3.29	*****				

Table 19. Effect Estimates for Risk of Angioedema Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARB) 14-Day Gap in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Sex and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	7,405	*****	*****	*****	*****	0.7	*****	-1.13	*****	0.38 (0.05, 2.83)	0.345
ARB (14-Day Gap)	56,410	*****	*****	*****	*****	1.83	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	2,559	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB (14-Day Gap)	2,559	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	7,315	*****	*****	*****	*****	0.71	*****	-1.83	*****	0.29 (0.03, 2.48)	0.258
ARB (14-Day Gap)	9,864	*****	*****	*****	*****	2.54	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	4,632	*****	*****	*****	*****	1.03	*****	-1.13	*****	0.47 (0.06, 3.53)	0.464
ARB (14-Day Gap)	39,969	*****	*****	*****	*****	2.15	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	1,127	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB (14-Day Gap)	1,127	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	4,575	*****	*****	*****	*****	1.04	*****	0.33	*****	1.53 (0.10, 24.43)	0.764
ARB (14-Day Gap)	6,649	*****	*****	*****	*****	0.71	*****				
Sex: Female											
Overall											
Site-Adjusted Analysis											
SV (14-Day Gap)	15,466	*****	*****	*****	*****	2	*****	-1.11	*****	0.60 (0.33, 1.09)	0.096
ARB (14-Day Gap)	187,905	*****	*****	*****	*****	3.1	*****				

Table 19. Effect Estimates for Risk of Angioedema Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARB) 14-Day Gap in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Sex and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	15,267	*****	*****	*****	*****	1.77	*****	-0.29	*****	0.86 (0.29, 2.55)	0.782
ARB (14-Day Gap)	15,267	*****	*****	*****	*****	2.06	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	15,267	*****	*****	*****	*****	2.02	*****	0.68	*****	1.45 (0.60, 3.50)	0.41
ARB (14-Day Gap)	15,267	*****	*****	*****	*****	1.34	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	15,466	*****	*****	*****	*****	1.64	*****	-5.07	*****	0.25 (0.06, 1.01)	0.051
ARB (14-Day Gap)	187,905	*****	*****	*****	*****	6.71	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	15,267	*****	*****	*****	*****	1.71	*****	-0.85	*****	0.67 (0.11, 3.99)	0.657
ARB (14-Day Gap)	15,267	*****	*****	*****	*****	2.56	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	15,267	*****	*****	*****	*****	1.66	*****	-0.81	*****	0.67 (0.11, 3.99)	0.657
ARB (14-Day Gap)	15,267	*****	*****	*****	*****	2.47	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	13,973	*****	*****	*****	*****	1.06	*****	-2.78	*****	0.28 (0.04, 2.00)	0.202
ARB (14-Day Gap)	176,518	*****	*****	*****	*****	3.84	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	12,817	*****	*****	*****	*****	1.29	*****	-2.57	*****	0.33 (0.03, 3.20)	0.341
ARB (14-Day Gap)	12,817	*****	*****	*****	*****	3.86	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	13,795	*****	*****	*****	*****	1.07	*****	-1.86	*****	0.37 (0.04, 3.58)	0.392
ARB (14-Day Gap)	14,173	*****	*****	*****	*****	2.93	*****				

Table 19. Effect Estimates for Risk of Angioedema Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARB) 14-Day Gap in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Sex and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	9,257	*****	*****	*****	*****	4.33	*****	1.2	*****	1.47 (0.45, 4.80)	0.522
ARB (14-Day Gap)	136,170	*****	*****	*****	*****	3.13	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	6,544	*****	*****	*****	*****	4.32	*****	2.16	*****	2.00 (0.18, 22.06)	0.571
ARB (14-Day Gap)	6,544	*****	*****	*****	*****	2.16	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	9,145	*****	*****	*****	*****	4.38	*****	2	*****	1.88 (0.31, 11.28)	0.488
ARB (14-Day Gap)	10,897	*****	*****	*****	*****	2.38	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	7,503	*****	*****	*****	*****	3.02	*****	1.16	*****	1.66 (0.59, 4.63)	0.338
ARB (14-Day Gap)	120,080	*****	*****	*****	*****	1.86	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	4,666	*****	*****	*****	*****	1.61	*****	1.61	*****	-	-
ARB (14-Day Gap)	4,666	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	7,419	*****	*****	*****	*****	3.05	*****	3.05	*****	-	-
ARB (14-Day Gap)	9,505	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	4,060	*****	*****	*****	*****	1.28	*****	-0.98	*****	0.57 (0.08, 4.19)	0.582
ARB (14-Day Gap)	73,690	*****	*****	*****	*****	2.25	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	1,493	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB (14-Day Gap)	1,493	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											

Table 19. Effect Estimates for Risk of Angioedema Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARB) 14-Day Gap in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Sex and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
SV (14-Day Gap)	4,020	*****	*****	*****	*****	1.29	*****	1.29	*****	-	-
ARB (14-Day Gap)	5,591	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-Day Gap)	2,529	*****	*****	*****	*****	0	*****	-1.11	*****	-	-
ARB (14-Day Gap)	52,699	*****	*****	*****	*****	1.11	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-Day Gap)	646	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB (14-Day Gap)	646	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-Day Gap)	2,505	*****	*****	*****	*****	0	*****	-1.22	*****	-	-
ARB (14-Day Gap)	3,802	*****	*****	*****	*****	1.22	*****				

[1]Conditional analysis accounts for informative events and person-time.

[2]Data presented by a dash are unable to be calculated. This table may not use all data representations.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 20. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Age Group

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Age Group: 18-44 years											
Site-Adjusted Analysis											
SV	1,634	*****	*****	*****	*****	1.87	*****	-6.02	*****	0.27 (0.04, 2.05)	0.207
ARBs	8,500	*****	*****	*****	*****	7.89	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	1,448	*****	*****	*****	*****	3.8	*****	3.8	*****	-	-
ARBs	1,448	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	1,448	*****	*****	*****	*****	2.11	*****	-0.02	*****	1.00 (0.06, 16.19)	0.998
ARBs	1,448	*****	*****	*****	*****	2.13	*****				
Age Group: 45-54 years											
Site-Adjusted Analysis											
SV	3,068	*****	*****	*****	*****	0.95	*****	-3.36	*****	0.23 (0.03, 1.70)	0.149
ARBs	18,297	*****	*****	*****	*****	4.32	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	2,938	*****	*****	*****	*****	1.72	*****	-1.72	*****	0.50 (0.05, 5.51)	0.571
ARBs	2,938	*****	*****	*****	*****	3.43	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	2,938	*****	*****	*****	*****	0.99	*****	-1.8	*****	0.37 (0.04, 3.57)	0.39
ARBs	2,938	*****	*****	*****	*****	2.8	*****				
Age Group: 55-64 years											
Site-Adjusted Analysis											
SV	6,120	*****	*****	*****	*****	1.88	*****	-2.12	*****	0.48 (0.17, 1.31)	0.152
ARBs	40,556	*****	*****	*****	*****	4	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	5,994	*****	*****	*****	*****	2.43	*****	0	*****	1.00 (0.20, 4.95)	1
ARBs	5,994	*****	*****	*****	*****	2.43	*****				

Table 20. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Age Group

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	5,994	*****	*****	*****	*****	1.91	*****	-0.18	*****	0.92 (0.25, 3.43)	0.899
ARBs	5,994	*****	*****	*****	*****	2.1	*****				
Age Group: ≥65 years											
Site-Adjusted Analysis											
SV	32,955	*****	*****	*****	*****	1.26	*****	-1.44	*****	0.43 (0.26, 0.72)	0.001
ARBs	269,804	*****	*****	*****	*****	2.71	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	32,649	*****	*****	*****	*****	1.22	*****	-0.81	*****	0.60 (0.26, 1.37)	0.226
ARBs	32,649	*****	*****	*****	*****	2.03	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	32,649	*****	*****	*****	*****	1.19	*****	-0.91	*****	0.55 (0.29, 1.03)	0.062
ARBs	32,649	*****	*****	*****	*****	2.1	*****				

[1]Conditional analysis accounts for informative events and person-time.

[2]Data presented by a dash are unable to be calculated. This table may not use all data representations.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 21. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Age Group: 18-44											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	1,634	*****	*****	*****	*****	1.87	*****	-6.02	*****	0.27 (0.04, 2.05)	0.207
ARBs (14-day gap)	8,500	*****	*****	*****	*****	7.89	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,448	*****	*****	*****	*****	3.8	*****	3.8	*****	-	-
ARBs (14-day gap)	1,448	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	1,448	*****	*****	*****	*****	2.11	*****	-0.02	*****	1.00 (0.06, 16.19)	0.998
ARBs (14-day gap)	1,448	*****	*****	*****	*****	2.13	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	1,788	*****	*****	*****	*****	0	*****	-5.84	*****	-	-
ARBs (14-day gap)	10,999	*****	*****	*****	*****	5.84	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,422	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	1,422	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	1,605	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	1,760	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	1,497	*****	*****	*****	*****	0	*****	-7.65	*****	-	-
ARBs (14-day gap)	7,924	*****	*****	*****	*****	7.65	*****				

Table 21. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,211	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	1,211	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	1,331	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	1,314	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	933	*****	*****	*****	*****	0	*****	-5.33	*****	-	-
ARBs (14-day gap)	5,002	*****	*****	*****	*****	5.33	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	492	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	492	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	830	*****	*****	*****	*****	0	*****	-15.86	*****	-	-
ARBs (14-day gap)	854	*****	*****	*****	*****	15.86	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	704	*****	*****	*****	*****	8.2	*****	-8.31	*****	0.63 (0.08, 4.94)	0.66
ARBs (14-day gap)	4,048	*****	*****	*****	*****	16.52	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	288	*****	*****	*****	*****	28.03	*****	28.03	*****	-	-
ARBs (14-day gap)	288	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	625	*****	*****	*****	*****	9.19	*****	9.19	*****	-	-
ARBs (14-day gap)	662	*****	*****	*****	*****	0	*****				

Table 21. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	371	*****	*****	*****	*****	0	*****	-5.1	*****	-	-
ARBs (14-day gap)	1,995	*****	*****	*****	*****	5.1	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	77	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	77	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	335	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	296	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	223	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	1,317	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	42	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	42	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	200	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	199	*****	*****	*****	*****	0	*****				
Age Group: 45-54											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	3,068	*****	*****	*****	*****	0.95	*****	-3.36	*****	0.23 (0.03, 1.70)	0.149
ARBs (14-day gap)	18,297	*****	*****	*****	*****	4.32	*****				

Table 21. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	2,938	*****	*****	*****	*****	1.72	*****	-1.72	*****	0.50 (0.05, 5.51)	0.571
ARBs (14-day gap)	2,938	*****	*****	*****	*****	3.43	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	2,938	*****	*****	*****	*****	0.99	*****	-1.8	*****	0.37 (0.04, 3.57)	0.39
ARBs (14-day gap)	2,938	*****	*****	*****	*****	2.8	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	3,068	*****	*****	*****	*****	0	*****	-10.27	*****	-	-
ARBs (14-day gap)	18,297	*****	*****	*****	*****	10.27	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	2,938	*****	*****	*****	*****	0	*****	-4.45	*****	-	-
ARBs (14-day gap)	2,938	*****	*****	*****	*****	4.45	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	2,938	*****	*****	*****	*****	0	*****	-4.3	*****	-	-
ARBs (14-day gap)	2,938	*****	*****	*****	*****	4.3	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	2,806	*****	*****	*****	*****	0	*****	-4.29	*****	-	-
ARBs (14-day gap)	17,086	*****	*****	*****	*****	4.29	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	2,467	*****	*****	*****	*****	0	*****	-6.86	*****	-	-
ARBs (14-day gap)	2,467	*****	*****	*****	*****	6.86	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	2,693	*****	*****	*****	*****	0	*****	-5.42	*****	-	-
ARBs (14-day gap)	2,684	*****	*****	*****	*****	5.42	*****				

Table 21. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	1,779	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	11,645	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,093	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	1,093	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	1,711	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	1,863	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	1,412	*****	*****	*****	*****	0	*****	-3.6	*****	-	-
ARBs (14-day gap)	9,740	*****	*****	*****	*****	3.6	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	729	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	729	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	1,357	*****	*****	*****	*****	0	*****	-3.83	*****	-	-
ARBs (14-day gap)	1,544	*****	*****	*****	*****	3.83	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	744	*****	*****	*****	*****	6.99	*****	5.05	*****	3.89 (0.34, 44.69)	0.275
ARBs (14-day gap)	5,203	*****	*****	*****	*****	1.94	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	211	*****	*****	*****	*****	29.15	*****	29.15	*****	-	-
ARBs (14-day gap)	211	*****	*****	*****	*****	0	*****				

Table 21. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	721	*****	*****	*****	*****	7.19	*****	7.19	*****	-	-
ARBs (14-day gap)	782	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	468	*****	*****	*****	*****	0	*****	-2.69	*****	-	-
ARBs (14-day gap)	3,437	*****	*****	*****	*****	2.69	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	88	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	88	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	454	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	496	*****	*****	*****	*****	0	*****				
Age Group: 55-64											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	6,120	*****	*****	*****	*****	1.88	*****	-2.12	*****	0.48 (0.17, 1.31)	0.152
ARBs (14-day gap)	40,556	*****	*****	*****	*****	4	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	5,994	*****	*****	*****	*****	2.43	*****	0	*****	1.00 (0.20, 4.95)	1
ARBs (14-day gap)	5,994	*****	*****	*****	*****	2.43	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	5,994	*****	*****	*****	*****	1.91	*****	-0.18	*****	0.92 (0.25, 3.43)	0.899
ARBs (14-day gap)	5,994	*****	*****	*****	*****	2.1	*****				

Table 21. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	6,120	*****	*****	*****	*****	2.07	*****	-5.95	*****	0.25 (0.03, 1.84)	0.173
ARBs (14-day gap)	40,556	*****	*****	*****	*****	8.01	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	5,994	*****	*****	*****	*****	2.18	*****	-4.36	*****	0.33 (0.03, 3.20)	0.341
ARBs (14-day gap)	5,994	*****	*****	*****	*****	6.54	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	5,994	*****	*****	*****	*****	2.11	*****	-4.19	*****	0.33 (0.03, 3.20)	0.341
ARBs (14-day gap)	5,994	*****	*****	*****	*****	6.3	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	5,561	*****	*****	*****	*****	0	*****	-2.25	*****	-	-
ARBs (14-day gap)	37,960	*****	*****	*****	*****	2.25	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	5,036	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	5,036	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	5,453	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	5,536	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	3,609	*****	*****	*****	*****	7.43	*****	5.04	*****	3.55 (0.68, 18.41)	0.131
ARBs (14-day gap)	27,418	*****	*****	*****	*****	2.38	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	2,358	*****	*****	*****	*****	6.08	*****	6.08	*****	-	-
ARBs (14-day gap)	2,358	*****	*****	*****	*****	0	*****				

Table 21. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	3,547	*****	*****	*****	*****	7.57	*****	7.57	*****	-	-
ARBs (14-day gap)	4,002	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	2,898	*****	*****	*****	*****	1.98	*****	-1.4	*****	0.61 (0.08, 4.69)	0.637
ARBs (14-day gap)	23,333	*****	*****	*****	*****	3.39	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,619	*****	*****	*****	*****	4.79	*****	4.79	*****	-	-
ARBs (14-day gap)	1,619	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	2,846	*****	*****	*****	*****	2.02	*****	0.33	*****	1.31 (0.08, 20.90)	0.85
ARBs (14-day gap)	3,362	*****	*****	*****	*****	1.69	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	1,528	*****	*****	*****	*****	0	*****	-3.39	*****	-	-
ARBs (14-day gap)	13,310	*****	*****	*****	*****	3.39	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	483	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	483	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	1,507	*****	*****	*****	*****	0	*****	-2.73	*****	-	-
ARBs (14-day gap)	1,880	*****	*****	*****	*****	2.73	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	958	*****	*****	*****	*****	0	*****	-3.54	*****	-	-
ARBs (14-day gap)	9,053	*****	*****	*****	*****	3.54	*****				

Table 21. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	203	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	203	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	946	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	1,209	*****	*****	*****	*****	0	*****				
Age Group: 65+											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	32,955	*****	*****	*****	*****	1.26	*****	-1.44	*****	0.43 (0.26, 0.72)	0.001
ARBs (14-day gap)	269,804	*****	*****	*****	*****	2.71	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	32,649	*****	*****	*****	*****	1.22	*****	-0.81	*****	0.60 (0.26, 1.37)	0.226
ARBs (14-day gap)	32,649	*****	*****	*****	*****	2.03	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	32,649	*****	*****	*****	*****	1.19	*****	-0.91	*****	0.55 (0.29, 1.03)	0.062
ARBs (14-day gap)	32,649	*****	*****	*****	*****	2.1	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	32,955	*****	*****	*****	*****	1.15	*****	-4.22	*****	0.22 (0.07, 0.68)	0.009
ARBs (14-day gap)	269,804	*****	*****	*****	*****	5.36	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	32,556	*****	*****	*****	*****	1.19	*****	-1.99	*****	0.38 (0.10, 1.41)	0.147
ARBs (14-day gap)	32,556	*****	*****	*****	*****	3.18	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	32,600	*****	*****	*****	*****	1.16	*****	-1.92	*****	0.38 (0.10, 1.42)	0.15
ARBs (14-day gap)	32,605	*****	*****	*****	*****	3.07	*****				

Table 21. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	29,979	*****	*****	*****	*****	1.98	*****	-1.43	*****	0.58 (0.21, 1.59)	0.291
ARBs (14-day gap)	253,331	*****	*****	*****	*****	3.41	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	27,574	*****	*****	*****	*****	1.78	*****	0	*****	1.00 (0.20, 4.95)	1
ARBs (14-day gap)	27,574	*****	*****	*****	*****	1.78	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	29,701	*****	*****	*****	*****	1.99	*****	-1.17	*****	0.64 (0.19, 2.18)	0.474
ARBs (14-day gap)	30,313	*****	*****	*****	*****	3.17	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	19,875	*****	*****	*****	*****	1.34	*****	-1.63	*****	0.46 (0.11, 1.88)	0.278
ARBs (14-day gap)	199,450	*****	*****	*****	*****	2.97	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	14,351	*****	*****	*****	*****	0.98	*****	-1.96	*****	0.33 (0.03, 3.20)	0.341
ARBs (14-day gap)	14,351	*****	*****	*****	*****	2.95	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	19,699	*****	*****	*****	*****	0.67	*****	-1.5	*****	0.31 (0.03, 2.79)	0.298
ARBs (14-day gap)	23,789	*****	*****	*****	*****	2.17	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	16,273	*****	*****	*****	*****	1.4	*****	-0.35	*****	0.81 (0.29, 2.24)	0.687
ARBs (14-day gap)	177,174	*****	*****	*****	*****	1.75	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	10,320	*****	*****	*****	*****	0.73	*****	0	*****	1.00 (0.06, 15.99)	1
ARBs (14-day gap)	10,320	*****	*****	*****	*****	0.73	*****				

Table 21. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	16,124	*****	*****	*****	*****	1.41	*****	-0.17	*****	0.90 (0.25, 3.18)	0.867
ARBs (14-day gap)	20,952	*****	*****	*****	*****	1.59	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	8,822	*****	*****	*****	*****	0.59	*****	-1.28	*****	0.32 (0.04, 2.30)	0.256
ARBs (14-day gap)	109,601	*****	*****	*****	*****	1.87	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	3,325	*****	*****	*****	*****	1.87	*****	1.87	*****	-	-
ARBs (14-day gap)	3,325	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	8,739	*****	*****	*****	*****	0.59	*****	-1.01	*****	0.38 (0.04, 3.38)	0.384
ARBs (14-day gap)	12,445	*****	*****	*****	*****	1.6	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	5,512	*****	*****	*****	*****	0.85	*****	-0.46	*****	0.67 (0.09, 4.94)	0.693
ARBs (14-day gap)	78,866	*****	*****	*****	*****	1.31	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,436	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	1,436	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	5,458	*****	*****	*****	*****	0.86	*****	-0.24	*****	0.79 (0.07, 8.75)	0.85
ARBs (14-day gap)	8,510	*****	*****	*****	*****	1.1	*****				

[1]Conditional analysis accounts for informative events and person-time.

[2]Data presented by a dash are unable to be calculated. This table may not use all data representations.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 22. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Race

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Race: Unknown											
Site-Adjusted Analysis											
SV	7,289	*****	*****	*****	*****	0.75	*****	-1.77	*****	0.30 (0.07, 1.22)	0.092
ARBs	47,812	*****	*****	*****	*****	2.51	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	7,159	*****	*****	*****	*****	0.65	*****	-1.31	*****	0.33 (0.03, 3.20)	0.341
ARBs	7,159	*****	*****	*****	*****	1.96	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	7,159	*****	*****	*****	*****	0.76	*****	-1.32	*****	0.38 (0.08, 1.87)	0.232
ARBs	7,159	*****	*****	*****	*****	2.08	*****				
Race: American Indian											
Site-Adjusted Analysis											
SV	143	*****	*****	*****	*****	0	*****	-1.36	*****	-	-
ARBs	1,947	*****	*****	*****	*****	1.36	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	138	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs	138	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	138	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs	138	*****	*****	*****	*****	0	*****				
Race: Asian											
Site-Adjusted Analysis											
SV	511	*****	*****	*****	*****	0	*****	-0.81	*****	-	-
ARBs	7,817	*****	*****	*****	*****	0.81	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	484	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs	484	*****	*****	*****	*****	0	*****				

Table 22. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Race

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	484	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs	484	*****	*****	*****	*****	0	*****				
Race: Black											
Site-Adjusted Analysis											
SV	5,853	*****	*****	*****	*****	4.01	*****	-2.79	*****	0.54 (0.25, 1.15)	0.11
ARBs	55,815	*****	*****	*****	*****	6.8	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	5,765	*****	*****	*****	*****	3.76	*****	0	*****	1.00 (0.25, 4.00)	1
ARBs	5,765	*****	*****	*****	*****	3.76	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	5,765	*****	*****	*****	*****	4.06	*****	0.36	*****	1.08 (0.39, 3.00)	0.879
ARBs	5,765	*****	*****	*****	*****	3.7	*****				
Race: Pacific Islander											
Site-Adjusted Analysis											
SV	46	*****	*****	*****	*****	0	*****	-8.97	*****	-	-
ARBs	478	*****	*****	*****	*****	8.97	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	31	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs	31	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	31	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs	31	*****	*****	*****	*****	0	*****				
Race: White											
Site-Adjusted Analysis											
SV	29,935	*****	*****	*****	*****	1.1	*****	-1.3	*****	0.42 (0.24, 0.76)	0.004
ARBs	223,288	*****	*****	*****	*****	2.4	*****				

Table 22. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Race

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	29,757	*****	*****	*****	*****	1.03	*****	-1.18	*****	0.47 (0.19, 1.14)	0.096
ARBs	29,757	*****	*****	*****	*****	2.21	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	29,757	*****	*****	*****	*****	1.11	*****	-0.97	*****	0.51 (0.26, 1.00)	0.051
ARBs	29,757	*****	*****	*****	*****	2.08	*****				

[1]Conditional analysis accounts for informative events and person-time.

[2]Data presented by a dash are unable to be calculated. This table may not use all data representations.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 23. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Race: Unknown											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	7,289	*****	*****	*****	*****	0.75	*****	-1.77	*****	0.30 (0.07, 1.22)	0.092
ARBs (14-day gap)	47,812	*****	*****	*****	*****	2.51	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	7,159	*****	*****	*****	*****	0.65	*****	-1.31	*****	0.33 (0.03, 3.20)	0.341
ARBs (14-day gap)	7,159	*****	*****	*****	*****	1.96	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	7,159	*****	*****	*****	*****	0.76	*****	-1.32	*****	0.38 (0.08, 1.87)	0.232
ARBs (14-day gap)	7,159	*****	*****	*****	*****	2.08	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	7,289	*****	*****	*****	*****	0	*****	-3.41	*****	-	-
ARBs (14-day gap)	47,812	*****	*****	*****	*****	3.41	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	7,125	*****	*****	*****	*****	0	*****	-1.85	*****	-	-
ARBs (14-day gap)	7,125	*****	*****	*****	*****	1.85	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	7,209	*****	*****	*****	*****	0	*****	-1.77	*****	-	-
ARBs (14-day gap)	7,398	*****	*****	*****	*****	1.77	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	6,560	*****	*****	*****	*****	0	*****	-2.52	*****	-	-
ARBs (14-day gap)	44,564	*****	*****	*****	*****	2.52	*****				

Table 23. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	5,874	*****	*****	*****	*****	0	*****	-2.82	*****	-	-
ARBs (14-day gap)	5,874	*****	*****	*****	*****	2.82	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	6,446	*****	*****	*****	*****	0	*****	-4.33	*****	-	-
ARBs (14-day gap)	6,520	*****	*****	*****	*****	4.33	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	4,440	*****	*****	*****	*****	3.01	*****	1.44	*****	2.80 (0.31, 25.43)	0.36
ARBs (14-day gap)	33,271	*****	*****	*****	*****	1.57	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	2,963	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	2,963	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	4,367	*****	*****	*****	*****	3.06	*****	3.06	*****	-	-
ARBs (14-day gap)	4,816	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	3,591	*****	*****	*****	*****	1.53	*****	-1.76	*****	0.47 (0.06, 3.53)	0.46
ARBs (14-day gap)	28,540	*****	*****	*****	*****	3.29	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	2,019	*****	*****	*****	*****	3.63	*****	0	*****	1.00 (0.06, 15.99)	1
ARBs (14-day gap)	2,019	*****	*****	*****	*****	3.63	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	3,541	*****	*****	*****	*****	1.55	*****	-1.21	*****	0.54 (0.05, 5.93)	0.612
ARBs (14-day gap)	4,059	*****	*****	*****	*****	2.76	*****				

Table 23. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	2,040	*****	*****	*****	*****	0	*****	-2.06	*****	-	-
ARBs (14-day gap)	16,763	*****	*****	*****	*****	2.06	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	657	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	657	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	2,021	*****	*****	*****	*****	0	*****	-2.21	*****	-	-
ARBs (14-day gap)	2,273	*****	*****	*****	*****	2.21	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	1,297	*****	*****	*****	*****	0	*****	-1.16	*****	-	-
ARBs (14-day gap)	11,721	*****	*****	*****	*****	1.16	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	292	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	292	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	1,284	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	1,522	*****	*****	*****	*****	0	*****				
Race: American Indian											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	143	*****	*****	*****	*****	0	*****	-1.36	*****	-	-
ARBs (14-day gap)	1,947	*****	*****	*****	*****	1.36	*****				

Table 23. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	138	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	138	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	138	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	138	*****	*****	*****	*****	0	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	211	*****	*****	*****	*****	0	*****	-5.6	*****	-	-
ARBs (14-day gap)	2,647	*****	*****	*****	*****	5.6	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	143	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	143	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	205	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	237	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	126	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	1,839	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	115	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	115	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	122	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	131	*****	*****	*****	*****	0	*****				

Table 23. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	78	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	1,234	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	57	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	57	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	77	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	93	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	63	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	1,023	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	40	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	40	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	62	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	81	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	32	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	551	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	15	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	15	*****	*****	*****	*****	0	*****				

Table 23. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	33	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	47	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	18	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	370	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	19	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	31	*****	*****	*****	*****	0	*****				
Race: Asian											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	511	*****	*****	*****	*****	0	*****	-0.81	*****	-	-
ARBs (14-day gap)	7,817	*****	*****	*****	*****	0.81	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	484	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	484	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	484	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	484	*****	*****	*****	*****	0	*****				

Table 23. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	509	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	7,782	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	437	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	437	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	448	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	453	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	472	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	7,373	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	405	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	405	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	432	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	442	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	325	*****	*****	*****	*****	0	*****	-2.16	*****	-	-
ARBs (14-day gap)	5,973	*****	*****	*****	*****	2.16	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	251	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	251	*****	*****	*****	*****	0	*****				

Table 23. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	316	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	376	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	247	*****	*****	*****	*****	0	*****	-1.04	*****	-	-
ARBs (14-day gap)	5,297	*****	*****	*****	*****	1.04	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	158	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	158	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	235	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	326	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	135	*****	*****	*****	*****	0	*****	-1.55	*****	-	-
ARBs (14-day gap)	3,218	*****	*****	*****	*****	1.55	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	60	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	60	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	128	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	177	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	87	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	2,249	*****	*****	*****	*****	0	*****				

Table 23. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	31	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	31	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	83	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	115	*****	*****	*****	*****	0	*****				
Race: Black											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	5,853	*****	*****	*****	*****	4.01	*****	-2.79	*****	0.54 (0.25, 1.15)	0.11
ARBs (14-day gap)	55,815	*****	*****	*****	*****	6.8	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	5,765	*****	*****	*****	*****	3.76	*****	0	*****	1.00 (0.25, 4.00)	1
ARBs (14-day gap)	5,765	*****	*****	*****	*****	3.76	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	5,765	*****	*****	*****	*****	4.06	*****	0.36	*****	1.08 (0.39, 3.00)	0.879
ARBs (14-day gap)	5,765	*****	*****	*****	*****	3.7	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	5,853	*****	*****	*****	*****	2.16	*****	-11.49	*****	0.16 (0.02, 1.14)	0.067
ARBs (14-day gap)	55,815	*****	*****	*****	*****	13.65	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	5,765	*****	*****	*****	*****	2.26	*****	-2.26	*****	0.50 (0.05, 5.51)	0.571
ARBs (14-day gap)	5,765	*****	*****	*****	*****	4.52	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	5,765	*****	*****	*****	*****	2.19	*****	-2.17	*****	0.50 (0.04, 5.46)	0.566
ARBs (14-day gap)	5,765	*****	*****	*****	*****	4.36	*****				

Table 23. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	5,322	*****	*****	*****	*****	2.94	*****	-4.46	*****	0.40 (0.05, 2.93)	0.366
ARBs (14-day gap)	52,284	*****	*****	*****	*****	7.4	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	4,860	*****	*****	*****	*****	3.66	*****	-3.66	*****	0.50 (0.05, 5.51)	0.571
ARBs (14-day gap)	4,860	*****	*****	*****	*****	7.32	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	5,243	*****	*****	*****	*****	2.98	*****	-2.41	*****	0.54 (0.05, 5.99)	0.618
ARBs (14-day gap)	5,333	*****	*****	*****	*****	5.39	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	3,101	*****	*****	*****	*****	4.4	*****	-2.21	*****	0.68 (0.09, 5.08)	0.707
ARBs (14-day gap)	37,460	*****	*****	*****	*****	6.61	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,993	*****	*****	*****	*****	7.33	*****	7.33	*****	-	-
ARBs (14-day gap)	1,993	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	3,058	*****	*****	*****	*****	4.46	*****	-2.48	*****	0.62 (0.06, 6.83)	0.696
ARBs (14-day gap)	3,789	*****	*****	*****	*****	6.93	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	2,361	*****	*****	*****	*****	5.3	*****	1.07	*****	1.29 (0.30, 5.45)	0.734
ARBs (14-day gap)	32,147	*****	*****	*****	*****	4.23	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,289	*****	*****	*****	*****	6.83	*****	6.83	*****	-	-
ARBs (14-day gap)	1,289	*****	*****	*****	*****	0	*****				

Table 23. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	2,333	*****	*****	*****	*****	5.37	*****	3.49	*****	2.88 (0.26, 31.78)	0.388
ARBs (14-day gap)	3,196	*****	*****	*****	*****	1.88	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	1,072	*****	*****	*****	*****	9.93	*****	5.76	*****	2.36 (0.54, 10.37)	0.257
ARBs (14-day gap)	17,235	*****	*****	*****	*****	4.18	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	303	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	303	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	1,058	*****	*****	*****	*****	10.05	*****	6.84	*****	3.03 (0.27, 33.45)	0.365
ARBs (14-day gap)	1,640	*****	*****	*****	*****	3.21	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	650	*****	*****	*****	*****	0	*****	-2.9	*****	-	-
ARBs (14-day gap)	11,241	*****	*****	*****	*****	2.9	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	115	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	115	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	643	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	1,001	*****	*****	*****	*****	0	*****				

Table 23. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Race: Pacific Islander											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	46	*****	*****	*****	*****	0	*****	-8.97	*****	-	-
ARBs (14-day gap)	478	*****	*****	*****	*****	8.97	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	31	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	31	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	31	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	31	*****	*****	*****	*****	0	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	69	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	1,590	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	29	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	29	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	65	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	111	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	43	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	446	*****	*****	*****	*****	0	*****				

Table 23. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	28	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	28	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	29	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	30	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	30	*****	*****	*****	*****	0	*****	-34.86	*****	-	-
ARBs (14-day gap)	359	*****	*****	*****	*****	34.86	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	13	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	13	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	18	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	23	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	27	*****	*****	*****	*****	0	*****	-17.55	*****	-	-
ARBs (14-day gap)	335	*****	*****	*****	*****	17.55	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	12	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	12	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	17	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	21	*****	*****	*****	*****	0	*****				

Table 23. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	15	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	194	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	12	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	14	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	138	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	12	*****	*****	*****	*****	0	*****				
Race: White											
Overall											
Site-Adjusted Analysis											
SV (14-day gap)	29,935	*****	*****	*****	*****	1.1	*****	-1.3	*****	0.42 (0.24, 0.76)	0.004
ARBs (14-day gap)	223,288	*****	*****	*****	*****	2.4	*****				

Table 23. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	29,757	*****	*****	*****	*****	1.03	*****	-1.18	*****	0.47 (0.19, 1.14)	0.096
ARBs (14-day gap)	29,757	*****	*****	*****	*****	2.21	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	29,757	*****	*****	*****	*****	1.11	*****	-0.97	*****	0.51 (0.26, 1.00)	0.051
ARBs (14-day gap)	29,757	*****	*****	*****	*****	2.08	*****				
0 - 30 Days											
Site-Adjusted Analysis											
SV (14-day gap)	29,935	*****	*****	*****	*****	1.26	*****	-3.54	*****	0.26 (0.08, 0.83)	0.023
ARBs (14-day gap)	223,288	*****	*****	*****	*****	4.8	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	29,757	*****	*****	*****	*****	1.31	*****	-2.61	*****	0.33 (0.09, 1.23)	0.099
ARBs (14-day gap)	29,757	*****	*****	*****	*****	3.92	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	29,757	*****	*****	*****	*****	1.27	*****	-2.52	*****	0.33 (0.09, 1.24)	0.101
ARBs (14-day gap)	29,757	*****	*****	*****	*****	3.79	*****				
31 - 60 Days											
Site-Adjusted Analysis											
SV (14-day gap)	27,322	*****	*****	*****	*****	1.62	*****	-1.19	*****	0.58 (0.18, 1.87)	0.36
ARBs (14-day gap)	209,796	*****	*****	*****	*****	2.81	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	25,245	*****	*****	*****	*****	1.3	*****	0.65	*****	2.00 (0.18, 22.06)	0.571
ARBs (14-day gap)	25,245	*****	*****	*****	*****	0.65	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	27,160	*****	*****	*****	*****	1.63	*****	-0.36	*****	0.82 (0.18, 3.66)	0.792
ARBs (14-day gap)	27,657	*****	*****	*****	*****	1.99	*****				

Table 23. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
61 - 90 Days											
Site-Adjusted Analysis											
SV (14-day gap)	18,222	*****	*****	*****	*****	1.46	*****	-0.72	*****	0.68 (0.16, 2.84)	0.592
ARBs (14-day gap)	165,220	*****	*****	*****	*****	2.18	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	13,131	*****	*****	*****	*****	1.07	*****	-2.14	*****	0.33 (0.03, 3.20)	0.341
ARBs (14-day gap)	13,131	*****	*****	*****	*****	3.21	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	18,107	*****	*****	*****	*****	1.47	*****	-0.33	*****	0.83 (0.14, 4.94)	0.833
ARBs (14-day gap)	21,598	*****	*****	*****	*****	1.8	*****				
91 - 180 Days											
Site-Adjusted Analysis											
SV (14-day gap)	14,999	*****	*****	*****	*****	1.14	*****	-0.55	*****	0.67 (0.21, 2.16)	0.505
ARBs (14-day gap)	146,951	*****	*****	*****	*****	1.69	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	9,524	*****	*****	*****	*****	0.79	*****	0	*****	1.00 (0.06, 15.99)	1
ARBs (14-day gap)	9,524	*****	*****	*****	*****	0.79	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	14,904	*****	*****	*****	*****	1.15	*****	-0.89	*****	0.56 (0.15, 2.18)	0.407
ARBs (14-day gap)	19,006	*****	*****	*****	*****	2.03	*****				
181 - 270 Days											
Site-Adjusted Analysis											
SV (14-day gap)	8,170	*****	*****	*****	*****	0	*****	-1.73	*****	-	-
ARBs (14-day gap)	92,144	*****	*****	*****	*****	1.73	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	3,108	*****	*****	*****	*****	0	*****	-1.99	*****	-	-
ARBs (14-day gap)	3,108	*****	*****	*****	*****	1.99	*****				

Table 23. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	8,117	*****	*****	*****	*****	0	*****	-1.31	*****	-	-
ARBs (14-day gap)	11,357	*****	*****	*****	*****	1.31	*****				
271 - 365 Days											
Site-Adjusted Analysis											
SV (14-day gap)	5,100	*****	*****	*****	*****	0.93	*****	-0.54	*****	0.65 (0.09, 4.80)	0.671
ARBs (14-day gap)	66,959	*****	*****	*****	*****	1.47	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV (14-day gap)	1,370	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs (14-day gap)	1,370	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV (14-day gap)	5,063	*****	*****	*****	*****	0.93	*****	-0.26	*****	0.80 (0.07, 8.78)	0.852
ARBs (14-day gap)	7,812	*****	*****	*****	*****	1.19	*****				

[1]Conditional analysis accounts for informative events and person-time.

[2]Data presented by a dash are unable to be calculated. This table may not use all data representations.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 24. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 7-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Site-Adjusted Analysis											
SV	41,998	*****	*****	*****	*****	1.11	*****	-5.8	*****	0.15 (0.09, 0.25)	<0.001
ACEI	695,012	*****	*****	*****	*****	6.91	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	41,998	*****	*****	*****	*****	1.5	*****	-9.97	*****	0.13 (0.07, 0.25)	<0.001
ACEI	41,998	*****	*****	*****	*****	11.48	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	41,998	*****	*****	*****	*****	1.11	*****	-6.09	*****	0.14 (0.08, 0.25)	<0.001
ACEI	41,998	*****	*****	*****	*****	7.2	*****				

[1]Conditional analysis accounts for informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 25. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 7-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Site-Adjusted Analysis											
SV	43,777	*****	*****	*****	*****	1.14	*****	-1.9	*****	0.35 (0.21, 0.58)	<0.001
ARBs	337,157	*****	*****	*****	*****	3.04	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	43,755	*****	*****	*****	*****	1.26	*****	-1.13	*****	0.53 (0.24, 1.13)	0.1
ARBs	43,755	*****	*****	*****	*****	2.39	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	43,755	*****	*****	*****	*****	1.14	*****	-1.13	*****	0.48 (0.27, 0.88)	0.017
ARBs	43,755	*****	*****	*****	*****	2.27	*****				

[1]Conditional analysis accounts for informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 26. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Site-Adjusted Analysis											
SV	41,998	*****	*****	*****	*****	0.6	*****	-1.4	*****	0.28 (0.15, 0.54)	<0.001
ACEI	695,012	*****	*****	*****	*****	2	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	41,998	*****	*****	*****	*****	0.68	*****	-2.04	*****	0.25 (0.10, 0.61)	0.002
ACEI	41,998	*****	*****	*****	*****	2.72	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	41,998	*****	*****	*****	*****	0.6	*****	-1.47	*****	0.28 (0.13, 0.58)	<0.001
ACEI	41,998	*****	*****	*****	*****	2.07	*****				

[1]Conditional analysis accounts for informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 27. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1)

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
No Angioedema (-183, -1)											
Site-Adjusted Analysis											
SV	41,941	*****	*****	*****	*****	0.53	*****	-1.39	*****	0.26 (0.13, 0.52)	<0.001
ACEI	694,148	*****	*****	*****	*****	1.93	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	41,930	*****	*****	*****	*****	0.57	*****	-2.16	*****	0.21 (0.08, 0.55)	0.001
ACEI	41,930	*****	*****	*****	*****	2.72	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	41,930	*****	*****	*****	*****	0.53	*****	-1.54	*****	0.25 (0.11, 0.53)	<0.001
ACEI	41,930	*****	*****	*****	*****	2.08	*****				
Angioedema (-183, -1)											
Site-Adjusted Analysis											
SV	57	*****	*****	*****	*****	44.8	*****	-30.56	*****	0.74 (0.10, 5.47)	0.767
ACEI	864	*****	*****	*****	*****	75.37	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	42	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI	42	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	42	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI	42	*****	*****	*****	*****	0	*****				

[1]Conditional analysis accounts for informative events and person-time.

[2]Data presented by a dash are unable to be calculated. This table may not use all data representations.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 28. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (ever, -1)

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No Angioedema (ever, -1)											
Site-Adjusted Analysis											
SV	41,427	*****	*****	*****	*****	0.54	*****	-1.21	*****	0.29 (0.15, 0.59)	<0.001
ACEI	687,692	*****	*****	*****	*****	1.75	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	41,416	*****	*****	*****	*****	0.57	*****	-1.95	*****	0.23 (0.09, 0.60)	0.003
ACEI	41,416	*****	*****	*****	*****	2.53	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	41,416	*****	*****	*****	*****	0.54	*****	-1.44	*****	0.26 (0.12, 0.57)	<0.001
ACEI	41,416	*****	*****	*****	*****	1.98	*****				
Angioedema (ever, -1)											
Site-Adjusted Analysis											
SV	571	*****	*****	*****	*****	4.77	*****	-23.95	*****	0.17 (0.02, 1.19)	0.074
ACEI	7,320	*****	*****	*****	*****	28.72	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	437	*****	*****	*****	*****	11.58	*****	-11.58	*****	0.50 (0.05, 5.51)	0.571
ACEI	437	*****	*****	*****	*****	23.17	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	437	*****	*****	*****	*****	6.31	*****	-5.35	*****	0.50 (0.05, 5.53)	0.573
ACEI	437	*****	*****	*****	*****	11.66	*****				

[1]Conditional analysis accounts for informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 29. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Serious Allergies

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No Serious Allergies											
Site-Adjusted Analysis											
SV	36,314	*****	*****	*****	*****	0.38	*****	-1.47	*****	0.19 (0.08, 0.46)	<0.001
ACEI	584,032	*****	*****	*****	*****	1.85	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	36,159	*****	*****	*****	*****	0.52	*****	-1.94	*****	0.21 (0.07, 0.62)	0.005
ACEI	36,159	*****	*****	*****	*****	2.45	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	36,159	*****	*****	*****	*****	0.38	*****	-1.52	*****	0.19 (0.07, 0.49)	<0.001
ACEI	36,159	*****	*****	*****	*****	1.9	*****				
Serious Allergies											
Site-Adjusted Analysis											
SV	5,684	*****	*****	*****	*****	2.14	*****	-0.78	*****	0.70 (0.26, 1.90)	0.489
ACEI	110,980	*****	*****	*****	*****	2.92	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	5,545	*****	*****	*****	*****	1.92	*****	-1.92	*****	0.50 (0.09, 2.73)	0.423
ACEI	5,545	*****	*****	*****	*****	3.84	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	5,545	*****	*****	*****	*****	2.19	*****	-1.26	*****	0.63 (0.18, 2.16)	0.465
ACEI	5,545	*****	*****	*****	*****	3.45	*****				

[1]Conditional analysis accounts for informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 30. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Sex

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Sex: Male											
Site-Adjusted Analysis											
SV	27,131	*****	*****	*****	*****	0.31	*****	-1.26	*****	0.18 (0.06, 0.57)	0.003
ACEI	353,126	*****	*****	*****	*****	1.57	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	26,865	*****	*****	*****	*****	0.53	*****	-2.28	*****	0.19 (0.05, 0.64)	0.008
ACEI	26,865	*****	*****	*****	*****	2.81	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	26,865	*****	*****	*****	*****	0.31	*****	-1.52	*****	0.16 (0.05, 0.54)	0.003
ACEI	26,865	*****	*****	*****	*****	1.83	*****				
Sex: Female											
Site-Adjusted Analysis											
SV	14,867	*****	*****	*****	*****	1.13	*****	-1.32	*****	0.44 (0.20, 0.98)	0.045
ACEI	341,886	*****	*****	*****	*****	2.45	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	14,820	*****	*****	*****	*****	0.97	*****	-1.62	*****	0.38 (0.10, 1.41)	0.147
ACEI	14,820	*****	*****	*****	*****	2.59	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	14,820	*****	*****	*****	*****	1.13	*****	-1.25	*****	0.47 (0.18, 1.21)	0.117
ACEI	14,820	*****	*****	*****	*****	2.38	*****				

[1]Conditional analysis accounts for informative events and person-time.

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Table 31. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Age Group

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Age Group: 18-44 years											
Site-Adjusted Analysis											
SV	1,538	*****	*****	*****	*****	0	*****	-3.36	*****	-	-
ACEI	21,594	*****	*****	*****	*****	3.36	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	1,408	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI	1,408	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	1,408	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI	1,408	*****	*****	*****	*****	0	*****				
Age Group: 45-54 years											
Site-Adjusted Analysis											
SV	2,863	*****	*****	*****	*****	0	*****	-2.79	*****	-	-
ACEI	45,064	*****	*****	*****	*****	2.79	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	2,789	*****	*****	*****	*****	0	*****	-5.52	*****	-	-
ACEI	2,789	*****	*****	*****	*****	5.52	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	2,789	*****	*****	*****	*****	0	*****	-2.87	*****	-	-
ACEI	2,789	*****	*****	*****	*****	2.87	*****				
Age Group: 55-64 years											
Site-Adjusted Analysis											
SV	5,807	*****	*****	*****	*****	1.48	*****	-1.77	*****	0.47 (0.15, 1.46)	0.191
ACEI	97,267	*****	*****	*****	*****	3.25	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	5,692	*****	*****	*****	*****	1.76	*****	-3.51	*****	0.33 (0.07, 1.65)	0.178
ACEI	5,692	*****	*****	*****	*****	5.27	*****				

Table 31. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Age Group

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	5,692	*****	*****	*****	*****	1.51	*****	-3.07	*****	0.32 (0.09, 1.18)	0.087
ACEI	5,692	*****	*****	*****	*****	4.58	*****				
Age Group: ≥65 years											
Site-Adjusted Analysis											
SV	31,790	*****	*****	*****	*****	0.52	*****	-1.17	*****	0.29 (0.13, 0.64)	0.002
ACEI	531,087	*****	*****	*****	*****	1.69	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	31,082	*****	*****	*****	*****	0.6	*****	-1.2	*****	0.33 (0.11, 1.03)	0.057
ACEI	31,082	*****	*****	*****	*****	1.8	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	31,082	*****	*****	*****	*****	0.53	*****	-1.03	*****	0.33 (0.13, 0.82)	0.017
ACEI	31,082	*****	*****	*****	*****	1.56	*****				

[1]Conditional analysis accounts for informative events and person-time.

[2]Data presented by a dash are unable to be calculated. This table may not use all data representations.

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Table 32. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Race

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Race: Unknown											
Site-Adjusted Analysis											
SV	7,029	*****	*****	*****	*****	0	*****	-1.93	*****	-	-
ACEI	99,645	*****	*****	*****	*****	1.93	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	6,992	*****	*****	*****	*****	0	*****	-3.47	*****	-	-
ACEI	6,992	*****	*****	*****	*****	3.47	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	6,992	*****	*****	*****	*****	0	*****	-3.05	*****	-	-
ACEI	6,992	*****	*****	*****	*****	3.05	*****				
Race: American Indian											
Site-Adjusted Analysis											
SV	132	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI	4,529	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	123	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI	123	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	123	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI	123	*****	*****	*****	*****	0	*****				
Race: Asian											
Site-Adjusted Analysis											
SV	519	*****	*****	*****	*****	0	*****	-0.98	*****	-	-
ACEI	7,874	*****	*****	*****	*****	0.98	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	495	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI	495	*****	*****	*****	*****	0	*****				

Table 32. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Race

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	495	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI	495	*****	*****	*****	*****	0	*****				
Race: Black											
Site-Adjusted Analysis											
SV	5,566	*****	*****	*****	*****	2.99	*****	-4.36	*****	0.38 (0.16, 0.93)	0.033
ACEI	92,129	*****	*****	*****	*****	7.35	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	5,479	*****	*****	*****	*****	2.03	*****	-6.1	*****	0.25 (0.05, 1.18)	0.08
ACEI	5,479	*****	*****	*****	*****	8.14	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	5,479	*****	*****	*****	*****	3.04	*****	-3.14	*****	0.47 (0.17, 1.34)	0.157
ACEI	5,479	*****	*****	*****	*****	6.18	*****				
Race: Pacific Islander											
Site-Adjusted Analysis											
SV	46	*****	*****	*****	*****	0	*****	-3.59	*****	-	-
ACEI	741	*****	*****	*****	*****	3.59	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	39	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI	39	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	39	*****	*****	*****	*****	0	*****	0	*****	-	-
ACEI	39	*****	*****	*****	*****	0	*****				
Race: White											
Site-Adjusted Analysis											
SV	28,706	*****	*****	*****	*****	0.38	*****	-0.83	*****	0.29 (0.11, 0.79)	0.015
ACEI	490,094	*****	*****	*****	*****	1.21	*****				

Table 32. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Race

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	28,638	*****	*****	*****	*****	0.48	*****	-1.11	*****	0.30 (0.08, 1.09)	0.067
ACEI	28,638	*****	*****	*****	*****	1.59	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	28,638	*****	*****	*****	*****	0.38	*****	-0.87	*****	0.29 (0.10, 0.88)	0.028
ACEI	28,638	*****	*****	*****	*****	1.25	*****				

[1]Conditional analysis accounts for informative events and person-time.

[2]Data presented by a dash are unable to be calculated. This table may not use all data representations.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 33. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Site-Adjusted Analysis											
SV	43,777	*****	*****	*****	*****	0.58	*****	-0.32	*****	0.61 (0.31, 1.20)	0.15
ARBs	337,157	*****	*****	*****	*****	0.9	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	43,755	*****	*****	*****	*****	0.63	*****	-0.1	*****	0.86 (0.29, 2.55)	0.782
ARBs	43,755	*****	*****	*****	*****	0.73	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	43,755	*****	*****	*****	*****	0.58	*****	-0.05	*****	0.90 (0.38, 2.13)	0.802
ARBs	43,755	*****	*****	*****	*****	0.63	*****				

[1]Conditional analysis accounts for informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 34. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1)

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
No Angioedema (-183, -1)											
Site-Adjusted Analysis											
SV	43,717	*****	*****	*****	*****	0.51	*****	-0.26	*****	0.63 (0.31, 1.29)	0.208
ARBs	336,332	*****	*****	*****	*****	0.78	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	43,685	*****	*****	*****	*****	0.52	*****	-0.21	*****	0.71 (0.23, 2.25)	0.566
ARBs	43,685	*****	*****	*****	*****	0.73	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	43,685	*****	*****	*****	*****	0.51	*****	-0.12	*****	0.80 (0.33, 1.97)	0.631
ARBs	43,685	*****	*****	*****	*****	0.63	*****				
Angioedema (-183, -1)											
Site-Adjusted Analysis											
SV	60	*****	*****	*****	*****	40.67	*****	-11.71	*****	0.77 (0.10, 5.77)	0.8
ARBs	825	*****	*****	*****	*****	52.37	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	48	*****	*****	*****	*****	90.09	*****	90.09	*****	-	-
ARBs	48	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	48	*****	*****	*****	*****	48.19	*****	48.19	*****	-	-
ARBs	48	*****	*****	*****	*****	0	*****				

[1]Conditional analysis accounts for informative events and person-time.

[2]Data presented by a dash are unable to be calculated. This table may not use all data representations.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 35. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (ever, -1)

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No Angioedema (ever, -1)											
Site-Adjusted Analysis											
SV	43,178	*****	*****	*****	*****	0.52	*****	-0.16	*****	0.73 (0.36, 1.51)	0.401
ARBs	329,798	*****	*****	*****	*****	0.68	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	42,832	*****	*****	*****	*****	0.53	*****	0	*****	1.00 (0.29, 3.45)	1
ARBs	42,832	*****	*****	*****	*****	0.53	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	42,832	*****	*****	*****	*****	0.52	*****	-0.01	*****	0.97 (0.38, 2.47)	0.954
ARBs	42,832	*****	*****	*****	*****	0.54	*****				
Angioedema (ever, -1)											
Site-Adjusted Analysis											
SV	599	*****	*****	*****	*****	4.46	*****	-6.24	*****	0.38 (0.05, 2.79)	0.344
ARBs	7,359	*****	*****	*****	*****	10.71	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	591	*****	*****	*****	*****	7.29	*****	0	*****	1.00 (0.06, 15.99)	1
ARBs	591	*****	*****	*****	*****	7.29	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	591	220.75	*****	*****	*****	*****	*****	0.77	*****	1.06 (0.07, 17.03)	0.965
ARBs	591	266.21	*****	*****	*****	*****	*****				

[1]Conditional analysis accounts for informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 36. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Serious Allergies

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
No Serious Allergies											
Site-Adjusted Analysis											
SV	37,847	*****	*****	*****	*****	0.37	*****	-0.32	*****	0.50 (0.20, 1.23)	0.13
ARBs	282,725	*****	*****	*****	*****	0.69	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	37,637	*****	*****	*****	*****	0.36	*****	-0.24	*****	0.60 (0.14, 2.51)	0.484
ARBs	37,637	*****	*****	*****	*****	0.6	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	37,637	*****	*****	*****	*****	0.37	*****	-0.24	*****	0.58 (0.20, 1.71)	0.325
ARBs	37,637	*****	*****	*****	*****	0.6	*****				
Serious Allergies											
Site-Adjusted Analysis											
SV	5,930	*****	*****	*****	*****	2.05	*****	-0.06	*****	0.93 (0.34, 2.59)	0.894
ARBs	54,432	*****	*****	*****	*****	2.11	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	5,774	*****	*****	*****	*****	1.77	*****	1.77	*****	-	-
ARBs	5,774	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	5,774	*****	*****	*****	*****	2.11	*****	1.24	*****	2.55 (0.47, 13.98)	0.281
ARBs	5,774	*****	*****	*****	*****	0.87	*****				

[1]Conditional analysis accounts for informative events and person-time.

[2]Data presented by a dash are unable to be calculated. This table may not use all data representations.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 37. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Sex

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Sex: Male											
Site-Adjusted Analysis											
SV	28,311	*****	*****	*****	*****	0.3	*****	-0.6	*****	0.31 (0.10, 1.00)	0.05
ARBs	149,252	*****	*****	*****	*****	0.9	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	27,999	*****	*****	*****	*****	0.33	*****	-0.33	*****	0.50 (0.09, 2.73)	0.423
ARBs	27,999	*****	*****	*****	*****	0.66	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	27,999	*****	*****	*****	*****	0.3	*****	-0.53	*****	0.36 (0.10, 1.31)	0.12
ARBs	27,999	*****	*****	*****	*****	0.83	*****				
Sex: Female											
Site-Adjusted Analysis											
SV	15,466	*****	*****	*****	*****	1.09	*****	0.2	*****	1.15 (0.50, 2.64)	0.74
ARBs	187,905	*****	*****	*****	*****	0.89	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	15,267	*****	*****	*****	*****	0.88	*****	0.29	*****	1.50 (0.25, 8.98)	0.657
ARBs	15,267	*****	*****	*****	*****	0.59	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	15,267	*****	*****	*****	*****	1.1	*****	0.8	*****	3.56 (0.72, 17.70)	0.12
ARBs	15,267	*****	*****	*****	*****	0.3	*****				

[1]Conditional analysis accounts for informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 38. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Age Group

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-44 years											
Site-Adjusted Analysis											
SV	1,634	*****	*****	*****	*****	0	*****	-2.74	*****	-	-
ARBs	8,500	*****	*****	*****	*****	2.74	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	1,448	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs	1,448	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	1,448	*****	*****	*****	*****	0	*****	-2.13	*****	-	-
ARBs	1,448	*****	*****	*****	*****	2.13	*****				
Age Group: 45-54 years											
Site-Adjusted Analysis											
SV	3,068	*****	*****	*****	*****	0	*****	-2.01	*****	-	-
ARBs	18,297	*****	*****	*****	*****	2.01	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	2,938	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs	2,938	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	2,938	*****	*****	*****	*****	0	*****	-0.93	*****	-	-
ARBs	2,938	*****	*****	*****	*****	0.93	*****				
Age Group: 55-64 years											
Site-Adjusted Analysis											
SV	6,120	*****	*****	*****	*****	1.41	*****	-0.5	*****	0.81 (0.25, 2.66)	0.732
ARBs	40,556	*****	*****	*****	*****	1.91	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	5,994	*****	*****	*****	*****	2.43	*****	2.43	*****	-	-
ARBs	5,994	*****	*****	*****	*****	0	*****				

Table 38. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Age Group

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	5,994	*****	*****	*****	*****	1.44	*****	1.02	*****	3.59 (0.37, 34.57)	0.269
ARBs	5,994	*****	*****	*****	*****	0.42	*****				
Age Group: ≥65 years											
Site-Adjusted Analysis											
SV	32,955	*****	*****	*****	*****	0.51	*****	-0.16	*****	0.69 (0.30, 1.58)	0.377
ARBs	269,804	*****	*****	*****	*****	0.66	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	32,649	*****	*****	*****	*****	0.54	*****	-0.27	*****	0.67 (0.19, 2.36)	0.53
ARBs	32,649	*****	*****	*****	*****	0.81	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	32,649	*****	*****	*****	*****	0.43	*****	-0.18	*****	0.66 (0.22, 1.96)	0.451
ARBs	32,649	*****	*****	*****	*****	0.61	*****				

[1]Conditional analysis accounts for informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 39. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Race

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Race: Unknown											
Site-Adjusted Analysis											
SV	7,289	*****	*****	*****	*****	0	*****	-0.63	*****	-	-
ARBs	47,812	*****	*****	*****	*****	0.63	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	7,159	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs	7,159	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	7,159	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs	7,159	*****	*****	*****	*****	0	*****				
Race: American Indian											
Site-Adjusted Analysis											
SV	143	*****	*****	*****	*****	0	*****	-1.36	*****	-	-
ARBs	1,947	*****	*****	*****	*****	1.36	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	138	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs	138	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	138	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs	138	*****	*****	*****	*****	0	*****				
Race: Asian											
Site-Adjusted Analysis											
SV	511	*****	*****	*****	*****	0	*****	-0.54	*****	-	-
ARBs	7,817	*****	*****	*****	*****	0.54	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	484	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs	484	*****	*****	*****	*****	0	*****				

Table 39. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Race

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	484	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs	484	*****	*****	*****	*****	0	*****				
Race: Black											
Site-Adjusted Analysis											
SV	5,853	*****	*****	*****	*****	2.86	*****	0.07	*****	0.94 (0.38, 2.34)	0.892
ARBs	55,815	*****	*****	*****	*****	2.79	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	5,765	*****	*****	*****	*****	3.76	*****	3.76	*****	-	-
ARBs	5,765	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	5,765	*****	*****	*****	*****	2.9	*****	1.98	*****	3.08 (0.60, 15.94)	0.18
ARBs	5,765	*****	*****	*****	*****	0.92	*****				
Race: Pacific Islander											
Site-Adjusted Analysis											
SV	46	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs	478	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	31	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs	31	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	31	*****	*****	*****	*****	0	*****	0	*****	-	-
ARBs	31	*****	*****	*****	*****	0	*****				
Race: White											
Site-Adjusted Analysis											
SV	29,935	*****	*****	*****	*****	0.37	*****	-0.2	*****	0.60 (0.22, 1.64)	0.316
ARBs	223,288	*****	*****	*****	*****	0.57	*****				

Table 39. Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Race

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)[2]	Wald P-Value[2]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
SV	29,757	*****	*****	*****	*****	0.29	*****	-0.44	*****	0.40 (0.08, 2.06)	0.273
ARBs	29,757	*****	*****	*****	*****	0.74	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	29,757	*****	*****	*****	*****	0.37	*****	-0.37	*****	0.47 (0.15, 1.51)	0.208
ARBs	29,757	*****	*****	*****	*****	0.74	*****				

[1]Conditional analysis accounts for informative events and person-time.

[2]Data presented by a dash are unable to be calculated. This table may not use all data representations.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Figure 1a. Histograms of Propensity Score (PS) Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, Aggregated

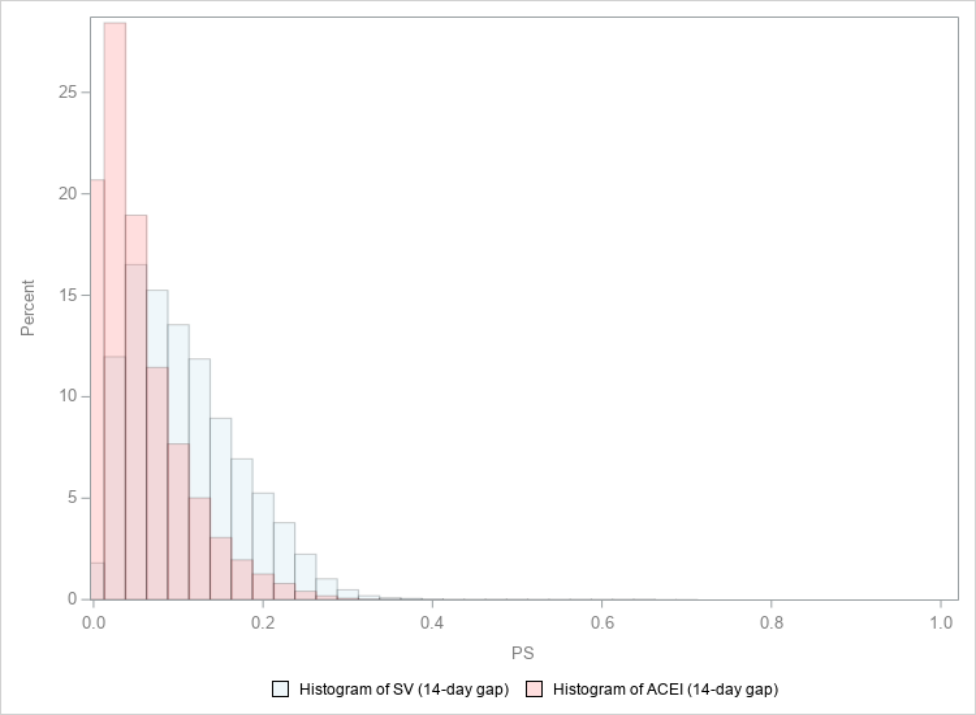
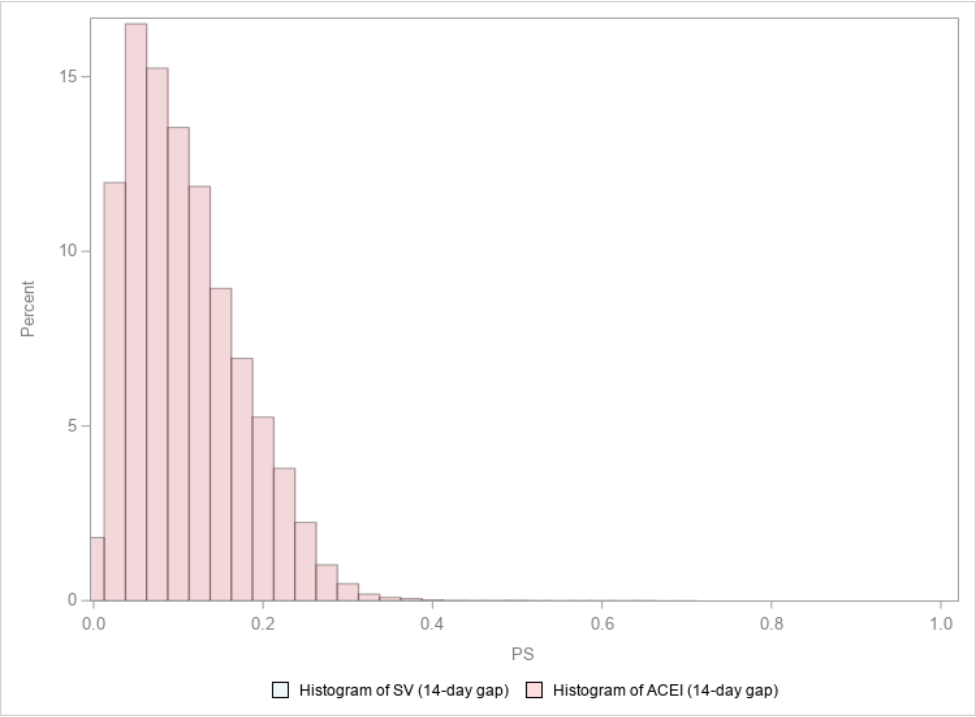


Figure 1b. Histograms of Propensity Score (PS) Fixed Ratio 1:1 Matched Cohort, Matched Caliper = 0.05 Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap



Figures 2a. Histograms of Propensity Score (PS) Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin II Receptor Blockers (ARBs), 14-day gap, Aggregated

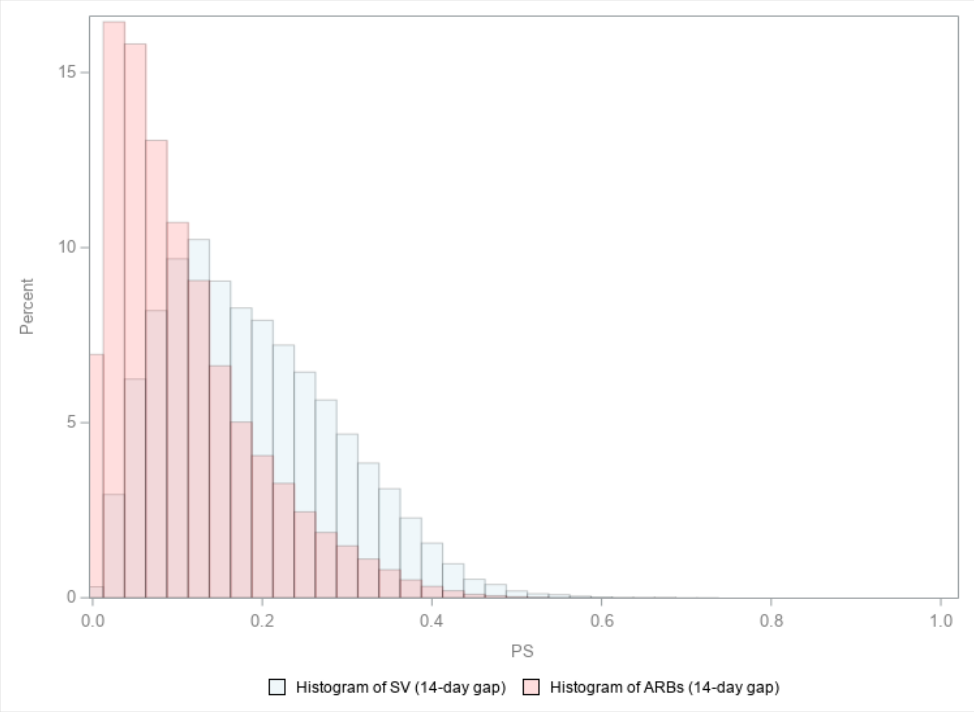
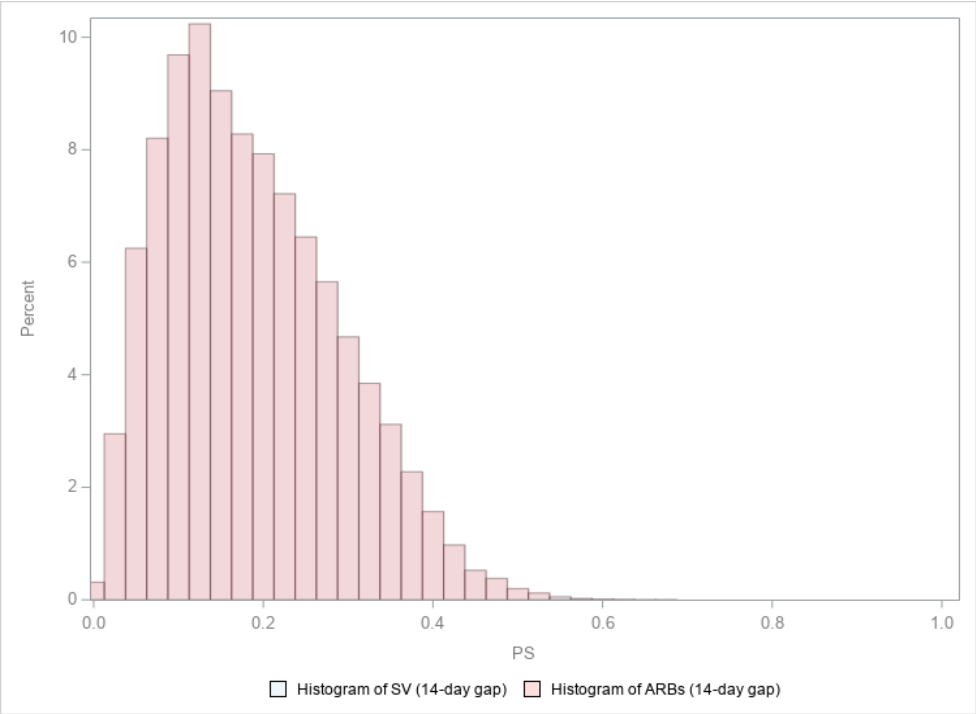


Figure 2b. Histograms of Propensity Score (PS) Fixed Ratio 1:1 Matched Cohort, Matched Caliper = 0.05 Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin II Receptor Blockers (ARBs), 14-Day Gap



Figures 3a. Histograms of Propensity Score (PS) Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin-Converting Enzyme Inhibitors (ACEI), 7-Day Gap, Aggregated

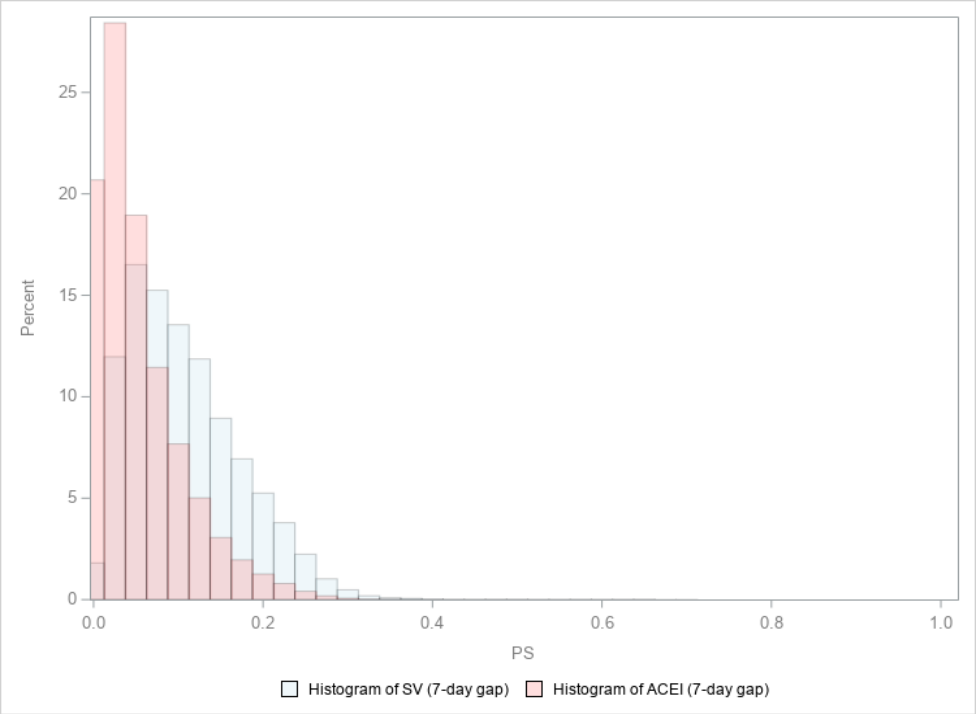
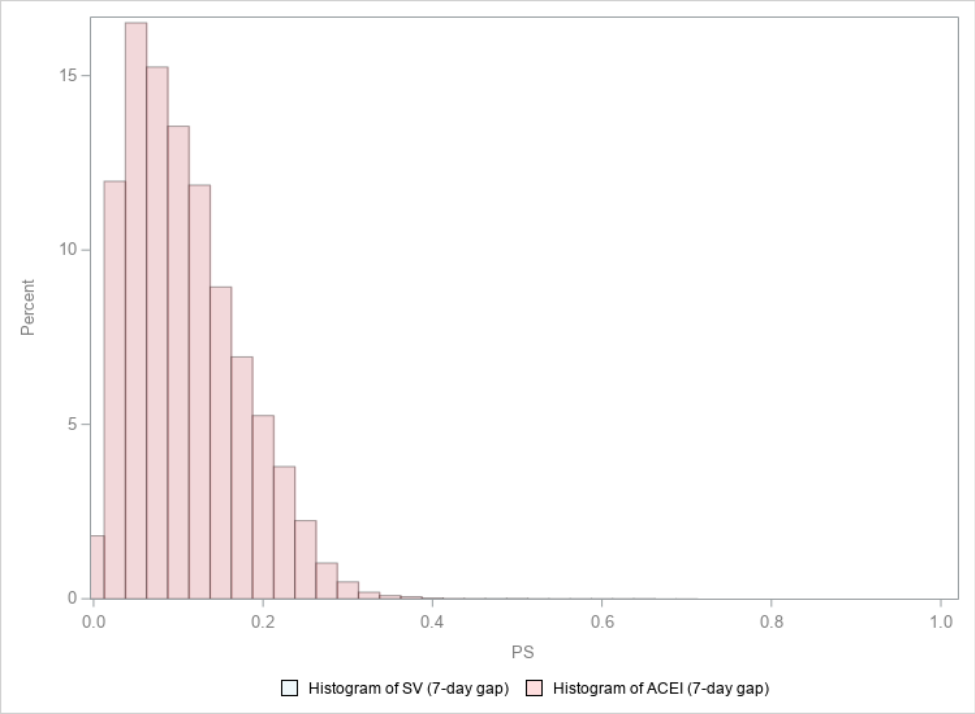


Figure 3b. Histograms of Propensity Score (PS) Fixed Ratio 1:1 Matched Cohort, Matched Caliper = 0.05 Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin-Converting Enzyme Inhibitors (ACEI), 7-Day Gap



Figures 4a. Histograms of Propensity Score (PS) Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin II Receptor Blockers (ARBs), 7-day gap, Aggregated

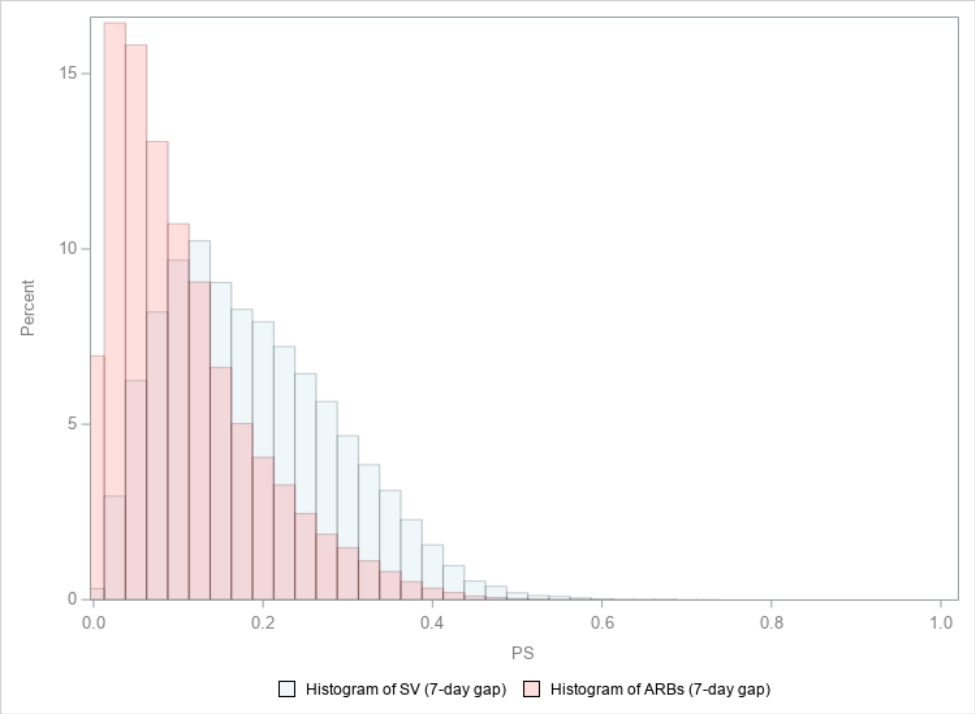


Figure 4b. Histograms of Propensity Score (PS) Fixed Ratio 1:1 Matched Cohort, Matched Caliper = 0.05 Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin II Receptor Blockers (ARBs), 7-Day Gap

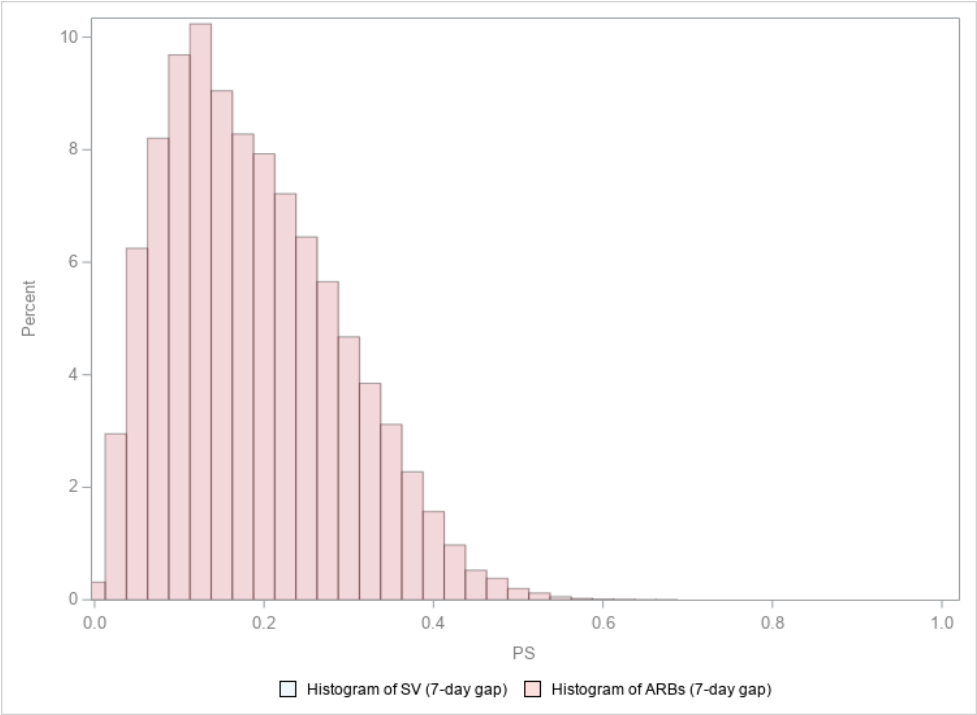


Figure 5. Kaplan Meier Survival Curves for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema

Kaplan Meier Survival Curves of Events and Followup Time for Risk of Angioedema, Unconditional Propensity Score (PS) Adjusted Matched Cohort.

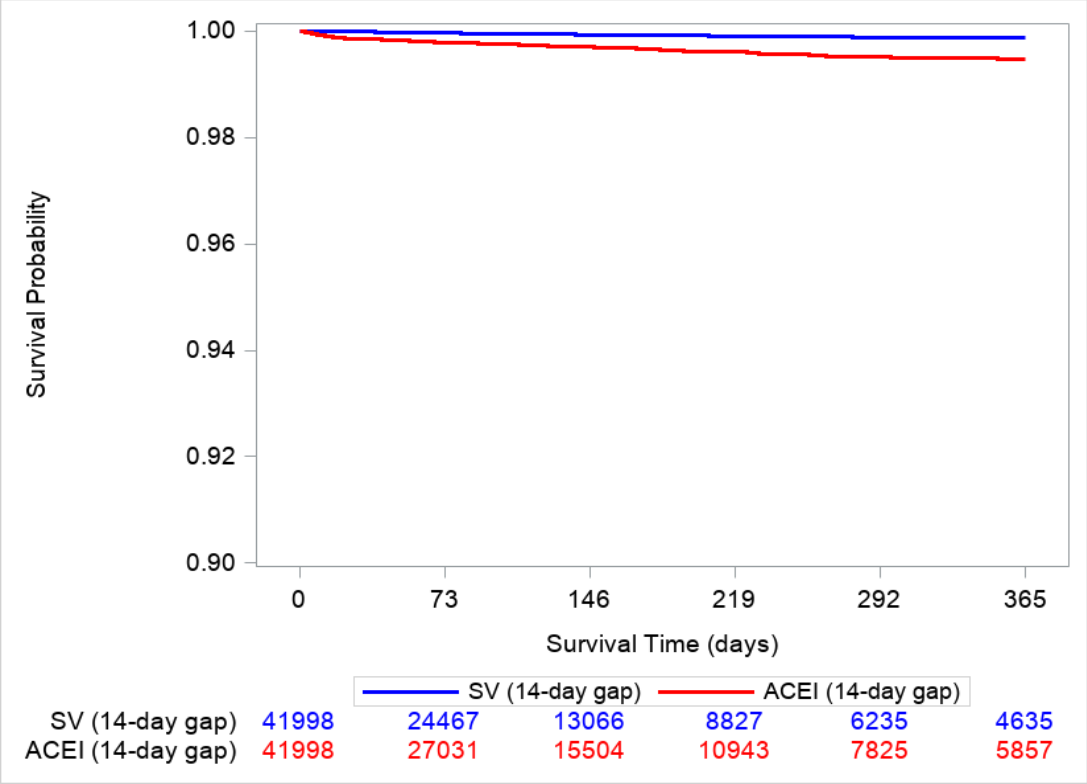


Figure 6. Kaplan Meier Survival Curves for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema

Kaplan Meier Survival Curves of Events and Followup Time for Risk of Angioedema, Unconditional Propensity Score (PS) Adjusted Matched Cohort.

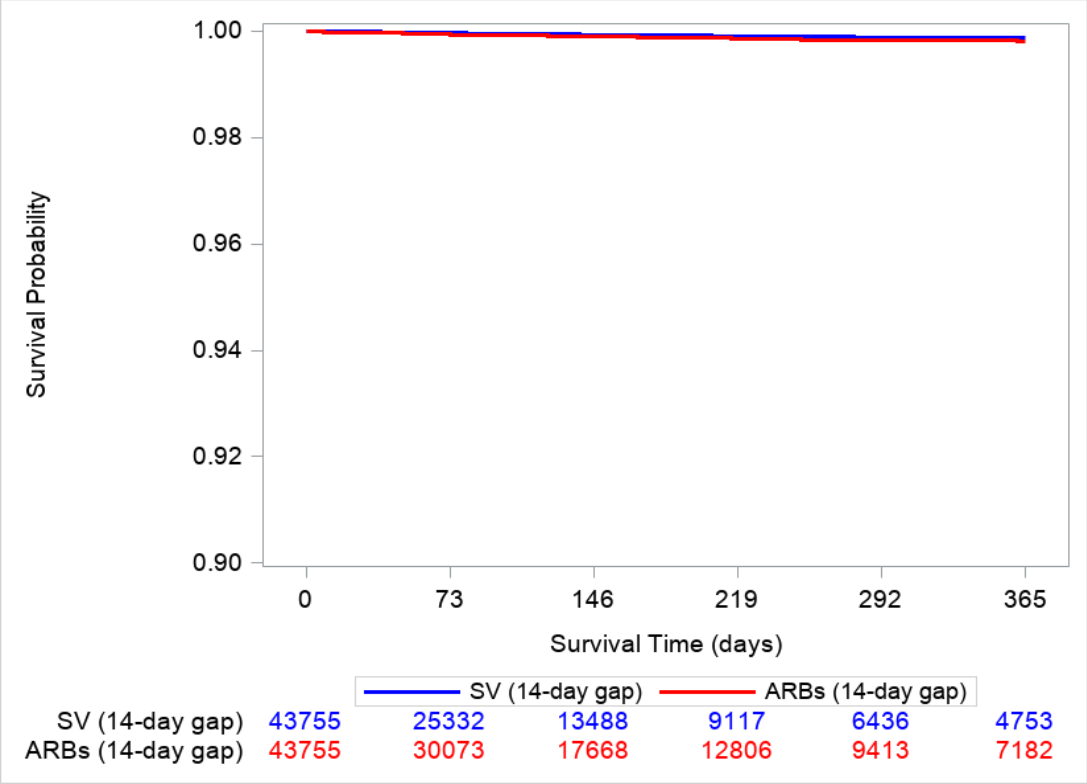


Figure 7. Kaplan Meier Survival Curves for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 7-Day Gap, and Risk of Angioedema

Kaplan Meier Survival Curves of Events and Followup Time for Risk of Angioedema, Unconditional Propensity Score (PS) Adjusted Matched Cohort.

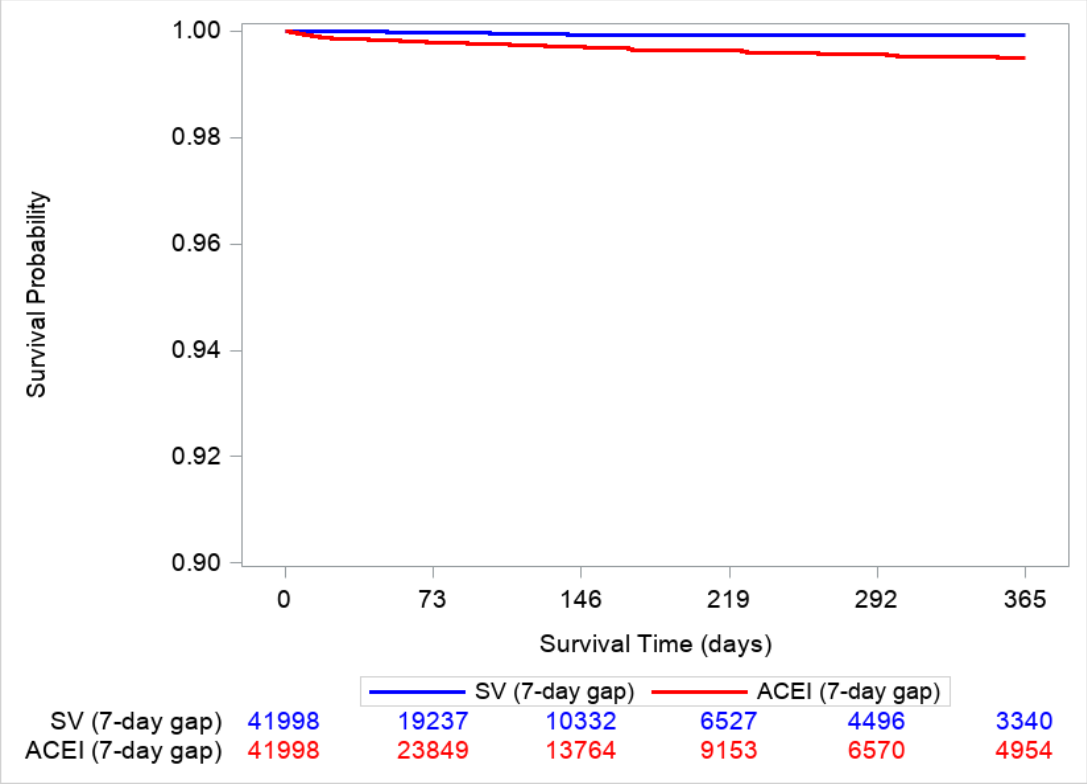


Figure 8. Kaplan Meier Survival Curves for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 7-Day Gap, and Risk of Angioedema

Kaplan Meier Survival Curves of Events and Followup Time for Risk of Angioedema, Unconditional Propensity Score (PS) Adjusted Matched Cohort.

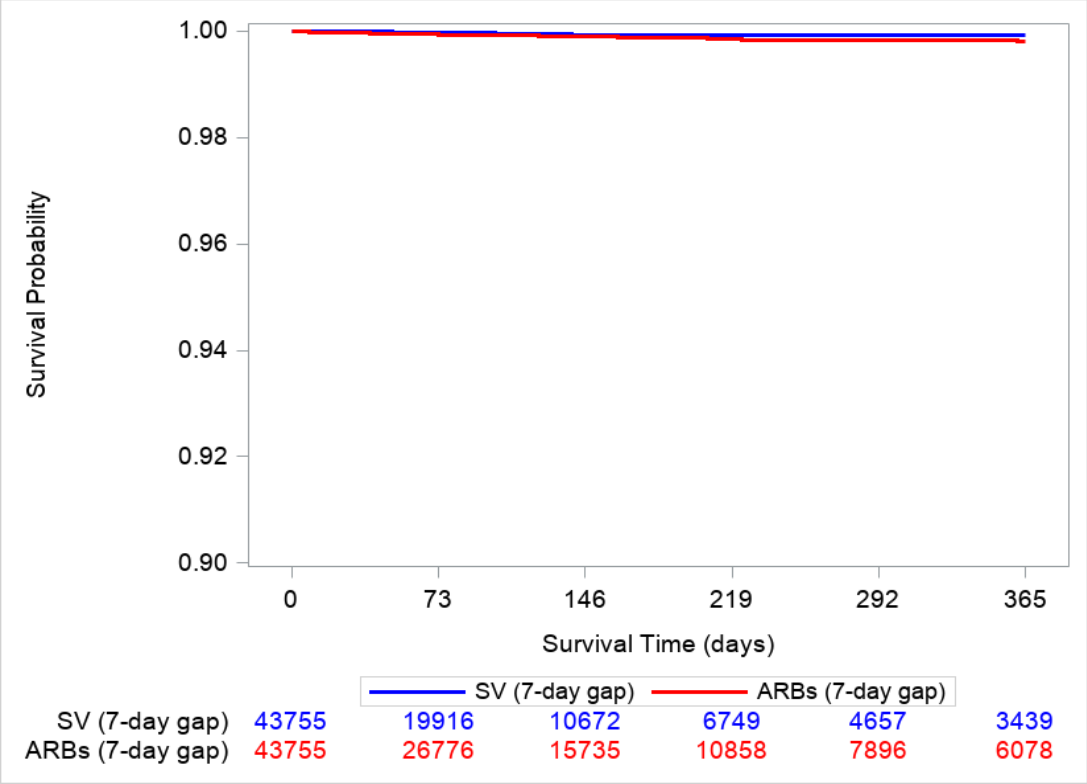


Figure 9. Kaplan Meier Survival Curves for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Serious Angioedema

Kaplan Meier Survival Curves of Events and Followup Time for Risk of Serious Angioedema, Unconditional Propensity Score (PS) Adjusted Matched Cohort.

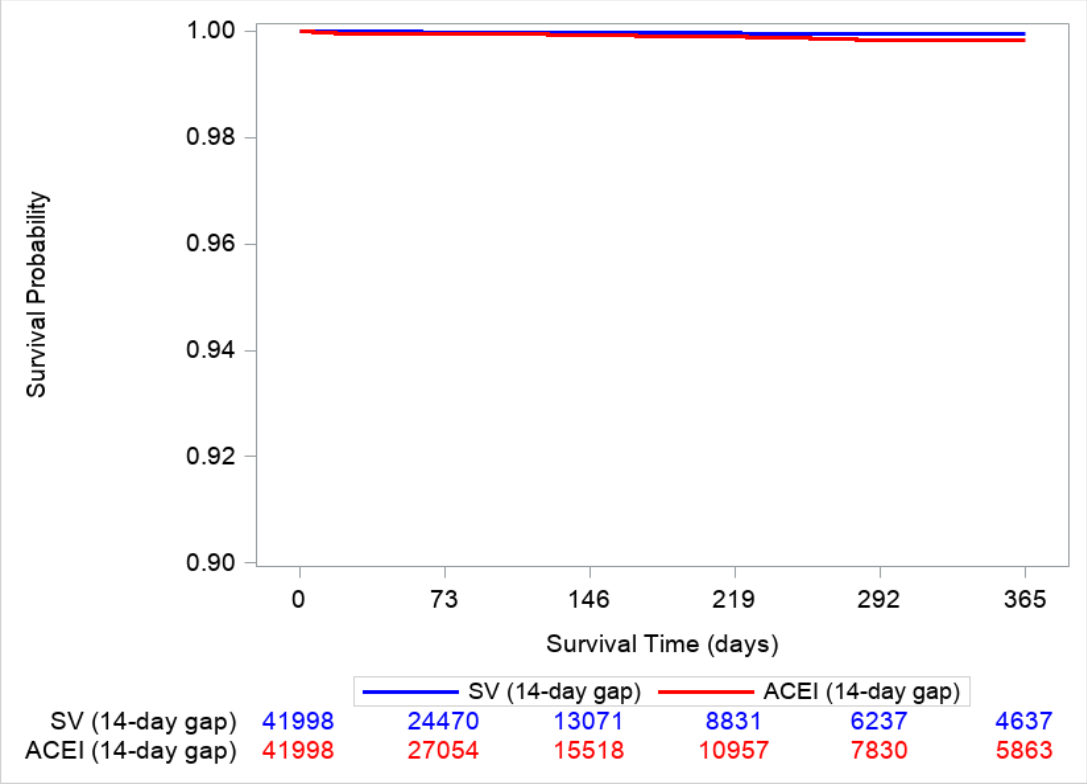


Figure 10. Kaplan Meier Survival Curves for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Serious Angioedema

Kaplan Meier Survival Curves of Events and Followup Time for Risk of Serious Angioedema, Unconditional Propensity Score (PS) Adjusted Matched Cohort.

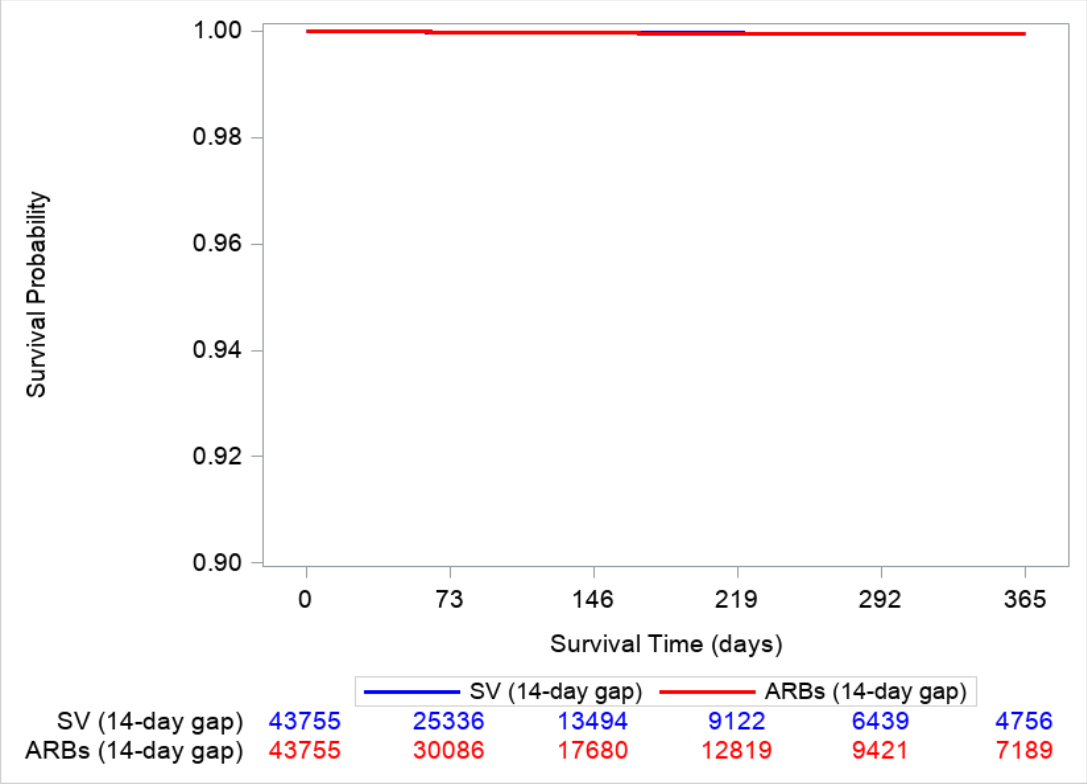


Figure 11. Kaplan Meier Survival Curves for Risk of Angioedema, Sacubitril/Valsartan (SV) (14-day gap) and Angiotensin-Converting Enzyme Inhibitors (ACEI) (14-day gap)

Kaplan Meier Survival Curves of Events and Followup Time for Risk of Angioedema, Unconditional Propensity Score Adjusted Matched Cohort, No Baseline Angioedema (-183, -1)

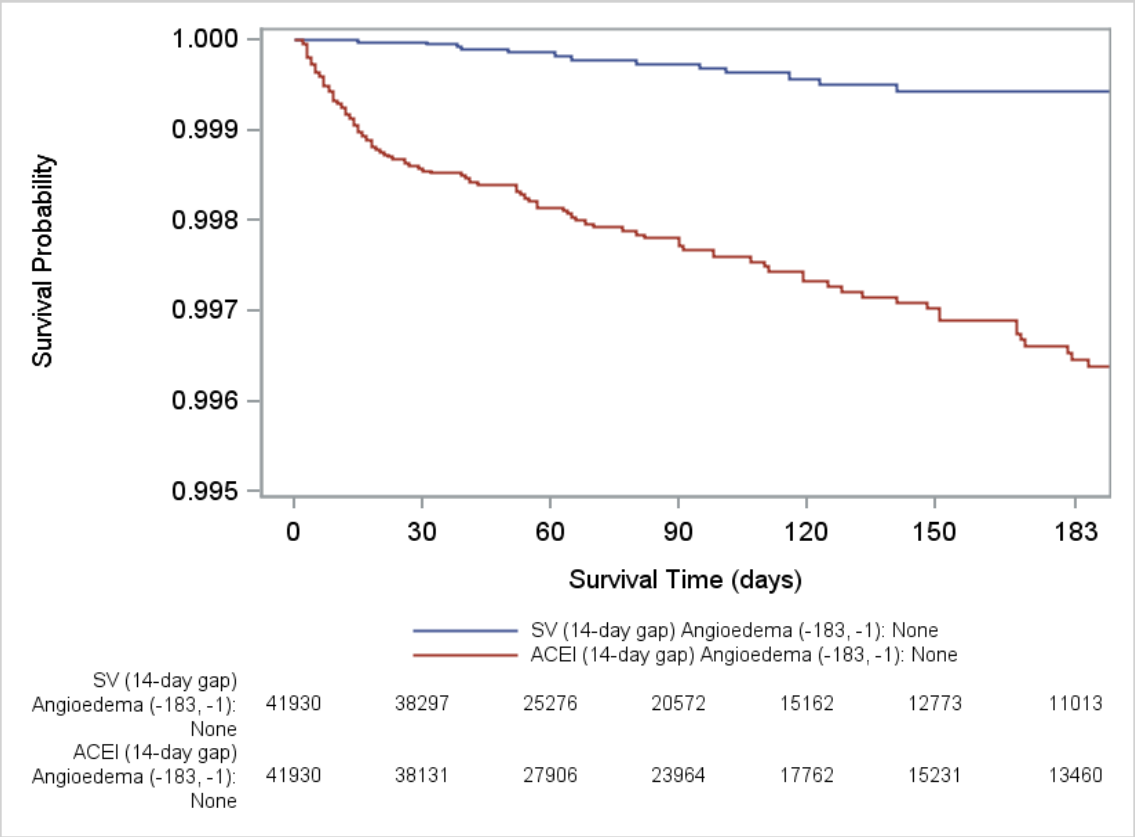
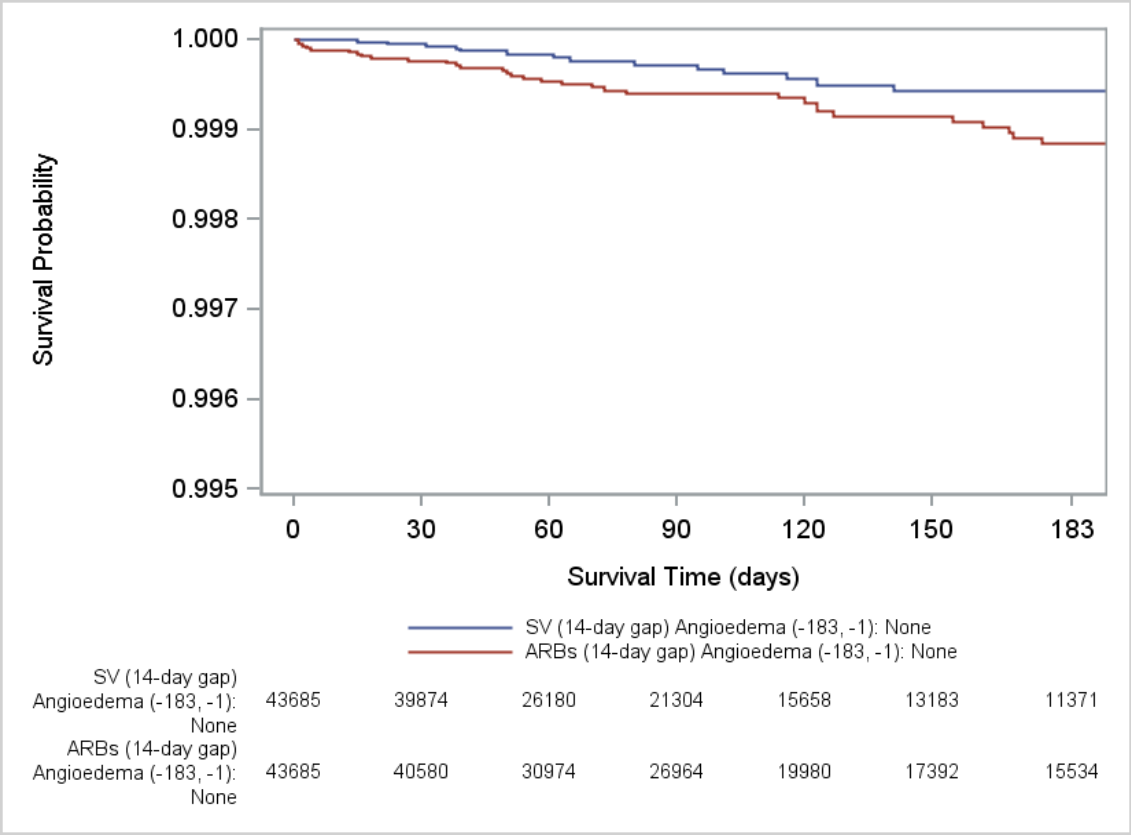


Figure 12. Kaplan Meier Survival Curves for Risk of Angioedema, Sacubitril/Valsartan (SV) (14-day gap) and Angiotensin II Receptor Blockers (ARBs) (14-day gap)

Kaplan Meier Survival Curves of Events and Followup Time for Risk of Angioedema, Unconditional Propensity Score Adjusted Matched Cohort, No Baseline Angioedema (-183, -1)



Appendix A: Start and End Dates for Each Data Partner up to Request End Date (02/29/2020)

Masked ID	DP Start Date	DP End Date[1]
DP01	06/01/2007	10/31/2019
DP02	01/01/2008	12/31/2019
DP03	01/01/2010	12/31/2019
DP04	01/01/2008	02/29/2020
DP05	01/01/2006	01/31/2020

[1] End Date represents the earlier of: (1) query end date, or (2) most recent year-month of data for which all of a Data Partner's data tables (enrollment, dispensing, etc.) have at least 80% of the record count relative to the prior month.

Appendix B. Generic and Brand Names of Medical Products Used to Define Exposures in this Request

Generic Name	Brand Name
Angiotensin-Converting Enzyme Inhibitors (ACEI)	
AMLODIPINE BESYLATE/BENAZEPRIL HCL	Lotrel
AMLODIPINE BESYLATE/BENAZEPRIL HCL	amlodipine-benazepril
BENAZEPRIL HCL	Lotensin
BENAZEPRIL HCL	benazepril
BENAZEPRIL HCL/HYDROCHLOROTHIAZIDE	Lotensin HCT
BENAZEPRIL HCL/HYDROCHLOROTHIAZIDE	benazepril-hydrochlorothiazide
CAPTOPRIL	captopril
CAPTOPRIL/HYDROCHLOROTHIAZIDE	captopril-hydrochlorothiazide
ENALAPRIL MALEATE	Epaned
ENALAPRIL MALEATE	Vasotec
ENALAPRIL MALEATE	enalapril maleate
ENALAPRIL MALEATE/HYDROCHLOROTHIAZIDE	Vaseretic
ENALAPRIL MALEATE/HYDROCHLOROTHIAZIDE	enalapril-hydrochlorothiazide
FOSINOPRIL SODIUM	fosinopril
FOSINOPRIL SODIUM/HYDROCHLOROTHIAZIDE	fosinopril-hydrochlorothiazide
LISINOPRIL	Prinivil
LISINOPRIL	Qbrelis
LISINOPRIL	Zestril
LISINOPRIL	lisinopril
LISINOPRIL/HYDROCHLOROTHIAZIDE	Zestoretic
LISINOPRIL/HYDROCHLOROTHIAZIDE	lisinopril-hydrochlorothiazide
MOEXIPRIL HCL	Univasc
MOEXIPRIL HCL	moexipril
MOEXIPRIL HCL/HYDROCHLOROTHIAZIDE	Uniretic
MOEXIPRIL HCL/HYDROCHLOROTHIAZIDE	moexipril-hydrochlorothiazide
PERINDOPRIL ARGININE/AMLODIPINE BESYLATE	Prestalia
PERINDOPRIL ERBUMINE	Aceon
PERINDOPRIL ERBUMINE	perindopril erbumine
QUINAPRIL HCL	Accupril
QUINAPRIL HCL	quinapril
QUINAPRIL HCL/HYDROCHLOROTHIAZIDE	Accuretic
QUINAPRIL HCL/HYDROCHLOROTHIAZIDE	quinapril-hydrochlorothiazide
RAMIPRIL	Altace
RAMIPRIL	ramipril
TRANDOLAPRIL	Mavik
TRANDOLAPRIL	trandolapril
TRANDOLAPRIL/VERAPAMIL HCL	Tarka
TRANDOLAPRIL/VERAPAMIL HCL	trandolapril-verapamil
amlodipine besylate/benazepril HCl	amlodipine-benazepril
benazepril HCl	Lotensin
benazepril HCl	benazepril
captopril	captopril
enalapril maleate	enalapril maleate
lisinopril	lisinopril
lisinopril/hydrochlorothiazide	lisinopril-hydrochlorothiazide

Appendix B. Generic and Brand Names of Medical Products Used to Define Exposures in this Request

Generic Name	Brand Name
quinapril HCl	quinapril
ramipril	ramipril
trandolapril	trandolapril
Angiotensin II Receptor Blockers (ARB)	
AMLODIPINE BESYLATE/OLMESARTAN MEDOXOMIL	Azor
AMLODIPINE BESYLATE/OLMESARTAN MEDOXOMIL	amlodipine-olmesartan
AMLODIPINE BESYLATE/VALSARTAN	Exforge
AMLODIPINE BESYLATE/VALSARTAN	amlodipine-valsartan
AMLODIPINE BESYLATE/VALSARTAN /HYDROCHLOROTHIAZIDE	Exforge HCT
AMLODIPINE BESYLATE/VALSARTAN /HYDROCHLOROTHIAZIDE	amlodipine-valsartan-hcthiazid
AZILSARTAN MEDOXOMIL	Edarbi
AZILSARTAN MEDOXOMIL/CHLORTHALIDONE	Edarbyclor
CANDESARTAN CILEXETIL	Atacand
CANDESARTAN CILEXETIL	candesartan
CANDESARTAN CILEXETIL/HYDROCHLOROTHIAZIDE	Atacand HCT
CANDESARTAN CILEXETIL/HYDROCHLOROTHIAZIDE	candesartan-hydrochlorothiazid
EPROSARTAN MESYLATE	Teveten
EPROSARTAN MESYLATE	eprosartan
EPROSARTAN MESYLATE/HYDROCHLOROTHIAZIDE	Teveten HCT
IRBESARTAN	Avapro
IRBESARTAN	irbesartan
IRBESARTAN/HYDROCHLOROTHIAZIDE	Avalide
IRBESARTAN/HYDROCHLOROTHIAZIDE	irbesartan-hydrochlorothiazide
LOSARTAN POTASSIUM	Cozaar
LOSARTAN POTASSIUM	losartan
LOSARTAN POTASSIUM/HYDROCHLOROTHIAZIDE	Hyzaar
LOSARTAN POTASSIUM/HYDROCHLOROTHIAZIDE	losartan-hydrochlorothiazide
NEBIVOLOL HCL/VALSARTAN	Byvalson
OLMESARTAN MEDOXOMIL	Benicar
OLMESARTAN MEDOXOMIL	olmesartan
OLMESARTAN MEDOXOMIL/AMLODIPINE BESYLATE/HYDROCHLOROTHIAZIDE	Tribenzor
OLMESARTAN MEDOXOMIL/AMLODIPINE BESYLATE/HYDROCHLOROTHIAZIDE	olmesartan-amlodipin-hcthiazid
OLMESARTAN MEDOXOMIL/HYDROCHLOROTHIAZIDE	Benicar HCT
OLMESARTAN MEDOXOMIL/HYDROCHLOROTHIAZIDE	olmesartan-hydrochlorothiazide
TELMISARTAN	Micardis
TELMISARTAN	telmisartan
TELMISARTAN/AMLODIPINE BESYLATE	Twynsta
TELMISARTAN/AMLODIPINE BESYLATE	telmisartan-amlodipine
TELMISARTAN/HYDROCHLOROTHIAZIDE	Micardis HCT
TELMISARTAN/HYDROCHLOROTHIAZIDE	telmisartan-hydrochlorothiazid
VALSARTAN	Diovan
VALSARTAN	valsartan
VALSARTAN/HYDROCHLOROTHIAZIDE	Diovan HCT
VALSARTAN/HYDROCHLOROTHIAZIDE	valsartan-hydrochlorothiazide

Appendix B. Generic and Brand Names of Medical Products Used to Define Exposures in this Request

Generic Name	Brand Name
amlodipine besylate/olmesartan medoxomil	amlodipine-olmesartan
amlodipine besylate/valsartan	amlodipine-valsartan
amlodipine besylate/valsartan/hydrochlorothiazide	amlodipine-valsartan-hcthiazid
candesartan cilexetil	Atacand
candesartan cilexetil	candesartan
candesartan cilexetil/hydrochlorothiazide	Atacand HCT
candesartan cilexetil/hydrochlorothiazide	candesartan-hydrochlorothiazid
irbesartan	irbesartan
irbesartan/hydrochlorothiazide	irbesartan-hydrochlorothiazide
losartan potassium	losartan
losartan potassium/hydrochlorothiazide	losartan-hydrochlorothiazide
olmesartan medoxomil	Benicar
olmesartan medoxomil	olmesartan
olmesartan medoxomil/amlodipine besylate/hydrochlorothiazide	olmesartan-amlodipin-hcthiazid
olmesartan medoxomil/hydrochlorothiazide	Benicar HCT
telmisartan	telmisartan
telmisartan/hydrochlorothiazide	telmisartan-hydrochlorothiazid
valsartan	valsartan
valsartan/hydrochlorothiazide	valsartan-hydrochlorothiazide
Sacubitril/Valsartan	
SACUBITRIL/VALSARTAN	Entresto

Appendix C. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), Current Procedural Terminology, Fourth Edition (CPT-4), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Outcome in this Request

Code	Description	Code Category	Code Type
	Intensive Care Unit Admission, Intubation, Tracheostomy, or Laryngoscopy		
09HN7BZ	Insertion of Airway into Nasopharynx, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
09HN8BZ	Insertion of Airway into Nasopharynx, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0B110F4	Bypass Trachea to Cutaneous with Tracheostomy Device, Open Approach	Procedure	ICD-10-PCS
0B110Z4	Bypass Trachea to Cutaneous, Open Approach	Procedure	ICD-10-PCS
0B113F4	Bypass Trachea to Cutaneous with Tracheostomy Device, Percutaneous Approach	Procedure	ICD-10-PCS
0B113Z4	Bypass Trachea to Cutaneous, Percutaneous Approach	Procedure	ICD-10-PCS
0B114F4	Bypass Trachea to Cutaneous with Tracheostomy Device, Percutaneous Endoscopic Approac	Procedure	ICD-10-PCS
0B114Z4	Bypass Trachea to Cutaneous, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
0B710DZ	Dilation of Trachea with Intraluminal Device, Open Approach	Procedure	ICD-10-PCS
0B710ZZ	Dilation of Trachea, Open Approach	Procedure	ICD-10-PCS
0B713DZ	Dilation of Trachea with Intraluminal Device, Percutaneous Approach	Procedure	ICD-10-PCS
0B713ZZ	Dilation of Trachea, Percutaneous Approach	Procedure	ICD-10-PCS
0B714DZ	Dilation of Trachea with Intraluminal Device, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
0B714ZZ	Dilation of Trachea, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
0B717DZ	Dilation of Trachea with Intraluminal Device, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
0B717ZZ	Dilation of Trachea, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
0B718DZ	Dilation of Trachea with Intraluminal Device, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0B718ZZ	Dilation of Trachea, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0B720DZ	Dilation of Carina with Intraluminal Device, Open Approach	Procedure	ICD-10-PCS
0B720ZZ	Dilation of Carina, Open Approach	Procedure	ICD-10-PCS
0B723DZ	Dilation of Carina with Intraluminal Device, Percutaneous Approach	Procedure	ICD-10-PCS
0B723ZZ	Dilation of Carina, Percutaneous Approach	Procedure	ICD-10-PCS
0B724DZ	Dilation of Carina with Intraluminal Device, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
0B724ZZ	Dilation of Carina, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
0B727DZ	Dilation of Carina with Intraluminal Device, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
0B727ZZ	Dilation of Carina, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
0B728DZ	Dilation of Carina with Intraluminal Device, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0B728ZZ	Dilation of Carina, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0BH07DZ	Insertion of Intraluminal Device into Tracheobronchial Tree, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
0BH17EZ	Insertion of Endotracheal Airway into Trachea, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
0BH18EZ	Insertion of Endotracheal Airway into Trachea, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0BJ14ZZ	Inspection of Trachea, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
0BJ18ZZ	Inspection of Trachea, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0BQ10ZZ	Repair Trachea, Open Approach	Procedure	ICD-10-PCS
0BQ13ZZ	Repair Trachea, Percutaneous Approach	Procedure	ICD-10-PCS
0BQ14ZZ	Repair Trachea, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
0BQ17ZZ	Repair Trachea, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
0BQ18ZZ	Repair Trachea, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0BQ20ZZ	Repair Carina, Open Approach	Procedure	ICD-10-PCS
0BQ23ZZ	Repair Carina, Percutaneous Approach	Procedure	ICD-10-PCS

Appendix C. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), Current Procedural Terminology, Fourth Edition (CPT-4), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Outcome in this Request

Code	Description	Code Category	Code Type
0BQ24ZZ	Repair Carina, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
0BQ27ZZ	Repair Carina, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
0BQ28ZZ	Repair Carina, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0CHY7BZ	Insertion of Airway into Mouth and Throat, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
0CHY8BZ	Insertion of Airway into Mouth and Throat, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0CJS4ZZ	Inspection of Larynx, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
0CJS8ZZ	Inspection of Larynx, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0DH57BZ	Insertion of Airway into Esophagus, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
0DH58BZ	Insertion of Airway into Esophagus, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0DL57DZ	Occlusion of Esophagus with Intraluminal Device, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
0DL58DZ	Occlusion of Esophagus with Intraluminal Device, Via Natural or Artificial Opening Endoscop	Procedure	ICD-10-PCS
0WHQ7YZ	Insertion of Other Device into Respiratory Tract, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
31.1	Tracheostomy	Procedure	ICD-9-CM
31.2	Tracheostomy	Procedure	ICD-9-CM
31.21	Tracheostomy	Procedure	ICD-9-CM
31.29	Tracheostomy	Procedure	ICD-9-CM
31.42	Laryngoscopy	Procedure	ICD-9-CM
31.99	Intubation	Procedure	ICD-9-CM
31231	Laryngoscopy	Procedure	CPT-4
31502	Intubation	Procedure	CPT-4
31505	Laryngoscopy	Procedure	CPT-4
31525	Laryngoscopy	Procedure	CPT-4
31526	Laryngoscopy	Procedure	CPT-4
31527	Laryngoscopy	Procedure	CPT-4
31528	Laryngoscopy	Procedure	CPT-4
31529	Laryngoscopy	Procedure	CPT-4
31560	Laryngoscopy	Procedure	CPT-4
31561	Laryngoscopy	Procedure	CPT-4
31603	Tracheostomy	Procedure	CPT-4
31605	Tracheostomy	Procedure	CPT-4
31610	Tracheostomy	Procedure	CPT-4
31612	Tracheostomy	Procedure	CPT-4
31615	Tracheostomy	Procedure	CPT-4
3E1F78Z	Irrigation of Respiratory Tract using Irrigating Substance, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
3E1F88Z	Irrigation of Respiratory Tract using Irrigating Substance, Via Natural or Artificial Opening En	Procedure	ICD-10-PCS
5A1935Z	Respiratory Ventilation, Less than 24 Consecutive Hours	Procedure	ICD-10-PCS
5A1945Z	Respiratory Ventilation, 24-96 Consecutive Hours	Procedure	ICD-10-PCS
5A1955Z	Respiratory Ventilation, Greater than 96 Consecutive Hours	Procedure	ICD-10-PCS
91000	Intubation	Procedure	CPT-4
96	Intubation	Procedure	ICD-9-CM
96.0	Intubation	Procedure	ICD-9-CM

Appendix C. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), Current Procedural Terminology, Fourth Edition (CPT-4), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Outcome in this Request

Code	Description	Code Category	Code Type
96.01	Intubation	Procedure	ICD-9-CM
96.02	Intubation	Procedure	ICD-9-CM
96.03	Intubation	Procedure	ICD-9-CM
96.04	Intubation	Procedure	ICD-9-CM
96.05	Intubation	Procedure	ICD-9-CM
96.06	Intubation	Procedure	ICD-9-CM
96.56	Intubation	Procedure	ICD-9-CM
96.7	Intubation	Procedure	ICD-9-CM
96.70	Intubation	Procedure	ICD-9-CM
96.71	Intubation	Procedure	ICD-9-CM
96.72	Intubation	Procedure	ICD-9-CM
99220	ICU Admission	Procedure	CPT-4
99221	ICU Admission	Procedure	CPT-4
99222	ICU Admission	Procedure	CPT-4
99223	ICU Admission	Procedure	CPT-4
99224	ICU Admission	Procedure	CPT-4
99225	ICU Admission	Procedure	CPT-4
99226	ICU Admission	Procedure	CPT-4
99291	ICU Admission	Procedure	CPT-4
99292	ICU Admission	Procedure	CPT-4
A0396	Intubation	Procedure	HCPCS
V44.0	Tracheostomy	Diagnosis	ICD-9-CM
V55.0	Tracheostomy	Diagnosis	ICD-9-CM
Z43.0	Encounter for Attention to Tracheostomy	Diagnosis	ICD-10-CM
Z93.0	Tracheostomy Status	Diagnosis	ICD-10-CM
	Angioedema		
995.1	Angioedema	Diagnosis	ICD-9-CM
T783XXA	Angioedema	Diagnosis	ICD-10-CM

Appendix D. Generic and Brand Names of Medical Products Used to Define Exposure Incidence and Exclusion Criteria in this Request

Generic Name	Brand Name
Angiotensin-Converting Enzyme Inhibitors (ACEI)	
AMLODIPINE BESYLATE/BENAZEPRIL HCL	Lotrel
AMLODIPINE BESYLATE/BENAZEPRIL HCL	amlodipine-benazepril
BENAZEPRIL HCL	Lotensin
BENAZEPRIL HCL	benazepril
BENAZEPRIL HCL/HYDROCHLOROTHIAZIDE	Lotensin HCT
BENAZEPRIL HCL/HYDROCHLOROTHIAZIDE	benazepril-hydrochlorothiazide
CAPTOPRIL	captopril
CAPTOPRIL/HYDROCHLOROTHIAZIDE	captopril-hydrochlorothiazide
ENALAPRIL MALEATE	Epaned
ENALAPRIL MALEATE	Vasotec
ENALAPRIL MALEATE	enalapril maleate
ENALAPRIL MALEATE/HYDROCHLOROTHIAZIDE	Vaseretic
ENALAPRIL MALEATE/HYDROCHLOROTHIAZIDE	enalapril-hydrochlorothiazide
FOSINOPRIL SODIUM	fosinopril
FOSINOPRIL SODIUM/HYDROCHLOROTHIAZIDE	fosinopril-hydrochlorothiazide
LISINOPRIL	Prinivil
LISINOPRIL	Qbrelis
LISINOPRIL	Zestril
LISINOPRIL	lisinopril
LISINOPRIL/HYDROCHLOROTHIAZIDE	Zestoretic
LISINOPRIL/HYDROCHLOROTHIAZIDE	lisinopril-hydrochlorothiazide
MOEXIPRIL HCL	Univasc
MOEXIPRIL HCL	moexipril
MOEXIPRIL HCL/HYDROCHLOROTHIAZIDE	Uniretic
MOEXIPRIL HCL/HYDROCHLOROTHIAZIDE	moexipril-hydrochlorothiazide
PERINDOPRIL ARGININE/AMLODIPINE BESYLATE	Prestalia
PERINDOPRIL ERBUMINE	Aceon
PERINDOPRIL ERBUMINE	perindopril erbumine
QUINAPRIL HCL	Accupril
QUINAPRIL HCL	quinapril
QUINAPRIL HCL/HYDROCHLOROTHIAZIDE	Accuretic
QUINAPRIL HCL/HYDROCHLOROTHIAZIDE	quinapril-hydrochlorothiazide
RAMIPRIL	Altace
RAMIPRIL	ramipril
TRANDOLAPRIL	Mavik
TRANDOLAPRIL	trandolapril
TRANDOLAPRIL/VERAPAMIL HCL	Tarka
TRANDOLAPRIL/VERAPAMIL HCL	trandolapril-verapamil
amlodipine besylate/benazepril HCl	amlodipine-benazepril
benazepril HCl	Lotensin
benazepril HCl	benazepril
captopril	captopril
enalapril maleate	enalapril maleate

Appendix D. Generic and Brand Names of Medical Products Used to Define Exposure Incidence and Exclusion Criteria in this Request

Generic Name	Brand Name
lisinopril	lisinopril
lisinopril/hydrochlorothiazide	lisinopril-hydrochlorothiazide
quinapril HCl	quinapril
ramipril	ramipril
trandolapril	trandolapril
Angiotensin II Receptor Blockers (ARB)	
AMLODIPINE BESYLATE/OLMESARTAN MEDOXOMIL	Azor
AMLODIPINE BESYLATE/OLMESARTAN MEDOXOMIL	amlodipine-olmesartan
AMLODIPINE BESYLATE/VALSARTAN	Exforge
AMLODIPINE BESYLATE/VALSARTAN	amlodipine-valsartan
AMLODIPINE BESYLATE/VALSARTAN/HYDROCHLOROTHIAZIDE	Exforge HCT
AMLODIPINE BESYLATE/VALSARTAN/HYDROCHLOROTHIAZIDE	amlodipine-valsartan-hcthiazid
AZILSARTAN MEDOXOMIL	Edarbi
AZILSARTAN MEDOXOMIL/CHLORTHALIDONE	Edarbyclor
CANDESARTAN CILEXETIL	Atacand
CANDESARTAN CILEXETIL	candesartan
CANDESARTAN CILEXETIL/HYDROCHLOROTHIAZIDE	Atacand HCT
CANDESARTAN CILEXETIL/HYDROCHLOROTHIAZIDE	candesartan-hydrochlorothiazid
EPROSARTAN MESYLATE	Teveten
EPROSARTAN MESYLATE	eprosartan
EPROSARTAN MESYLATE/HYDROCHLOROTHIAZIDE	Teveten HCT
IRBESARTAN	Avapro
IRBESARTAN	irbesartan
IRBESARTAN/HYDROCHLOROTHIAZIDE	Avalide
IRBESARTAN/HYDROCHLOROTHIAZIDE	irbesartan-hydrochlorothiazide
LOSARTAN POTASSIUM	Cozaar
LOSARTAN POTASSIUM	losartan
LOSARTAN POTASSIUM/HYDROCHLOROTHIAZIDE	Hyzaar
LOSARTAN POTASSIUM/HYDROCHLOROTHIAZIDE	losartan-hydrochlorothiazide
NEBIVOLOL HCL/VALSARTAN	Byvalson
OLMESARTAN MEDOXOMIL	Benicar
OLMESARTAN MEDOXOMIL	olmesartan
OLMESARTAN MEDOXOMIL/AMLODIPINE BESYLATE/HYDROCHLOROTHIAZIDE	Tribenzor
OLMESARTAN MEDOXOMIL/AMLODIPINE BESYLATE/HYDROCHLOROTHIAZIDE	olmesartan-amlodipin-hcthiazid
OLMESARTAN MEDOXOMIL/HYDROCHLOROTHIAZIDE	Benicar HCT
OLMESARTAN MEDOXOMIL/HYDROCHLOROTHIAZIDE	olmesartan-hydrochlorothiazide
TELMISARTAN	Micardis
TELMISARTAN	telmisartan
TELMISARTAN/AMLODIPINE BESYLATE	Twynsta
TELMISARTAN/AMLODIPINE BESYLATE	telmisartan-amlodipine
TELMISARTAN/HYDROCHLOROTHIAZIDE	Micardis HCT

Appendix D. Generic and Brand Names of Medical Products Used to Define Exposure Incidence and Exclusion Criteria in this Request

Generic Name	Brand Name
TELMISARTAN/HYDROCHLOROTHIAZIDE	telmisartan-hydrochlorothiazid
VALSARTAN	Diovan
VALSARTAN	valsartan
VALSARTAN/HYDROCHLOROTHIAZIDE	Diovan HCT
VALSARTAN/HYDROCHLOROTHIAZIDE	valsartan-hydrochlorothiazide
amlodipine besylate/olmesartan medoxomil	amlodipine-olmesartan
amlodipine besylate/valsartan	amlodipine-valsartan
amlodipine besylate/valsartan/hydrochlorothiazide	amlodipine-valsartan-hcthiazid
candesartan cilexetil	Atacand
candesartan cilexetil	candesartan
candesartan cilexetil/hydrochlorothiazide	Atacand HCT
candesartan cilexetil/hydrochlorothiazide	candesartan-hydrochlorothiazid
irbesartan	irbesartan
irbesartan/hydrochlorothiazide	irbesartan-hydrochlorothiazide
losartan potassium	losartan
losartan potassium/hydrochlorothiazide	losartan-hydrochlorothiazide
olmesartan medoxomil	Benicar
olmesartan medoxomil	olmesartan
olmesartan medoxomil/amlodipine besylate/hydrochlorothiazide	olmesartan-amlodipin-hcthiazid
olmesartan medoxomil/hydrochlorothiazide	Benicar HCT
telmisartan	telmisartan
telmisartan/hydrochlorothiazide	telmisartan-hydrochlorothiazid
valsartan	valsartan
valsartan/hydrochlorothiazide	valsartan-hydrochlorothiazide

Appendix E. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Inclusion Criteria in this Request

Code	Description	Code Category	Code Type
	Heart failure		
402.01	Malignant hypertensive heart disease with heart failure	Diagnosis	ICD-9-CM
402.11	Benign hypertensive heart disease with heart failure	Diagnosis	ICD-9-CM
402.91	Hypertensive heart disease, unspecified, with heart failure	Diagnosis	ICD-9-CM
404.01	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified	Diagnosis	ICD-9-CM
404.03	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage V or end stage renal disease	Diagnosis	ICD-9-CM
404.11	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified	Diagnosis	ICD-9-CM
404.13	Hypertensive heart and chronic kidney disease, benign, with heart failure and chronic kidney disease stage V or end stage renal disease	Diagnosis	ICD-9-CM
404.91	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified	Diagnosis	ICD-9-CM
404.93	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease	Diagnosis	ICD-9-CM
428	Heart failure	Diagnosis	ICD-9-CM
428.0	Congestive heart failure, unspecified	Diagnosis	ICD-9-CM
428.1	Left heart failure	Diagnosis	ICD-9-CM
428.2	Systolic heart failure	Diagnosis	ICD-9-CM
428.20	Unspecified systolic heart failure	Diagnosis	ICD-9-CM
428.21	Acute systolic heart failure	Diagnosis	ICD-9-CM
428.22	Chronic systolic heart failure	Diagnosis	ICD-9-CM
428.23	Acute on chronic systolic heart failure	Diagnosis	ICD-9-CM
428.3	Diastolic heart failure	Diagnosis	ICD-9-CM
428.30	Unspecified diastolic heart failure	Diagnosis	ICD-9-CM
428.31	Acute diastolic heart failure	Diagnosis	ICD-9-CM
428.32	Chronic diastolic heart failure	Diagnosis	ICD-9-CM
428.33	Acute on chronic diastolic heart failure	Diagnosis	ICD-9-CM
428.4	Combined systolic and diastolic heart failure	Diagnosis	ICD-9-CM
428.40	Unspecified combined systolic and diastolic heart failure	Diagnosis	ICD-9-CM
428.41	Acute combined systolic and diastolic heart failure	Diagnosis	ICD-9-CM
428.42	Chronic combined systolic and diastolic heart failure	Diagnosis	ICD-9-CM
428.43	Acute on chronic combined systolic and diastolic heart failure	Diagnosis	ICD-9-CM
428.9	Unspecified heart failure	Diagnosis	ICD-9-CM
I11.0	Hypertensive heart disease with heart failure	Diagnosis	ICD-10-CM
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease	Diagnosis	ICD-10-CM
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease	Diagnosis	ICD-10-CM
I50	Heart failure	Diagnosis	ICD-10-CM
I50.1	Left ventricular failure, unspecified	Diagnosis	ICD-10-CM

Appendix E. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Inclusion Criteria in this Request

Code	Description	Code Category	Code Type
I50.2	Systolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.20	Unspecified systolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.21	Acute systolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.22	Chronic systolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.23	Acute on chronic systolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.3	Diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.30	Unspecified diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.31	Acute diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.32	Chronic diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.33	Acute on chronic diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.4	Combined systolic (congestive) and diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
I50.810	Right heart failure, unspecified	Diagnosis	ICD-10-CM
I50.811	Acute right heart failure	Diagnosis	ICD-10-CM
I50.812	Chronic right heart failure	Diagnosis	ICD-10-CM
I50.813	Acute on chronic right heart failure	Diagnosis	ICD-10-CM
I50.814	Right heart failure due to left heart failure	Diagnosis	ICD-10-CM
I50.82	Biventricular heart failure	Diagnosis	ICD-10-CM
I50.83	High output heart failure	Diagnosis	ICD-10-CM
I50.84	End stage heart failure	Diagnosis	ICD-10-CM
I50.89	Other heart failure	Diagnosis	ICD-10-CM
I50.9	Heart failure, unspecified	Diagnosis	ICD-10-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
	Allergies		
472.0	Chronic rhinitis	Diagnosis	ICD-9-CM
477.0	Allergic rhinitis due to pollen	Diagnosis	ICD-9-CM
477.1	Allergic rhinitis, due to food	Diagnosis	ICD-9-CM
477.2	Allergic rhinitis due to animal (cat) (dog) hair and dander	Diagnosis	ICD-9-CM
477.8	Allergic rhinitis due to other allergen	Diagnosis	ICD-9-CM
477.9	Allergic rhinitis, cause unspecified	Diagnosis	ICD-9-CM
478.8	Upper respiratory tract hypersensitivity reaction, site unspecified	Diagnosis	ICD-9-CM
558.3	Gastroenteritis and colitis, allergic	Diagnosis	ICD-9-CM
691.0	Diaper or napkin rash	Diagnosis	ICD-9-CM
691.8	Other atopic dermatitis and related conditions	Diagnosis	ICD-9-CM
692.0	Contact dermatitis and other eczema due to detergents	Diagnosis	ICD-9-CM
692.1	Contact dermatitis and other eczema due to oils and greases	Diagnosis	ICD-9-CM
692.2	Contact dermatitis and other eczema due to solvents	Diagnosis	ICD-9-CM
692.3	Contact dermatitis and other eczema due to drugs and medicines in contact with skin	Diagnosis	ICD-9-CM
692.4	Contact dermatitis and other eczema due to other chemical products	Diagnosis	ICD-9-CM
692.5	Contact dermatitis and other eczema due to food in contact with skin	Diagnosis	ICD-9-CM
692.6	Contact dermatitis and other eczema due to plants (except food)	Diagnosis	ICD-9-CM
692.70	Unspecified dermatitis due to sun	Diagnosis	ICD-9-CM
692.71	Contact dermatitis and other eczema due to sunburn	Diagnosis	ICD-9-CM
692.72	Acute dermatitis due to solar radiation	Diagnosis	ICD-9-CM
692.73	Actinic reticuloid and actinic granuloma	Diagnosis	ICD-9-CM
692.74	Other chronic dermatitis due to solar radiation	Diagnosis	ICD-9-CM
692.75	Disseminated superficial actinic porokeratosis (DSAP)	Diagnosis	ICD-9-CM
692.76	Sunburn of second degree	Diagnosis	ICD-9-CM
692.77	Sunburn of third degree	Diagnosis	ICD-9-CM
692.79	Other dermatitis due to solar radiation	Diagnosis	ICD-9-CM
692.81	Dermatitis due to cosmetics	Diagnosis	ICD-9-CM
692.82	Dermatitis due to other radiation	Diagnosis	ICD-9-CM
692.83	Dermatitis due to metals	Diagnosis	ICD-9-CM
692.84	Contact dermatitis and other eczema due to animal (cat) (dog) dander	Diagnosis	ICD-9-CM
692.89	Contact dermatitis and other eczema due to other specified agent	Diagnosis	ICD-9-CM
692.9	Contact dermatitis and other eczema, due to unspecified cause	Diagnosis	ICD-9-CM
693.0	Dermatitis due to drugs and medicines taken internally	Diagnosis	ICD-9-CM
693.1	Dermatitis due to food taken internally	Diagnosis	ICD-9-CM
693.8	Dermatitis due to other specified substances taken internally	Diagnosis	ICD-9-CM
693.9	Dermatitis due to unspecified substance taken internally	Diagnosis	ICD-9-CM
708.0	Allergic urticaria	Diagnosis	ICD-9-CM
708.1	Idiopathic urticaria	Diagnosis	ICD-9-CM
708.2	Urticaria due to cold and heat	Diagnosis	ICD-9-CM
708.3	Dermatographic urticaria	Diagnosis	ICD-9-CM
708.4	Vibratory urticaria	Diagnosis	ICD-9-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
708.5	Cholinergic urticaria	Diagnosis	ICD-9-CM
708.8	Other specified urticaria	Diagnosis	ICD-9-CM
708.9	Unspecified urticaria	Diagnosis	ICD-9-CM
995.0	Other anaphylactic reaction	Diagnosis	ICD-9-CM
995.27	Other drug allergy	Diagnosis	ICD-9-CM
995.3	Allergy, unspecified not elsewhere classified	Diagnosis	ICD-9-CM
995.7	Other adverse food reactions, not elsewhere classified	Diagnosis	ICD-9-CM
J30.0	Vasomotor rhinitis	Diagnosis	ICD-10-CM
J30.1	Allergic rhinitis due to pollen	Diagnosis	ICD-10-CM
J30.2	Other seasonal allergic rhinitis	Diagnosis	ICD-10-CM
J30.5	Allergic rhinitis due to food	Diagnosis	ICD-10-CM
J30.81	Allergic rhinitis due to animal (cat) (dog) hair and dander	Diagnosis	ICD-10-CM
J30.89	Other allergic rhinitis	Diagnosis	ICD-10-CM
J30.9	Allergic rhinitis, unspecified	Diagnosis	ICD-10-CM
J31.0	Chronic rhinitis	Diagnosis	ICD-10-CM
J39.3	Upper respiratory tract hypersensitivity reaction, site unspecified	Diagnosis	ICD-10-CM
K52.21	Food protein-induced enterocolitis syndrome	Diagnosis	ICD-10-CM
K52.22	Food protein-induced enteropathy	Diagnosis	ICD-10-CM
K52.29	Other allergic and dietetic gastroenteritis and colitis	Diagnosis	ICD-10-CM
L20.0	Besnier's prurigo	Diagnosis	ICD-10-CM
L20.81	Atopic neurodermatitis	Diagnosis	ICD-10-CM
L20.82	Flexural eczema	Diagnosis	ICD-10-CM
L20.84	Intrinsic (allergic) eczema	Diagnosis	ICD-10-CM
L20.89	Other atopic dermatitis	Diagnosis	ICD-10-CM
L20.9	Atopic dermatitis, unspecified	Diagnosis	ICD-10-CM
L22	Diaper dermatitis	Diagnosis	ICD-10-CM
L23.0	Allergic contact dermatitis due to metals	Diagnosis	ICD-10-CM
L23.1	Allergic contact dermatitis due to adhesives	Diagnosis	ICD-10-CM
L23.2	Allergic contact dermatitis due to cosmetics	Diagnosis	ICD-10-CM
L23.3	Allergic contact dermatitis due to drugs in contact with skin	Diagnosis	ICD-10-CM
L23.4	Allergic contact dermatitis due to dyes	Diagnosis	ICD-10-CM
L23.5	Allergic contact dermatitis due to other chemical products	Diagnosis	ICD-10-CM
L23.6	Allergic contact dermatitis due to food in contact with the skin	Diagnosis	ICD-10-CM
L23.7	Allergic contact dermatitis due to plants, except food	Diagnosis	ICD-10-CM
L23.81	Allergic contact dermatitis due to animal (cat) (dog) dander	Diagnosis	ICD-10-CM
L23.89	Allergic contact dermatitis due to other agents	Diagnosis	ICD-10-CM
L23.9	Allergic contact dermatitis, unspecified cause	Diagnosis	ICD-10-CM
L24.0	Irritant contact dermatitis due to detergents	Diagnosis	ICD-10-CM
L24.1	Irritant contact dermatitis due to oils and greases	Diagnosis	ICD-10-CM
L24.2	Irritant contact dermatitis due to solvents	Diagnosis	ICD-10-CM
L24.3	Irritant contact dermatitis due to cosmetics	Diagnosis	ICD-10-CM
L24.4	Irritant contact dermatitis due to drugs in contact with skin	Diagnosis	ICD-10-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
L24.5	Irritant contact dermatitis due to other chemical products	Diagnosis	ICD-10-CM
L24.6	Irritant contact dermatitis due to food in contact with skin	Diagnosis	ICD-10-CM
L24.7	Irritant contact dermatitis due to plants, except food	Diagnosis	ICD-10-CM
L24.81	Irritant contact dermatitis due to metals	Diagnosis	ICD-10-CM
L24.89	Irritant contact dermatitis due to other agents	Diagnosis	ICD-10-CM
L24.9	Irritant contact dermatitis, unspecified cause	Diagnosis	ICD-10-CM
L25.0	Unspecified contact dermatitis due to cosmetics	Diagnosis	ICD-10-CM
L25.1	Unspecified contact dermatitis due to drugs in contact with skin	Diagnosis	ICD-10-CM
L25.2	Unspecified contact dermatitis due to dyes	Diagnosis	ICD-10-CM
L25.3	Unspecified contact dermatitis due to other chemical products	Diagnosis	ICD-10-CM
L25.4	Unspecified contact dermatitis due to food in contact with skin	Diagnosis	ICD-10-CM
L25.5	Unspecified contact dermatitis due to plants, except food	Diagnosis	ICD-10-CM
L25.8	Unspecified contact dermatitis due to other agents	Diagnosis	ICD-10-CM
L25.9	Unspecified contact dermatitis, unspecified cause	Diagnosis	ICD-10-CM
L27.0	Generalized skin eruption due to drugs and medicaments taken internally	Diagnosis	ICD-10-CM
L27.1	Localized skin eruption due to drugs and medicaments taken internally	Diagnosis	ICD-10-CM
L27.2	Dermatitis due to ingested food	Diagnosis	ICD-10-CM
L27.8	Dermatitis due to other substances taken internally	Diagnosis	ICD-10-CM
L27.9	Dermatitis due to unspecified substance taken internally	Diagnosis	ICD-10-CM
L50.0	Allergic urticaria	Diagnosis	ICD-10-CM
L50.1	Idiopathic urticaria	Diagnosis	ICD-10-CM
L50.2	Urticaria due to cold and heat	Diagnosis	ICD-10-CM
L50.3	Dermatographic urticaria	Diagnosis	ICD-10-CM
L50.4	Vibratory urticaria	Diagnosis	ICD-10-CM
L50.5	Cholinergic urticaria	Diagnosis	ICD-10-CM
L50.6	Contact urticaria	Diagnosis	ICD-10-CM
L50.8	Other urticaria	Diagnosis	ICD-10-CM
L50.9	Urticaria, unspecified	Diagnosis	ICD-10-CM
L55.0	Sunburn of first degree	Diagnosis	ICD-10-CM
L55.1	Sunburn of second degree	Diagnosis	ICD-10-CM
L55.2	Sunburn of third degree	Diagnosis	ICD-10-CM
L55.9	Sunburn, unspecified	Diagnosis	ICD-10-CM
L56.0	Drug phototoxic response	Diagnosis	ICD-10-CM
L56.1	Drug photoallergic response	Diagnosis	ICD-10-CM
L56.2	Photocontact dermatitis [berloque dermatitis]	Diagnosis	ICD-10-CM
L56.3	Solar urticaria	Diagnosis	ICD-10-CM
L56.4	Polymorphous light eruption	Diagnosis	ICD-10-CM
L56.5	Disseminated superficial actinic porokeratosis (DSAP)	Diagnosis	ICD-10-CM
L56.8	Other specified acute skin changes due to ultraviolet radiation	Diagnosis	ICD-10-CM
L56.9	Acute skin change due to ultraviolet radiation, unspecified	Diagnosis	ICD-10-CM
L57.1	Actinic reticuloid	Diagnosis	ICD-10-CM
L57.5	Actinic granuloma	Diagnosis	ICD-10-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
L57.8	Other skin changes due to chronic exposure to nonionizing radiation	Diagnosis	ICD-10-CM
L57.9	Skin changes due to chronic exposure to nonionizing radiation, unspecified	Diagnosis	ICD-10-CM
L58.0	Acute radiodermatitis	Diagnosis	ICD-10-CM
L58.1	Chronic radiodermatitis	Diagnosis	ICD-10-CM
L58.9	Radiodermatitis, unspecified	Diagnosis	ICD-10-CM
T50.995A	Adverse effect of other drugs, medicaments and biological substances, initial encounter	Diagnosis	ICD-10-CM
T78.0	Anaphylactic reaction due to food	Diagnosis	ICD-10-CM
T78.00	Anaphylactic reaction due to unspecified food	Diagnosis	ICD-10-CM
T78.00XA	Anaphylactic reaction due to unspecified food, initial encounter	Diagnosis	ICD-10-CM
T78.00XD	Anaphylactic reaction due to unspecified food, subsequent encounter	Diagnosis	ICD-10-CM
T78.00XS	Anaphylactic reaction due to unspecified food, sequela	Diagnosis	ICD-10-CM
T78.01	Anaphylactic reaction due to peanuts	Diagnosis	ICD-10-CM
T78.01XA	Anaphylactic reaction due to peanuts, initial encounter	Diagnosis	ICD-10-CM
T78.01XD	Anaphylactic reaction due to peanuts, subsequent encounter	Diagnosis	ICD-10-CM
T78.01XS	Anaphylactic reaction due to peanuts, sequela	Diagnosis	ICD-10-CM
T78.02	Anaphylactic reaction due to shellfish (crustaceans)	Diagnosis	ICD-10-CM
T78.02XA	Anaphylactic reaction due to shellfish (crustaceans), initial encounter	Diagnosis	ICD-10-CM
T78.02XD	Anaphylactic reaction due to shellfish (crustaceans), subsequent encounter	Diagnosis	ICD-10-CM
T78.02XS	Anaphylactic reaction due to shellfish (crustaceans), sequela	Diagnosis	ICD-10-CM
T78.03	Anaphylactic reaction due to other fish	Diagnosis	ICD-10-CM
T78.03XA	Anaphylactic reaction due to other fish, initial encounter	Diagnosis	ICD-10-CM
T78.03XD	Anaphylactic reaction due to other fish, subsequent encounter	Diagnosis	ICD-10-CM
T78.03XS	Anaphylactic reaction due to other fish, sequela	Diagnosis	ICD-10-CM
T78.04	Anaphylactic reaction due to fruits and vegetables	Diagnosis	ICD-10-CM
T78.04XA	Anaphylactic reaction due to fruits and vegetables, initial encounter	Diagnosis	ICD-10-CM
T78.04XD	Anaphylactic reaction due to fruits and vegetables, subsequent encounter	Diagnosis	ICD-10-CM
T78.04XS	Anaphylactic reaction due to fruits and vegetables, sequela	Diagnosis	ICD-10-CM
T78.05	Anaphylactic reaction due to tree nuts and seeds	Diagnosis	ICD-10-CM
T78.05XA	Anaphylactic reaction due to tree nuts and seeds, initial encounter	Diagnosis	ICD-10-CM
T78.05XD	Anaphylactic reaction due to tree nuts and seeds, subsequent encounter	Diagnosis	ICD-10-CM
T78.05XS	Anaphylactic reaction due to tree nuts and seeds, sequela	Diagnosis	ICD-10-CM
T78.06	Anaphylactic reaction due to food additives	Diagnosis	ICD-10-CM
T78.06XA	Anaphylactic reaction due to food additives, initial encounter	Diagnosis	ICD-10-CM
T78.06XD	Anaphylactic reaction due to food additives, subsequent encounter	Diagnosis	ICD-10-CM
T78.06XS	Anaphylactic reaction due to food additives, sequela	Diagnosis	ICD-10-CM
T78.07	Anaphylactic reaction due to milk and dairy products	Diagnosis	ICD-10-CM
T78.07XA	Anaphylactic reaction due to milk and dairy products, initial encounter	Diagnosis	ICD-10-CM
T78.07XD	Anaphylactic reaction due to milk and dairy products, subsequent encounter	Diagnosis	ICD-10-CM
T78.07XS	Anaphylactic reaction due to milk and dairy products, sequela	Diagnosis	ICD-10-CM
T78.08	Anaphylactic reaction due to eggs	Diagnosis	ICD-10-CM
T78.08XA	Anaphylactic reaction due to eggs, initial encounter	Diagnosis	ICD-10-CM
T78.08XD	Anaphylactic reaction due to eggs, subsequent encounter	Diagnosis	ICD-10-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
T78.08XS	Anaphylactic reaction due to eggs, sequela	Diagnosis	ICD-10-CM
T78.09	Anaphylactic reaction due to other food products	Diagnosis	ICD-10-CM
T78.09XA	Anaphylactic reaction due to other food products, initial encounter	Diagnosis	ICD-10-CM
T78.09XD	Anaphylactic reaction due to other food products, subsequent encounter	Diagnosis	ICD-10-CM
T78.09XS	Anaphylactic reaction due to other food products, sequela	Diagnosis	ICD-10-CM
T78.1XXA	Other adverse food reactions, not elsewhere classified, initial encounter	Diagnosis	ICD-10-CM
T78.2	Anaphylactic shock, unspecified	Diagnosis	ICD-10-CM
T78.2XXA	Anaphylactic shock, unspecified, initial encounter	Diagnosis	ICD-10-CM
T78.2XXD	Anaphylactic shock, unspecified, subsequent encounter	Diagnosis	ICD-10-CM
T78.2XXS	Anaphylactic shock, unspecified, sequela	Diagnosis	ICD-10-CM
T78.40	Allergy, unspecified	Diagnosis	ICD-10-CM
T78.40XA	Allergy, unspecified, initial encounter	Diagnosis	ICD-10-CM
T78.40XD	Allergy, unspecified, subsequent encounter	Diagnosis	ICD-10-CM
T78.40XS	Allergy, unspecified, sequela	Diagnosis	ICD-10-CM
T78.49XA	Other allergy, initial encounter	Diagnosis	ICD-10-CM
T80.5	Anaphylactic reaction due to serum	Diagnosis	ICD-10-CM
T80.51	Anaphylactic reaction due to administration of blood and blood products	Diagnosis	ICD-10-CM
T80.51XA	Anaphylactic reaction due to administration of blood and blood products, initial encounter	Diagnosis	ICD-10-CM
T80.51XD	Anaphylactic reaction due to administration of blood and blood products, subsequent encounter	Diagnosis	ICD-10-CM
T80.51XS	Anaphylactic reaction due to administration of blood and blood products, sequela	Diagnosis	ICD-10-CM
T80.52	Anaphylactic reaction due to vaccination	Diagnosis	ICD-10-CM
T80.52XA	Anaphylactic reaction due to vaccination, initial encounter	Diagnosis	ICD-10-CM
T80.52XD	Anaphylactic reaction due to vaccination, subsequent encounter	Diagnosis	ICD-10-CM
T80.52XS	Anaphylactic reaction due to vaccination, sequela	Diagnosis	ICD-10-CM
T80.59	Anaphylactic reaction due to other serum	Diagnosis	ICD-10-CM
T80.59XA	Anaphylactic reaction due to other serum, initial encounter	Diagnosis	ICD-10-CM
T80.59XD	Anaphylactic reaction due to other serum, subsequent encounter	Diagnosis	ICD-10-CM
T80.59XS	Anaphylactic reaction due to other serum, sequela	Diagnosis	ICD-10-CM
T88.6	Anaphylactic reaction due to adverse effect of correct drug or medicament properly administered	Diagnosis	ICD-10-CM
T88.6XXA	Anaphylactic reaction due to adverse effect of correct drug or medicament properly administered, initial encounter	Diagnosis	ICD-10-CM
T88.6XXD	Anaphylactic reaction due to adverse effect of correct drug or medicament properly administered, subsequent encounter	Diagnosis	ICD-10-CM
T88.6XXS	Anaphylactic reaction due to adverse effect of correct drug or medicament properly administered, sequela	Diagnosis	ICD-10-CM
V07.1	Need for desensitization to allergens	Diagnosis	ICD-9-CM
V13.81	Personal history of anaphylaxis	Diagnosis	ICD-9-CM
V14.0	Personal history of allergy to penicillin	Diagnosis	ICD-9-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
V14.1	Personal history of allergy to other antibiotic agent	Diagnosis	ICD-9-CM
V14.2	Personal history of allergy to sulfonamides	Diagnosis	ICD-9-CM
V14.3	Personal history of allergy to other anti-infective agent	Diagnosis	ICD-9-CM
V14.4	Personal history of allergy to anesthetic agent	Diagnosis	ICD-9-CM
V14.5	Personal history of allergy to narcotic agent	Diagnosis	ICD-9-CM
V14.6	Personal history of allergy to analgesic agent	Diagnosis	ICD-9-CM
V14.7	Personal history of allergy to serum or vaccine	Diagnosis	ICD-9-CM
V14.8	Personal history of allergy to other specified medicinal agents	Diagnosis	ICD-9-CM
V14.9	Personal history of allergy to unspecified medicinal agent	Diagnosis	ICD-9-CM
V15.09	Personal history of other allergy, other than to medicinal agents	Diagnosis	ICD-9-CM
V72.7	Diagnostic skin and sensitization tests	Diagnosis	ICD-9-CM
Z01.82	Encounter for allergy testing	Diagnosis	ICD-10-CM
Z01.89	Encounter for other specified special examinations	Diagnosis	ICD-10-CM
Z51.6	Encounter for desensitization to allergens	Diagnosis	ICD-10-CM
Z87.892	Personal history of anaphylaxis	Diagnosis	ICD-10-CM
Z88.0	Allergy status to penicillin	Diagnosis	ICD-10-CM
Z88.1	Allergy status to other antibiotic agents status	Diagnosis	ICD-10-CM
Z88.2	Allergy status to sulfonamides status	Diagnosis	ICD-10-CM
Z88.3	Allergy status to other anti-infective agents status	Diagnosis	ICD-10-CM
Z88.4	Allergy status to anesthetic agent status	Diagnosis	ICD-10-CM
Z88.5	Allergy status to narcotic agent status	Diagnosis	ICD-10-CM
Z88.6	Allergy status to analgesic agent status	Diagnosis	ICD-10-CM
Z88.7	Allergy status to serum and vaccine status	Diagnosis	ICD-10-CM
Z88.8	Allergy status to other drugs, medicaments and biological substances status	Diagnosis	ICD-10-CM
Z88.9	Allergy status to unspecified drugs, medicaments and biological substances status	Diagnosis	ICD-10-CM
Z91.0	Allergy status, other than to drugs and biological substances	Diagnosis	ICD-10-CM
Z91.01	Food allergy status	Diagnosis	ICD-10-CM
Z91.010	Allergy to peanuts	Diagnosis	ICD-10-CM
Z91.011	Allergy to milk products	Diagnosis	ICD-10-CM
Z91.012	Allergy to eggs	Diagnosis	ICD-10-CM
Z91.013	Allergy to seafood	Diagnosis	ICD-10-CM
Z91.018	Allergy to other foods	Diagnosis	ICD-10-CM
Z91.02	Food additives allergy status	Diagnosis	ICD-10-CM
Z91.03	Insect allergy status	Diagnosis	ICD-10-CM
Z91.030	Bee allergy status	Diagnosis	ICD-10-CM
Z91.038	Other insect allergy status	Diagnosis	ICD-10-CM
Z91.04	Nonmedicinal substance allergy status	Diagnosis	ICD-10-CM
Z91.040	Latex allergy status	Diagnosis	ICD-10-CM
Z91.041	Radiographic dye allergy status	Diagnosis	ICD-10-CM
Z91.048	Other nonmedicinal substance allergy status	Diagnosis	ICD-10-CM
Z91.09	Other allergy status, other than to drugs and biological substances	Diagnosis	ICD-10-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
	Angioedema		
995.1	Angioedema	Diagnosis	ICD-9-CM
T783XXA	Angioedema	Diagnosis	ICD-10-CM
T783XXD	Angioneurotic edema, sequela	Diagnosis	ICD-10-CM
T783XXS	Angioneurotic edema, subsequent encounter	Diagnosis	ICD-10-CM
	Diabetes		
250	Diabetes mellitus	Diagnosis	ICD-9-CM
250.0	Diabetes mellitus without mention of complication	Diagnosis	ICD-9-CM
250.00	Diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.01	Diabetes mellitus without mention of complication, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.02	Diabetes mellitus without mention of complication, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.03	Diabetes mellitus without mention of complication, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
250.1	Diabetes with ketoacidosis	Diagnosis	ICD-9-CM
250.10	Diabetes with ketoacidosis, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.11	Diabetes with ketoacidosis, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.12	Diabetes with ketoacidosis, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.13	Diabetes with ketoacidosis, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
250.2	Diabetes with hyperosmolarity	Diagnosis	ICD-9-CM
250.20	Diabetes with hyperosmolarity, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.21	Diabetes with hyperosmolarity, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.22	Diabetes with hyperosmolarity, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.23	Diabetes with hyperosmolarity, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
250.3	Diabetes with other coma	Diagnosis	ICD-9-CM
250.30	Diabetes with other coma, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.31	Diabetes with other coma, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.32	Diabetes with other coma, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.33	Diabetes with other coma, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
250.4	Diabetes with renal manifestations	Diagnosis	ICD-9-CM
250.40	Diabetes with renal manifestations, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.41	Diabetes with renal manifestations, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.42	Diabetes with renal manifestations, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.43	Diabetes with renal manifestations, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
250.5	Diabetes with ophthalmic manifestations	Diagnosis	ICD-9-CM
250.50	Diabetes with ophthalmic manifestations, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.51	Diabetes with ophthalmic manifestations, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.52	Diabetes with ophthalmic manifestations, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
250.53	Diabetes with ophthalmic manifestations, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
250.6	Diabetes with neurological manifestations	Diagnosis	ICD-9-CM
250.60	Diabetes with neurological manifestations, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.61	Diabetes with neurological manifestations, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.62	Diabetes with neurological manifestations, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.63	Diabetes with neurological manifestations, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
250.7	Diabetes with peripheral circulatory disorders	Diagnosis	ICD-9-CM
250.70	Diabetes with peripheral circulatory disorders, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.71	Diabetes with peripheral circulatory disorders, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.72	Diabetes with peripheral circulatory disorders, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.73	Diabetes with peripheral circulatory disorders, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
250.8	Diabetes with other specified manifestations	Diagnosis	ICD-9-CM
250.80	Diabetes with other specified manifestations, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.81	Diabetes with other specified manifestations, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.82	Diabetes with other specified manifestations, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.83	Diabetes with other specified manifestations, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
250.9	Diabetes with unspecified complication	Diagnosis	ICD-9-CM
250.90	Diabetes with unspecified complication, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.91	Diabetes with unspecified complication, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.92	Diabetes with unspecified complication, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.93	Diabetes with unspecified complication, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
A5500	For diabetics only, fitting (including follow-up), custom preparation and supply of off-the-shelf depth-inlay shoe manufactured to accommodate multidensity insert(s), per shoe	Procedure	HCPCS
A5501	For diabetics only, fitting (including follow-up), custom preparation and supply of shoe molded from cast(s) of patient's foot (custom molded shoe), per shoe	Procedure	HCPCS
A5503	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with roller or rigid rocker bottom, per shoe	Procedure	HCPCS
A5504	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with wedge(s), per shoe	Procedure	HCPCS
A5505	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with metatarsal bar, per shoe	Procedure	HCPCS
A5506	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with off-set heel(s), per shoe	Procedure	HCPCS

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
A5507	For diabetics only, not otherwise specified modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe, per shoe	Procedure	HCPCS
A5508	For diabetics only, deluxe feature of off-the-shelf depth-inlay shoe or custom molded shoe, per shoe	Procedure	HCPCS
A5510	For diabetics only, direct formed, compression molded to patient's foot without external heat source, multiple-density insert(s) prefabricated, per shoe	Procedure	HCPCS
A5512	For diabetics only, multiple density insert, direct formed, molded to foot after external heat source of 230 degrees Fahrenheit or higher, total contact with patient's foot, including arch, base layer minimum of 1/4 inch material of Shore A 35 durometer or 3/16 inch material of Shore A 40 durometer (or higher), prefabricated, each	Procedure	HCPCS
A5513	For diabetics only, multiple density insert, custom molded from model of patient's foot, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material of Shore A 35 durometer (or higher), includes arch filler and other shaping material, custom fabricated, each	Procedure	HCPCS
E10.10	Type 1 diabetes mellitus with ketoacidosis without coma	Diagnosis	ICD-10-CM
E10.11	Type 1 diabetes mellitus with ketoacidosis with coma	Diagnosis	ICD-10-CM
E10.21	Type 1 diabetes mellitus with diabetic nephropathy	Diagnosis	ICD-10-CM
E10.22	Type 1 diabetes mellitus with diabetic chronic kidney disease	Diagnosis	ICD-10-CM
E10.29	Type 1 diabetes mellitus with other diabetic kidney complication	Diagnosis	ICD-10-CM
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema	Diagnosis	ICD-10-CM
E10.319	Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema	Diagnosis	ICD-10-CM
E10.3211	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye	Diagnosis	ICD-10-CM
E10.3212	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye	Diagnosis	ICD-10-CM
E10.3213	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM
E10.3219	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye	Diagnosis	ICD-10-CM
E10.3291	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye	Diagnosis	ICD-10-CM
E10.3292	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye	Diagnosis	ICD-10-CM
E10.3293	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral	Diagnosis	ICD-10-CM
E10.3299	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye	Diagnosis	ICD-10-CM
E10.3311	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye	Diagnosis	ICD-10-CM
E10.3312	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye	Diagnosis	ICD-10-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
E10.3313	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM
E10.3319	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye	Diagnosis	ICD-10-CM
E10.3391	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye	Diagnosis	ICD-10-CM
E10.3392	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye	Diagnosis	ICD-10-CM
E10.3393	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral	Diagnosis	ICD-10-CM
E10.3399	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye	Diagnosis	ICD-10-CM
E10.3411	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye	Diagnosis	ICD-10-CM
E10.3412	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye	Diagnosis	ICD-10-CM
E10.3413	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM
E10.3419	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye	Diagnosis	ICD-10-CM
E10.3491	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye	Diagnosis	ICD-10-CM
E10.3492	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye	Diagnosis	ICD-10-CM
E10.3493	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral	Diagnosis	ICD-10-CM
E10.3499	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye	Diagnosis	ICD-10-CM
E10.3511	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye	Diagnosis	ICD-10-CM
E10.3512	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye	Diagnosis	ICD-10-CM
E10.3513	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM
E10.3519	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye	Diagnosis	ICD-10-CM
E10.3521	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye	Diagnosis	ICD-10-CM
E10.3522	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye	Diagnosis	ICD-10-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
E10.3523	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral	Diagnosis	ICD-10-CM
E10.3529	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye	Diagnosis	ICD-10-CM
E10.3531	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye	Diagnosis	ICD-10-CM
E10.3532	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye	Diagnosis	ICD-10-CM
E10.3533	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral	Diagnosis	ICD-10-CM
E10.3539	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye	Diagnosis	ICD-10-CM
E10.3541	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye	Diagnosis	ICD-10-CM
E10.3542	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye	Diagnosis	ICD-10-CM
E10.3543	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral	Diagnosis	ICD-10-CM
E10.3549	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye	Diagnosis	ICD-10-CM
E10.3551	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, right eye	Diagnosis	ICD-10-CM
E10.3552	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, left eye	Diagnosis	ICD-10-CM
E10.3553	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral	Diagnosis	ICD-10-CM
E10.3559	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye	Diagnosis	ICD-10-CM
E10.3591	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye	Diagnosis	ICD-10-CM
E10.3592	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye	Diagnosis	ICD-10-CM
E10.3593	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral	Diagnosis	ICD-10-CM
E10.3599	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye	Diagnosis	ICD-10-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
E10.36	Type 1 diabetes mellitus with diabetic cataract	Diagnosis	ICD-10-CM
E10.37X1	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye	Diagnosis	ICD-10-CM
E10.37X2	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye	Diagnosis	ICD-10-CM
E10.37X3	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral	Diagnosis	ICD-10-CM
E10.37X9	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye	Diagnosis	ICD-10-CM
E10.39	Type 1 diabetes mellitus with other diabetic ophthalmic complication	Diagnosis	ICD-10-CM
E10.40	Type 1 diabetes mellitus with diabetic neuropathy, unspecified	Diagnosis	ICD-10-CM
E10.41	Type 1 diabetes mellitus with diabetic mononeuropathy	Diagnosis	ICD-10-CM
E10.42	Type 1 diabetes mellitus with diabetic polyneuropathy	Diagnosis	ICD-10-CM
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy	Diagnosis	ICD-10-CM
E10.44	Type 1 diabetes mellitus with diabetic amyotrophy	Diagnosis	ICD-10-CM
E10.49	Type 1 diabetes mellitus with other diabetic neurological complication	Diagnosis	ICD-10-CM
E10.51	Type 1 diabetes mellitus with diabetic peripheral angiopathy without gangrene	Diagnosis	ICD-10-CM
E10.52	Type 1 diabetes mellitus with diabetic peripheral angiopathy with gangrene	Diagnosis	ICD-10-CM
E10.59	Type 1 diabetes mellitus with other circulatory complications	Diagnosis	ICD-10-CM
E10.610	Type 1 diabetes mellitus with diabetic neuropathic arthropathy	Diagnosis	ICD-10-CM
E10.618	Type 1 diabetes mellitus with other diabetic arthropathy	Diagnosis	ICD-10-CM
E10.620	Type 1 diabetes mellitus with diabetic dermatitis	Diagnosis	ICD-10-CM
E10.621	Type 1 diabetes mellitus with foot ulcer	Diagnosis	ICD-10-CM
E10.622	Type 1 diabetes mellitus with other skin ulcer	Diagnosis	ICD-10-CM
E10.628	Type 1 diabetes mellitus with other skin complications	Diagnosis	ICD-10-CM
E10.630	Type 1 diabetes mellitus with periodontal disease	Diagnosis	ICD-10-CM
E10.638	Type 1 diabetes mellitus with other oral complications	Diagnosis	ICD-10-CM
E10.641	Type 1 diabetes mellitus with hypoglycemia with coma	Diagnosis	ICD-10-CM
E10.649	Type 1 diabetes mellitus with hypoglycemia without coma	Diagnosis	ICD-10-CM
E10.65	Type 1 diabetes mellitus with hyperglycemia	Diagnosis	ICD-10-CM
E10.69	Type 1 diabetes mellitus with other specified complication	Diagnosis	ICD-10-CM
E10.8	Type 1 diabetes mellitus with unspecified complications	Diagnosis	ICD-10-CM
E10.9	Type 1 diabetes mellitus without complications	Diagnosis	ICD-10-CM
E11.00	Type 2 diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)	Diagnosis	ICD-10-CM
E11.01	Type 2 diabetes mellitus with hyperosmolarity with coma	Diagnosis	ICD-10-CM
E11.21	Type 2 diabetes mellitus with diabetic nephropathy	Diagnosis	ICD-10-CM
E11.22	Type 2 diabetes mellitus with diabetic chronic kidney disease	Diagnosis	ICD-10-CM
E11.29	Type 2 diabetes mellitus with other diabetic kidney complication	Diagnosis	ICD-10-CM
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema	Diagnosis	ICD-10-CM
E11.319	Type 2 diabetes mellitus with unspecified diabetic retinopathy without macular edema	Diagnosis	ICD-10-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
E11.3211	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye	Diagnosis	ICD-10-CM
E11.3212	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye	Diagnosis	ICD-10-CM
E11.3213	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM
E11.3219	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye	Diagnosis	ICD-10-CM
E11.3291	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye	Diagnosis	ICD-10-CM
E11.3292	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye	Diagnosis	ICD-10-CM
E11.3293	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral	Diagnosis	ICD-10-CM
E11.3299	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye	Diagnosis	ICD-10-CM
E11.3311	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye	Diagnosis	ICD-10-CM
E11.3312	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye	Diagnosis	ICD-10-CM
E11.3313	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM
E11.3319	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye	Diagnosis	ICD-10-CM
E11.3391	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye	Diagnosis	ICD-10-CM
E11.3392	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye	Diagnosis	ICD-10-CM
E11.3393	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral	Diagnosis	ICD-10-CM
E11.3399	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye	Diagnosis	ICD-10-CM
E11.3411	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye	Diagnosis	ICD-10-CM
E11.3412	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye	Diagnosis	ICD-10-CM
E11.3413	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM
E11.3419	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye	Diagnosis	ICD-10-CM
E11.3491	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye	Diagnosis	ICD-10-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
E11.3492	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye	Diagnosis	ICD-10-CM
E11.3493	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral	Diagnosis	ICD-10-CM
E11.3499	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye	Diagnosis	ICD-10-CM
E11.3511	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye	Diagnosis	ICD-10-CM
E11.3512	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye	Diagnosis	ICD-10-CM
E11.3513	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM
E11.3519	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye	Diagnosis	ICD-10-CM
E11.3521	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye	Diagnosis	ICD-10-CM
E11.3522	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye	Diagnosis	ICD-10-CM
E11.3523	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral	Diagnosis	ICD-10-CM
E11.3529	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye	Diagnosis	ICD-10-CM
E11.3531	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye	Diagnosis	ICD-10-CM
E11.3532	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye	Diagnosis	ICD-10-CM
E11.3533	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral	Diagnosis	ICD-10-CM
E11.3539	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye	Diagnosis	ICD-10-CM
E11.3541	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye	Diagnosis	ICD-10-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
E11.3542	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye	Diagnosis	ICD-10-CM
E11.3543	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral	Diagnosis	ICD-10-CM
E11.3549	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye	Diagnosis	ICD-10-CM
E11.3551	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, right eye	Diagnosis	ICD-10-CM
E11.3552	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, left eye	Diagnosis	ICD-10-CM
E11.3553	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral	Diagnosis	ICD-10-CM
E11.3559	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye	Diagnosis	ICD-10-CM
E11.3591	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye	Diagnosis	ICD-10-CM
E11.3592	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye	Diagnosis	ICD-10-CM
E11.3593	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral	Diagnosis	ICD-10-CM
E11.3599	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye	Diagnosis	ICD-10-CM
E11.36	Type 2 diabetes mellitus with diabetic cataract	Diagnosis	ICD-10-CM
E11.37X1	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye	Diagnosis	ICD-10-CM
E11.37X2	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye	Diagnosis	ICD-10-CM
E11.37X3	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral	Diagnosis	ICD-10-CM
E11.37X9	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye	Diagnosis	ICD-10-CM
E11.39	Type 2 diabetes mellitus with other diabetic ophthalmic complication	Diagnosis	ICD-10-CM
E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified	Diagnosis	ICD-10-CM
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy	Diagnosis	ICD-10-CM
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy	Diagnosis	ICD-10-CM
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy	Diagnosis	ICD-10-CM
E11.44	Type 2 diabetes mellitus with diabetic amyotrophy	Diagnosis	ICD-10-CM
E11.49	Type 2 diabetes mellitus with other diabetic neurological complication	Diagnosis	ICD-10-CM
E11.51	Type 2 diabetes mellitus with diabetic peripheral angiopathy without gangrene	Diagnosis	ICD-10-CM
E11.52	Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene	Diagnosis	ICD-10-CM
E11.59	Type 2 diabetes mellitus with other circulatory complications	Diagnosis	ICD-10-CM
E11.610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy	Diagnosis	ICD-10-CM
E11.618	Type 2 diabetes mellitus with other diabetic arthropathy	Diagnosis	ICD-10-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
E11.620	Type 2 diabetes mellitus with diabetic dermatitis	Diagnosis	ICD-10-CM
E11.621	Type 2 diabetes mellitus with foot ulcer	Diagnosis	ICD-10-CM
E11.622	Type 2 diabetes mellitus with other skin ulcer	Diagnosis	ICD-10-CM
E11.628	Type 2 diabetes mellitus with other skin complications	Diagnosis	ICD-10-CM
E11.630	Type 2 diabetes mellitus with periodontal disease	Diagnosis	ICD-10-CM
E11.638	Type 2 diabetes mellitus with other oral complications	Diagnosis	ICD-10-CM
E11.641	Type 2 diabetes mellitus with hypoglycemia with coma	Diagnosis	ICD-10-CM
E11.649	Type 2 diabetes mellitus with hypoglycemia without coma	Diagnosis	ICD-10-CM
E11.65	Type 2 diabetes mellitus with hyperglycemia	Diagnosis	ICD-10-CM
E11.69	Type 2 diabetes mellitus with other specified complication	Diagnosis	ICD-10-CM
E11.8	Type 2 diabetes mellitus with unspecified complications	Diagnosis	ICD-10-CM
E11.9	Type 2 diabetes mellitus without complications	Diagnosis	ICD-10-CM
E13.00	Other specified diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)	Diagnosis	ICD-10-CM
E13.01	Other specified diabetes mellitus with hyperosmolarity with coma	Diagnosis	ICD-10-CM
E13.10	Other specified diabetes mellitus with ketoacidosis without coma	Diagnosis	ICD-10-CM
E13.11	Other specified diabetes mellitus with ketoacidosis with coma	Diagnosis	ICD-10-CM
E13.21	Other specified diabetes mellitus with diabetic nephropathy	Diagnosis	ICD-10-CM
E13.22	Other specified diabetes mellitus with diabetic chronic kidney disease	Diagnosis	ICD-10-CM
E13.29	Other specified diabetes mellitus with other diabetic kidney complication	Diagnosis	ICD-10-CM
E13.311	Other specified diabetes mellitus with unspecified diabetic retinopathy with macular edema	Diagnosis	ICD-10-CM
E13.319	Other specified diabetes mellitus with unspecified diabetic retinopathy without macular edema	Diagnosis	ICD-10-CM
E13.3211	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye	Diagnosis	ICD-10-CM
E13.3212	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye	Diagnosis	ICD-10-CM
E13.3213	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM
E13.3219	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye	Diagnosis	ICD-10-CM
E13.3291	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye	Diagnosis	ICD-10-CM
E13.3292	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye	Diagnosis	ICD-10-CM
E13.3293	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral	Diagnosis	ICD-10-CM
E13.3299	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye	Diagnosis	ICD-10-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
E13.3311	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye	Diagnosis	ICD-10-CM
E13.3312	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye	Diagnosis	ICD-10-CM
E13.3313	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM
E13.3319	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye	Diagnosis	ICD-10-CM
E13.3391	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye	Diagnosis	ICD-10-CM
E13.3392	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye	Diagnosis	ICD-10-CM
E13.3393	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral	Diagnosis	ICD-10-CM
E13.3399	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye	Diagnosis	ICD-10-CM
E13.3411	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye	Diagnosis	ICD-10-CM
E13.3412	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye	Diagnosis	ICD-10-CM
E13.3413	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM
E13.3419	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye	Diagnosis	ICD-10-CM
E13.3491	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye	Diagnosis	ICD-10-CM
E13.3492	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye	Diagnosis	ICD-10-CM
E13.3493	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral	Diagnosis	ICD-10-CM
E13.3499	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye	Diagnosis	ICD-10-CM
E13.3511	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye	Diagnosis	ICD-10-CM
E13.3512	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye	Diagnosis	ICD-10-CM
E13.3513	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
E13.3519	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye	Diagnosis	ICD-10-CM
E13.3521	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye	Diagnosis	ICD-10-CM
E13.3522	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye	Diagnosis	ICD-10-CM
E13.3523	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral	Diagnosis	ICD-10-CM
E13.3529	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye	Diagnosis	ICD-10-CM
E13.3531	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye	Diagnosis	ICD-10-CM
E13.3532	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye	Diagnosis	ICD-10-CM
E13.3533	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral	Diagnosis	ICD-10-CM
E13.3539	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye	Diagnosis	ICD-10-CM
E13.3541	Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye	Diagnosis	ICD-10-CM
E13.3542	Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye	Diagnosis	ICD-10-CM
E13.3543	Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral	Diagnosis	ICD-10-CM
E13.3549	Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye	Diagnosis	ICD-10-CM
E13.3551	Other specified diabetes mellitus with stable proliferative diabetic retinopathy, right eye	Diagnosis	ICD-10-CM
E13.3552	Other specified diabetes mellitus with stable proliferative diabetic retinopathy, left eye	Diagnosis	ICD-10-CM
E13.3553	Other specified diabetes mellitus with stable proliferative diabetic retinopathy, bilateral	Diagnosis	ICD-10-CM
E13.3559	Other specified diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye	Diagnosis	ICD-10-CM
E13.3591	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye	Diagnosis	ICD-10-CM
E13.3592	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye	Diagnosis	ICD-10-CM
E13.3593	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral	Diagnosis	ICD-10-CM
E13.3599	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye	Diagnosis	ICD-10-CM
E13.36	Other specified diabetes mellitus with diabetic cataract	Diagnosis	ICD-10-CM
E13.37X1	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, right eye	Diagnosis	ICD-10-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
E13.37X2	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, left eye	Diagnosis	ICD-10-CM
E13.37X3	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral	Diagnosis	ICD-10-CM
E13.37X9	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye	Diagnosis	ICD-10-CM
E13.39	Other specified diabetes mellitus with other diabetic ophthalmic complication	Diagnosis	ICD-10-CM
E13.40	Other specified diabetes mellitus with diabetic neuropathy, unspecified	Diagnosis	ICD-10-CM
E13.41	Other specified diabetes mellitus with diabetic mononeuropathy	Diagnosis	ICD-10-CM
E13.42	Other specified diabetes mellitus with diabetic polyneuropathy	Diagnosis	ICD-10-CM
E13.43	Other specified diabetes mellitus with diabetic autonomic (poly)neuropathy	Diagnosis	ICD-10-CM
E13.44	Other specified diabetes mellitus with diabetic amyotrophy	Diagnosis	ICD-10-CM
E13.49	Other specified diabetes mellitus with other diabetic neurological complication	Diagnosis	ICD-10-CM
E13.51	Other specified diabetes mellitus with diabetic peripheral angiopathy without gangrene	Diagnosis	ICD-10-CM
E13.52	Other specified diabetes mellitus with diabetic peripheral angiopathy with gangrene	Diagnosis	ICD-10-CM
E13.59	Other specified diabetes mellitus with other circulatory complications	Diagnosis	ICD-10-CM
E13.610	Other specified diabetes mellitus with diabetic neuropathic arthropathy	Diagnosis	ICD-10-CM
E13.618	Other specified diabetes mellitus with other diabetic arthropathy	Diagnosis	ICD-10-CM
E13.620	Other specified diabetes mellitus with diabetic dermatitis	Diagnosis	ICD-10-CM
E13.621	Other specified diabetes mellitus with foot ulcer	Diagnosis	ICD-10-CM
E13.622	Other specified diabetes mellitus with other skin ulcer	Diagnosis	ICD-10-CM
E13.628	Other specified diabetes mellitus with other skin complications	Diagnosis	ICD-10-CM
E13.630	Other specified diabetes mellitus with periodontal disease	Diagnosis	ICD-10-CM
E13.638	Other specified diabetes mellitus with other oral complications	Diagnosis	ICD-10-CM
E13.641	Other specified diabetes mellitus with hypoglycemia with coma	Diagnosis	ICD-10-CM
E13.649	Other specified diabetes mellitus with hypoglycemia without coma	Diagnosis	ICD-10-CM
E13.65	Other specified diabetes mellitus with hyperglycemia	Diagnosis	ICD-10-CM
E13.69	Other specified diabetes mellitus with other specified complication	Diagnosis	ICD-10-CM
E13.8	Other specified diabetes mellitus with unspecified complications	Diagnosis	ICD-10-CM
E13.9	Other specified diabetes mellitus without complications	Diagnosis	ICD-10-CM
G0108	Diabetes outpatient self-management training services, individual, per 30 minutes	Procedure	HCPCS
G0109	Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes	Procedure	HCPCS

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
	Initial physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) which must include: (1) the diagnosis of LOPS, (2) a patient history, (3) a physical examination that consists of at least the following elements: (a) visual inspection of the forefoot, hindfoot, and toe web spaces, (b) evaluation of a protective sensation, (c) evaluation of foot structure and biomechanics, (d) evaluation of vascular status and skin integrity, and (e) evaluation and recommendation of footwear, and (4) patient education	Procedure	HCPCS
	Follow-up physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include at least the following: (1) a patient history, (2) a physical examination that includes: (a) visual inspection of the forefoot, hindfoot, and toe web spaces, (b) evaluation of protective sensation, (c) evaluation of foot structure and biomechanics, (d) evaluation of vascular status and skin integrity, and (e) evaluation and recommendation of footwear, and (3) patient education	Procedure	HCPCS
G0247	Routine foot care by a physician of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include the local care of superficial wounds (i.e., superficial to muscle and fascia) and at least the following, if present: (1) local care of superficial wounds, (2) debridement of corns and calluses, and (3) trimming and debridement of nails	Procedure	HCPCS
G8015	Diabetic patient with most recent hemoglobin A1c level (within the last 6 months) documented as greater than 9%	Procedure	HCPCS
G8016	Diabetic patient with most recent hemoglobin A1c level (within the last 6 months) documented as less than or equal to 9%	Procedure	HCPCS
G8017	Clinician documented that diabetic patient was not eligible candidate for hemoglobin A1c measure	Procedure	HCPCS
G8018	Clinician has not provided care for the diabetic patient for the required time for hemoglobin A1c measure (6 months)	Procedure	HCPCS
G8019	Diabetic patient with most recent low-density lipoprotein (within the last 12 months) documented as greater than or equal to 100 mg/dl	Procedure	HCPCS
G8020	Diabetic patient with most recent low-density lipoprotein (within the last 12 months) documented as less than 100 mg/dl	Procedure	HCPCS
G8021	Clinician documented that diabetic patient was not eligible candidate for low-density lipoprotein measure	Procedure	HCPCS
G8022	Clinician has not provided care for the diabetic patient for the required time for low-density lipoprotein measure (12 months)	Procedure	HCPCS
G8023	Diabetic patient with most recent blood pressure (within the last 6 months) documented as equal to or greater than 140 systolic or equal to or greater than 80 mm Hg diastolic	Procedure	HCPCS
G8024	Diabetic patient with most recent blood pressure (within the last 6 months) documented as less than 140 systolic and less than 80 diastolic	Procedure	HCPCS
G8025	Clinician documented that the diabetic patient was not eligible candidate for blood pressure measure	Procedure	HCPCS

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
G8026	Clinician has not provided care for the diabetic patient for the required time for blood pressure measure (within the last 6 months)	Procedure	HCPCS
G8332	Clinician has not provided care for the diabetic retinopathy patient for the required time for macular edema and retinopathy measurement	Procedure	HCPCS
G8333	Patient documented to have had findings of macular or fundus exam communicated to the physician managing the diabetes care	Procedure	HCPCS
G8334	Documentation of findings of macular or fundus exam not communicated to the physician managing the patient's ongoing diabetes care	Procedure	HCPCS
G8335	Clinician documentation that patient was not an eligible candidate for the findings of their macular or fundus exam being communicated to the physician managing their diabetes care during the reporting year	Procedure	HCPCS
G8336	Clinician has not provided care for the diabetic retinopathy patient for the required time for physician communication measurement	Procedure	HCPCS
G8385	Diabetic patients with no documentation of hemoglobin A1c level (within the last 12 months)	Procedure	HCPCS
G8386	Diabetic patients with no documentation of low-density lipoprotein (within the last 12 months)	Procedure	HCPCS
G8390	Diabetic patients with no documentation of blood pressure measurement (within the last 12 months)	Procedure	HCPCS
	Ischemic Heart Disease		
411	Other acute and subacute forms of ischemic heart disease	Diagnosis	ICD-9-CM
411.0	Postmyocardial infarction syndrome	Diagnosis	ICD-9-CM
411.1	Intermediate coronary syndrome	Diagnosis	ICD-9-CM
411.8	Other acute and subacute forms of ischemic heart disease	Diagnosis	ICD-9-CM
411.81	Acute coronary occlusion without myocardial infarction	Diagnosis	ICD-9-CM
411.89	Other acute and subacute form of ischemic heart disease	Diagnosis	ICD-9-CM
413	Angina pectoris	Diagnosis	ICD-9-CM
413.0	Angina decubitus	Diagnosis	ICD-9-CM
413.1	Prinzmetal angina	Diagnosis	ICD-9-CM
413.9	Other and unspecified angina pectoris	Diagnosis	ICD-9-CM
414	Other forms of chronic ischemic heart disease	Diagnosis	ICD-9-CM
414.0	Coronary atherosclerosis	Diagnosis	ICD-9-CM
414.00	Coronary atherosclerosis of unspecified type of vessel, native or graft	Diagnosis	ICD-9-CM
414.01	Coronary atherosclerosis of native coronary artery	Diagnosis	ICD-9-CM
414.02	Coronary atherosclerosis of autologous vein bypass graft	Diagnosis	ICD-9-CM
414.03	Coronary atherosclerosis of nonautologous biological bypass graft	Diagnosis	ICD-9-CM
414.04	Coronary atherosclerosis of artery bypass graft	Diagnosis	ICD-9-CM
414.05	Coronary atherosclerosis of unspecified type of bypass graft	Diagnosis	ICD-9-CM
414.06	Coronary atherosclerosis, of native coronary artery of transplanted heart	Diagnosis	ICD-9-CM
414.07	Coronary atherosclerosis, of bypass graft (artery) (vein) of transplanted heart	Diagnosis	ICD-9-CM
414.1	Aneurysm and dissection of heart	Diagnosis	ICD-9-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
414.10	Aneurysm of heart	Diagnosis	ICD-9-CM
414.11	Aneurysm of coronary vessels	Diagnosis	ICD-9-CM
414.12	Dissection of coronary artery	Diagnosis	ICD-9-CM
414.19	Other aneurysm of heart	Diagnosis	ICD-9-CM
414.2	Chronic total occlusion of coronary artery	Diagnosis	ICD-9-CM
414.3	Coronary atherosclerosis due to lipid rich plaque	Diagnosis	ICD-9-CM
414.4	Coronary atherosclerosis due to calcified coronary lesion	Diagnosis	ICD-9-CM
414.8	Other specified forms of chronic ischemic heart disease	Diagnosis	ICD-9-CM
414.9	Unspecified chronic ischemic heart disease	Diagnosis	ICD-9-CM
429.2	Unspecified cardiovascular disease	Diagnosis	ICD-9-CM
429.5	Rupture of chordae tendineae	Diagnosis	ICD-9-CM
429.6	Rupture of papillary muscle	Diagnosis	ICD-9-CM
429.7	Certain sequelae of myocardial infarction, not elsewhere classified	Diagnosis	ICD-9-CM
429.71	Acquired cardiac septal defect	Diagnosis	ICD-9-CM
429.79	Other certain sequelae of myocardial infarction, not elsewhere classified	Diagnosis	ICD-9-CM
429.9	Unspecified heart disease	Diagnosis	ICD-9-CM
G8033	Prior myocardial infarction, coronary artery disease patient documented to be on beta-blocker therapy	Procedure	HCPCS
G8034	Prior myocardial infarction, coronary artery disease patient not documented to be on beta-blocker therapy	Procedure	HCPCS
G8035	Clinician documented that prior myocardial infarction, coronary artery disease patient was not eligible candidate for beta-blocker therapy measure	Procedure	HCPCS
G8036	Coronary artery disease patient documented to be on antiplatelet therapy	Procedure	HCPCS
G8037	Coronary artery disease patient not documented to be on antiplatelet therapy	Procedure	HCPCS
G8038	Clinician documented that coronary artery disease patient was not eligible candidate for antiplatelet therapy measure	Procedure	HCPCS
G8039	Coronary artery disease patient with low-density lipoprotein documented to be greater than 100 mg/dl	Procedure	HCPCS
G8040	Coronary artery disease patient with low-density lipoprotein documented to be less than or equal to 100 mg/dl	Procedure	HCPCS
G8041	Clinician documented that coronary artery disease patient was not eligible candidate for low-density lipoprotein measure	Procedure	HCPCS
I20.0	Unstable angina	Diagnosis	ICD-10-CM
I20.1	Angina pectoris with documented spasm	Diagnosis	ICD-10-CM
I20.8	Other forms of angina pectoris	Diagnosis	ICD-10-CM
I20.9	Angina pectoris, unspecified	Diagnosis	ICD-10-CM
I23.0	Hemopericardium as current complication following acute myocardial infarction	Diagnosis	ICD-10-CM
I23.1	Atrial septal defect as current complication following acute myocardial infarction	Diagnosis	ICD-10-CM
I23.2	Ventricular septal defect as current complication following acute myocardial infarction	Diagnosis	ICD-10-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
I23.3	Rupture of cardiac wall without hemopericardium as current complication following acute myocardial infarction	Diagnosis	ICD-10-CM
I23.4	Rupture of chordae tendineae as current complication following acute myocardial infarction	Diagnosis	ICD-10-CM
I23.5	Rupture of papillary muscle as current complication following acute myocardial infarction	Diagnosis	ICD-10-CM
I23.6	Thrombosis of atrium, auricular appendage, and ventricle as current complications following acute myocardial infarction	Diagnosis	ICD-10-CM
I23.7	Postinfarction angina	Diagnosis	ICD-10-CM
I23.8	Other current complications following acute myocardial infarction	Diagnosis	ICD-10-CM
I24.0	Acute coronary thrombosis not resulting in myocardial infarction	Diagnosis	ICD-10-CM
I24.1	Dressler's syndrome	Diagnosis	ICD-10-CM
I24.8	Other forms of acute ischemic heart disease	Diagnosis	ICD-10-CM
I24.9	Acute ischemic heart disease, unspecified	Diagnosis	ICD-10-CM
I25.10	Atherosclerotic heart disease of native coronary artery without angina pectoris	Diagnosis	ICD-10-CM
I25.110	Atherosclerotic heart disease of native coronary artery with unstable angina pectoris	Diagnosis	ICD-10-CM
I25.111	Atherosclerotic heart disease of native coronary artery with angina pectoris with documented spasm	Diagnosis	ICD-10-CM
I25.118	Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris	Diagnosis	ICD-10-CM
I25.119	Atherosclerotic heart disease of native coronary artery with unspecified angina pectoris	Diagnosis	ICD-10-CM
I25.3	Aneurysm of heart	Diagnosis	ICD-10-CM
I25.41	Coronary artery aneurysm	Diagnosis	ICD-10-CM
I25.42	Coronary artery dissection	Diagnosis	ICD-10-CM
I25.5	Ischemic cardiomyopathy	Diagnosis	ICD-10-CM
I25.6	Silent myocardial ischemia	Diagnosis	ICD-10-CM
I25.700	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unstable angina pectoris	Diagnosis	ICD-10-CM
I25.701	Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris with documented spasm	Diagnosis	ICD-10-CM
I25.708	Atherosclerosis of coronary artery bypass graft(s), unspecified, with other forms of angina pectoris	Diagnosis	ICD-10-CM
I25.709	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unspecified angina pectoris	Diagnosis	ICD-10-CM
I25.710	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unstable angina pectoris	Diagnosis	ICD-10-CM
I25.711	Atherosclerosis of autologous vein coronary artery bypass graft(s) with angina pectoris with documented spasm	Diagnosis	ICD-10-CM
I25.718	Atherosclerosis of autologous vein coronary artery bypass graft(s) with other forms of angina pectoris	Diagnosis	ICD-10-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
I25.719	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unspecified angina pectoris	Diagnosis	ICD-10-CM
I25.720	Atherosclerosis of autologous artery coronary artery bypass graft(s) with unstable angina pectoris	Diagnosis	ICD-10-CM
I25.721	Atherosclerosis of autologous artery coronary artery bypass graft(s) with angina pectoris with documented spasm	Diagnosis	ICD-10-CM
I25.728	Atherosclerosis of autologous artery coronary artery bypass graft(s) with other forms of angina pectoris	Diagnosis	ICD-10-CM
I25.729	Atherosclerosis of autologous artery coronary artery bypass graft(s) with unspecified angina pectoris	Diagnosis	ICD-10-CM
I25.730	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unstable angina pectoris	Diagnosis	ICD-10-CM
I25.731	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with angina pectoris with documented spasm	Diagnosis	ICD-10-CM
I25.738	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with other forms of angina pectoris	Diagnosis	ICD-10-CM
I25.739	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unspecified angina pectoris	Diagnosis	ICD-10-CM
I25.750	Atherosclerosis of native coronary artery of transplanted heart with unstable angina	Diagnosis	ICD-10-CM
I25.751	Atherosclerosis of native coronary artery of transplanted heart with angina pectoris with documented spasm	Diagnosis	ICD-10-CM
I25.758	Atherosclerosis of native coronary artery of transplanted heart with other forms of angina pectoris	Diagnosis	ICD-10-CM
I25.759	Atherosclerosis of native coronary artery of transplanted heart with unspecified angina pectoris	Diagnosis	ICD-10-CM
I25.760	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unstable angina	Diagnosis	ICD-10-CM
I25.761	Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina pectoris with documented spasm	Diagnosis	ICD-10-CM
I25.768	Atherosclerosis of bypass graft of coronary artery of transplanted heart with other forms of angina pectoris	Diagnosis	ICD-10-CM
I25.769	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unspecified angina pectoris	Diagnosis	ICD-10-CM
I25.790	Atherosclerosis of other coronary artery bypass graft(s) with unstable angina pectoris	Diagnosis	ICD-10-CM
I25.791	Atherosclerosis of other coronary artery bypass graft(s) with angina pectoris with documented spasm	Diagnosis	ICD-10-CM
I25.798	Atherosclerosis of other coronary artery bypass graft(s) with other forms of angina pectoris	Diagnosis	ICD-10-CM
I25.799	Atherosclerosis of other coronary artery bypass graft(s) with unspecified angina pectoris	Diagnosis	ICD-10-CM
I25.810	Atherosclerosis of coronary artery bypass graft(s) without angina pectoris	Diagnosis	ICD-10-CM
I25.811	Atherosclerosis of native coronary artery of transplanted heart without angina pectoris	Diagnosis	ICD-10-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
I25.812	Atherosclerosis of bypass graft of coronary artery of transplanted heart without angina pectoris	Diagnosis	ICD-10-CM
I25.82	Chronic total occlusion of coronary artery	Diagnosis	ICD-10-CM
I25.83	Coronary atherosclerosis due to lipid rich plaque	Diagnosis	ICD-10-CM
I25.84	Coronary atherosclerosis due to calcified coronary lesion	Diagnosis	ICD-10-CM
I25.89	Other forms of chronic ischemic heart disease	Diagnosis	ICD-10-CM
I25.9	Chronic ischemic heart disease, unspecified	Diagnosis	ICD-10-CM
I51.0	Cardiac septal defect, acquired	Diagnosis	ICD-10-CM
I51.1	Rupture of chordae tendineae, not elsewhere classified	Diagnosis	ICD-10-CM
I51.2	Rupture of papillary muscle, not elsewhere classified	Diagnosis	ICD-10-CM
I51.9	Heart disease, unspecified	Diagnosis	ICD-10-CM
I52	Other heart disorders in diseases classified elsewhere	Diagnosis	ICD-10-CM
	Renal Disorders		
584	Acute kidney failure	Diagnosis	ICD-9-CM
584.5	Acute kidney failure with lesion of tubular necrosis	Diagnosis	ICD-9-CM
584.6	Acute kidney failure with lesion of renal cortical necrosis	Diagnosis	ICD-9-CM
584.7	Acute kidney failure with lesion of medullary [papillary] necrosis	Diagnosis	ICD-9-CM
584.8	Acute kidney failure with other specified pathological lesion in kidney	Diagnosis	ICD-9-CM
584.9	Acute kidney failure, unspecified	Diagnosis	ICD-9-CM
585	Chronic kidney disease (CKD)	Diagnosis	ICD-9-CM
585.1	Chronic kidney disease, Stage I	Diagnosis	ICD-9-CM
585.2	Chronic kidney disease, Stage II (mild)	Diagnosis	ICD-9-CM
585.3	Chronic kidney disease, Stage III (moderate)	Diagnosis	ICD-9-CM
585.4	Chronic kidney disease, Stage IV (severe)	Diagnosis	ICD-9-CM
585.5	Chronic kidney disease, Stage V	Diagnosis	ICD-9-CM
585.6	End stage renal disease	Diagnosis	ICD-9-CM
585.9	Chronic kidney disease, unspecified	Diagnosis	ICD-9-CM
586	Unspecified renal failure	Diagnosis	ICD-9-CM
587	Unspecified renal sclerosis	Diagnosis	ICD-9-CM
N17.0	Acute kidney failure with tubular necrosis	Diagnosis	ICD-10-CM
N17.1	Acute kidney failure with acute cortical necrosis	Diagnosis	ICD-10-CM
N17.2	Acute kidney failure with medullary necrosis	Diagnosis	ICD-10-CM
N17.8	Other acute kidney failure	Diagnosis	ICD-10-CM
N17.9	Acute kidney failure, unspecified	Diagnosis	ICD-10-CM
N18.1	Chronic kidney disease, stage 1	Diagnosis	ICD-10-CM
N18.2	Chronic kidney disease, stage 2 (mild)	Diagnosis	ICD-10-CM
N18.3	Chronic kidney disease, stage 3 (moderate)	Diagnosis	ICD-10-CM
N18.4	Chronic kidney disease, stage 4 (severe)	Diagnosis	ICD-10-CM
N18.5	Chronic kidney disease, stage 5	Diagnosis	ICD-10-CM
N18.6	End stage renal disease	Diagnosis	ICD-10-CM
N18.9	Chronic kidney disease, unspecified	Diagnosis	ICD-10-CM
N19	Unspecified kidney failure	Diagnosis	ICD-10-CM

Appendix F. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
N26.1	Atrophy of kidney (terminal)	Diagnosis	ICD-10-CM
N26.9	Renal sclerosis, unspecified	Diagnosis	ICD-10-CM

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
Allergy Treatments	
Chlorpheniramine Maleate/Codeine Phosphate/Acetaminophen	Cotabflu
DIPHENHYDRAMINE HCL	Dicopanol
acetaminophen/dextromethorphan HBr	Child Cough and Sore Throat
aclidinium bromide	Tudorza Pressair
albuterol sulfate	ProAir HFA
albuterol sulfate	ProAir RespiClick
albuterol sulfate	Proventil HFA
albuterol sulfate	Ventolin HFA
albuterol sulfate	Vospire ER
albuterol sulfate	albuterol sulfate
alcaftadine	Lastacaft
aldosterone	aldosterone (bulk)
aminophylline	aminophylline
aminophylline	aminophylline (bulk)
arformoterol tartrate	Brovana
azelastine HCl	Astelin
azelastine HCl	Astepro
azelastine HCl	Optivar
azelastine HCl	azelastine
azelastine HCl/fluticasone propionate	Dymista
azelastine/fluticasone/sodium chloride/sodium bicarbonate	Ticalast
beclomethasone dipropionate	Beconase AQ
beclomethasone dipropionate	QNASL
beclomethasone dipropionate	Qvar
beclomethasone dipropionate	Qvar RediHaler
benralizumab	Fasenra
bepotastine besilate	Bepreve
betamethasone acetate and sodium phos in sterile water/PF	betameth ac,sodphos(PF)-water
betamethasone acetate and sodium phosph/norflurane/HFC 245fa	Betaloan SUIK
betamethasone acetate and sodium phosph/norflurane/HFC 245fa	Pod-Care 100CG
betamethasone acetate/betamethasone sodium phosphate	Beta-1
betamethasone acetate/betamethasone sodium phosphate	Celestone Soluspan
betamethasone acetate/betamethasone sodium phosphate	Pod-Care 100C
betamethasone acetate/betamethasone sodium phosphate	ReadySharp Betamethasone

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
betamethasone acetate/betamethasone sodium phosphate	betamethasone acet,sod phos
betamethasone acetate/betamethasone sodium phosphate/water	betamethasone ace,sodphos-wtr
betamethasone sodium phosph in sterile water for injection	betamethasone sodphosph-water
brompheniramine maleate	J-TAN PD
brompheniramine maleate	brompheniramine maleate(bulk)
brompheniramine maleate/phenylephrine HCl	Children's Cold-Allergy (PE)
brompheniramine maleate/phenylephrine HCl	Dimaphen (PE)
brompheniramine maleate/phenylephrine HCl	Glenmax PEB
brompheniramine maleate/phenylephrine HCl	Relhist BP
brompheniramine maleate/phenylephrine HCl/chlophedianol HCl	Trexbrom
brompheniramine maleate/phenylephrine HCl/codeine phosphate	M-END PE
brompheniramine maleate/phenylephrine HCl/codeine phosphate	Poly-Tussin AC
brompheniramine maleate/phenylephrine HCl/dextromethorphan	AP-Hist DM
brompheniramine maleate/phenylephrine HCl/dextromethorphan	Ala-Hist DM
brompheniramine maleate/phenylephrine HCl/dextromethorphan	Altipres-B
brompheniramine maleate/phenylephrine HCl/dextromethorphan	Bio T Pres-B
brompheniramine maleate/phenylephrine HCl/dextromethorphan	BroveX PEB DM
brompheniramine maleate/phenylephrine HCl/dextromethorphan	Children's Cold and Cough(PE)
brompheniramine maleate/phenylephrine HCl/dextromethorphan	Children's Cold and CoughDM
brompheniramine maleate/phenylephrine HCl/dextromethorphan	Children's Dibromm DMCold-Cou
brompheniramine maleate/phenylephrine HCl/dextromethorphan	Cold and Cough DM
brompheniramine maleate/phenylephrine HCl/dextromethorphan	Cold and Cough Elixir
brompheniramine maleate/phenylephrine HCl/dextromethorphan	Dimaphen DM
brompheniramine maleate/phenylephrine HCl/dextromethorphan	Dimetapp DM Cold-Cough(PE)
brompheniramine maleate/phenylephrine HCl/dextromethorphan	EndaCof - DM

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
brompheniramine maleate/phenylephrine HCl/dextromethorphan	Glenmax PEB DM
brompheniramine maleate/phenylephrine HCl/dextromethorphan	Glenmax PEB DM Forte
brompheniramine maleate/phenylephrine HCl/dextromethorphan	LoHist PEB DM
brompheniramine maleate/phenylephrine HCl/dextromethorphan	LoHist-DM
brompheniramine maleate/phenylephrine HCl/dextromethorphan	M-Hist DM
brompheniramine maleate/phenylephrine HCl/dextromethorphan	Niva-Hist DM
brompheniramine maleate/phenylephrine HCl/dextromethorphan	Presgen B
brompheniramine maleate/phenylephrine HCl/dextromethorphan	RelCof DM
brompheniramine maleate/phenylephrine HCl/dextromethorphan	Rynex DM
brompheniramine maleate/phenylephrine HCl/dextromethorphan	Tussi Pres-B
brompheniramine maleate/phenylephrine HCl/dextromethorphan	Wal-tap DM
brompheniramine maleate/phenylephrine HCl/dextromethorphan	brompheniramin-phenylephrin-DM
brompheniramine maleate/pseudoephedrine HCl/chlophedianol	Atuss DA
brompheniramine maleate/pseudoephedrine HCl/dextromethorphan	brompheniramine-pseudoeph-DM
budesonide	Pulmicort
budesonide	Pulmicort Flexhaler
budesonide	Rhinocort Allergy
budesonide	Rhinocort Aqua
budesonide	budesonide
budesonide, micronized	budesonide, micronized (bulk)
budesonide/formoterol fumarate	Symbicort
carbinoxamine maleate	Arbinoxa
carbinoxamine maleate	Karbinal ER
carbinoxamine maleate	PALGIC
carbinoxamine maleate	RyVent
carbinoxamine maleate	carbinoxamine maleate
cetirizine HCl	24Hour Allergy
cetirizine HCl	All Day Allergy (cetirizine)
cetirizine HCl	All Day Allergy Relief(cetir)
cetirizine HCl	Aller-Tec
cetirizine HCl	Allergy Relief (cetirizine)

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
cetirizine HCl	Child Allergy Relf(cetirizine)
cetirizine HCl	Child's All Day Allergy(cetir)
cetirizine HCl	Children's Aller-Tec
cetirizine HCl	Children's Allergy Complete
cetirizine HCl	Children's Allergy(cetirizine)
cetirizine HCl	Children's Cetirizine
cetirizine HCl	Children's Wal-Zyr
cetirizine HCl	Children's Zyrtec Allergy
cetirizine HCl	Wal-Zyr (cetirizine)
cetirizine HCl	Zyrtec
cetirizine HCl	cetirizine
cetirizine HCl/pseudoephedrine HCl	All Day Allergy-D
cetirizine HCl/pseudoephedrine HCl	Aller-Tec D
cetirizine HCl/pseudoephedrine HCl	Allergy Complete-D
cetirizine HCl/pseudoephedrine HCl	Allergy D-12
cetirizine HCl/pseudoephedrine HCl	Allergy Relief-D (cetirizine)
cetirizine HCl/pseudoephedrine HCl	Allergy-Congest Relief-D (cet)
cetirizine HCl/pseudoephedrine HCl	Cetiri-D
cetirizine HCl/pseudoephedrine HCl	Wal-Zyr D
cetirizine HCl/pseudoephedrine HCl	Zyrtec-D
cetirizine HCl/pseudoephedrine HCl	cetirizine-pseudoephedrine
chlophedianol HCl/guaifenesin	Chlo Tuss EX
chlophedianol HCl/guaifenesin	Vanacof G
chlophedianol HCl/guaifenesin	chlophedianol-guaifenesin
chlorcyclizine HCl	Ahist (chlorcyclizine)
chlorcyclizine HCl/codeine phosphate	Poly-Tussin
chlorcyclizine HCl/phenylephrine HCl	Dallergy (chlorcyclizine-PE)
chlorcyclizine HCl/pseudoephedrine HCl	Nasopen
chlorcyclizine HCl/pseudoephedrine HCl	Stahist AD
chlorcyclizine HCl/pseudoephedrine HCl/chlophedianol HCl	Biclora-D
chlorcyclizine HCl/pseudoephedrine HCl/codeine phosphate	Poly-Tussin D
chlorcyclizine hydrochloride/chlophedianol hydrochloride	Biclora
chlorpheniram/phenyleph/dextromethorphn /acetaminophen/guaifn	Cold-Flu M-SymptomDay-Night
chlorpheniram/phenyleph/dextromethorphn /acetaminophen/guaifn	Tylenol Cold-Flu SevereDay-Nt
chlorpheniramine maleate	Aller-Chlor
chlorpheniramine maleate	Allergy (chlorpheniramine)
chlorpheniramine maleate	Allergy 4-Hour
chlorpheniramine maleate	Allergy Relief(chlorpheniramn)
chlorpheniramine maleate	Allergy-Time
chlorpheniramine maleate	Chlor-Trimeton
chlorpheniramine maleate	Chlorphen SR

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
chlorpheniramine maleate	ED Chlorped Jr
chlorpheniramine maleate	Ed-ChlorPed
chlorpheniramine maleate	Ed-Chlortan
chlorpheniramine maleate	Pharbechlor
chlorpheniramine maleate	Wal-Finate
chlorpheniramine maleate	chlorpheniramine maleate
chlorpheniramine maleate/codeine phosphate	Codar AR
chlorpheniramine maleate/codeine phosphate	EndaCof-C
chlorpheniramine maleate/codeine phosphate	Tuxarin ER
chlorpheniramine maleate/codeine phosphate	Z-Tuss AC
chlorpheniramine maleate/codeine phosphate	Zodryl AC 25
chlorpheniramine maleate/codeine phosphate	Zodryl AC 30
chlorpheniramine maleate/codeine phosphate	Zodryl AC 35
chlorpheniramine maleate/codeine phosphate	Zodryl AC 40
chlorpheniramine maleate/codeine phosphate	Zodryl AC 50
chlorpheniramine maleate/codeine phosphate	Zodryl AC 60
chlorpheniramine maleate/codeine phosphate	Zodryl AC 80
chlorpheniramine maleate/dextromethorphan HBr	Chld Robitussin Night CoughDM
chlorpheniramine maleate/dextromethorphan HBr	Cough and Cold(chlorphen-DM)
chlorpheniramine maleate/dextromethorphan HBr	Cough-Cold Relief HBP
chlorpheniramine maleate/dextromethorphan HBr	Maxi-TussDM(chlorpheniramine)
chlorpheniramine maleate/dextromethorphan HBr	Scot-Tussin DM
chlorpheniramine maleate/phenylephrine HCl	Cold and Allergy
chlorpheniramine maleate/phenylephrine HCl	Sinus and Allergy PE
chlorpheniramine maleate/phenylephrine HCl	Sinus-Allergy (phenylephrine)
chlorpheniramine maleate/phenylephrine HCl/chlophedianol HCl	Carbaphen CH
chlorpheniramine maleate/phenylephrine HCl/chlophedianol HCl	Carbaphen Ped CH
chlorpheniramine maleate/phenylephrine HCl/chlophedianol HCl	ExaPhen CH
chlorpheniramine maleate/phenylephrine HCl/chlophedianol HCl	Phenagil CH
chlorpheniramine maleate/phenylephrine HCl/codeine phosphate	CapCof
chlorpheniramine maleate/phenylephrine HCl/codeine phosphate	Maxi-Tuss CD
chlorpheniramine maleate/phenylephrine HCl/dextromethorphan	Bio-Rytuss
chlorpheniramine maleate/phenylephrine HCl/dextromethorphan	Maxichlor PEH DM
chlorpheniramine maleate/phenylephrine HCl/ibuprofen	Advil Allergy-Congestion Rlf
chlorpheniramine maleate/phenylephrine bitartrate/aspirin	Cold Relief

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
chlorpheniramine maleate/phenylephrine bitartrate/aspirin	Cold Relief Plus
chlorpheniramine maleate/pseudoephedrine HCl/codeine	Tricode AR
chlorpheniramine maleate/pseudoephedrine HCl/codeine	Zodryl DAC 25
chlorpheniramine maleate/pseudoephedrine HCl/codeine	Zodryl DAC 30
chlorpheniramine maleate/pseudoephedrine HCl/codeine	Zodryl DAC 35
chlorpheniramine maleate/pseudoephedrine HCl/codeine	Zodryl DAC 40
chlorpheniramine maleate/pseudoephedrine HCl/codeine	Zodryl DAC 50
chlorpheniramine maleate/pseudoephedrine HCl/codeine	Zodryl DAC 60
chlorpheniramine maleate/pseudoephedrine HCl/codeine	Zodryl DAC 80
chlorpheniramine maleate/pseudoephedrine HCl/ibuprofen	Advil Allergy Sinus
ciclesonide	Alvesco
ciclesonide	Omnaris
ciclesonide	Zetonna
clemastine fumarate	Allergy Relief (clemastine)
clemastine fumarate	Allerhist (clemastine)
clemastine fumarate	Allerhist-1
clemastine fumarate	Dayhist Allergy
clemastine fumarate	Tavist-1
clemastine fumarate	clemastine
clemizole HCl	clemizole HCl (bulk)
codeine phosphate/guaifenesin	G Tussin AC
codeine phosphate/guaifenesin	Robafen AC
codeine phosphate/guaifenesin	Virtussin AC
codeine phosphate/guaifenesin	codeine-guaifenesin
codeine phosphate/pyrilamine maleate	Pro-Clear AC
codeine polistirex/chlorpheniramine polistirex	Tuzistra XR
cortisone acetate	cortisone
cromolyn sodium	Nasal Allergy SymptomControl
cromolyn sodium	cromolyn
cyproheptadine HCl	cyproheptadine
cyproheptadine HCl	cyproheptadine (bulk)
deflazacort	Emflaza
desloratadine	Clarinex
desloratadine	desloratadine
desloratadine/pseudoephedrine sulfate	Clarinex-D 12 HOUR

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
desloratadine/pseudoephedrine sulfate	Clarinex-D 24 HOUR
desoxycorticosterone acetate	desoxycorticosterone ac(bulk)
dexamethasone	Decadron
dexamethasone	DexPak 10 day
dexamethasone	DexPak 13 Day
dexamethasone	DexPak 6 Day
dexamethasone	Dexamethasone Intensol
dexamethasone	Dxevo
dexamethasone	HiDex
dexamethasone	LoCort
dexamethasone	TaperDex
dexamethasone	ZoDex
dexamethasone	ZonaCort
dexamethasone	dexamethasone
dexamethasone acetate and sodium phosphate in sterile water	dexamethasone ac, sodph-water
dexamethasone acetate in sodium chloride, iso-osmotic	dexamethasoneace-NaCl,iso-osm
dexamethasone acetate, micronized	dexamethasone ac, micro(bulk)
dexamethasone sodium phosphate	Dexonto
dexamethasone sodium phosphate	dexamethasone sod phos(bulk)
dexamethasone sodium phosphate in 0.9 % sodium chloride	dexamethasone-0.9 % sod.chlor
dexamethasone sodium phosphate/PF	Active Injection Kit D (PF)
dexamethasone sodium phosphate/PF	DoubleDex (PF)
dexamethasone sodium phosphate/PF	MAS Care-Pak (PF)
dexamethasone sodium phosphate/PF	dexamethasone sodium phos(PF)
dexamethasone sodium phosphate/lidocaine HCl	Lidocidex-I
dexamethasone, micronized	dexamethasone,micronized(bulk)
dexamethasone/PF/norflurane/pentafluoropropane (HFC 245fa)	DMT SUIK
dexbromphen-pseudoephedrine -dextromethorphan	M-End DMX
dexbrompheniramine maleate	Ala-Hist IR
dexbrompheniramine maleate	Pediavent
dexbrompheniramine maleate/chlophedianol HCl	Chlo Hist
dexbrompheniramine maleate/phenylephrine HCl	Ala-Hist PE
dexbrompheniramine maleate/phenylephrine HCl	Dallergy(dexbrompheniramn-PE)
dexbrompheniramine maleate/phenylephrine HCl	dexbrompheniramine-phenyleph
dexbrompheniramine maleate/pseudoephedrine HCl	Acticon (dexbromph-pse)
dexbrompheniramine maleate/pseudoephedrine HCl/codeine phos	M-End Max D
dexchlorpheniramine maleate	Ryclora
dexchlorpheniramine maleate	dexchlorpheniramine maleate

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
dexchlorpheniramine maleate/phenylephrine HCl	Rymed(dexchlorpheniramine-PE)
dexchlorpheniramine maleate/phenylephrine HCl	Stahist (dexchlorpheniramine)
dexchlorpheniramine maleate/phenylephrine HCl/codeine	Pro-Red AC (w/dexchlorphenir)
dexchlorpheniramine maleate/phenylephrine/dextromethorphan	Polytussin DM
dextromethorphan HBr/acetaminophen/chlorpheniramine maleate	Child Plus Cough andRunnyNose
dextromethorphan HBr/acetaminophen/chlorpheniramine maleate	Child's TylenolplusCough,RNos
dextromethorphan HBr/acetaminophen/chlorpheniramine maleate	Coricidin HBP Flu
dextromethorphan HBr/acetaminophen/chlorpheniramine maleate	Flu BP
dextromethorphan HBr/acetaminophen/chlorpheniramine maleate	Flu HBP
dextromethorphan HBr/acetaminophen/chlorpheniramine maleate	Maximum Strength Flu
dextromethorphan HBr/acetaminophen/chlorpheniramine maleate	Vicks NyQuil Cold/Flu (cpm)
dextromethorphan HBr/acetaminophen/diphenhydramine HCl	Diabetic Tussin Night Time
dextromethorphan HBr/acetaminophen/doxylamine	All-Nite Cold-Flu
dextromethorphan HBr/acetaminophen/doxylamine	Cold-Flu Relief
dextromethorphan HBr/acetaminophen/doxylamine	Contac Cold-Flu Night
dextromethorphan HBr/acetaminophen/doxylamine	Coricidin HBP Cold-MultiSympt
dextromethorphan HBr/acetaminophen/doxylamine	Cough-Sore Throat Night
dextromethorphan HBr/acetaminophen/doxylamine	Night Time
dextromethorphan HBr/acetaminophen/doxylamine	Night Time Cold
dextromethorphan HBr/acetaminophen/doxylamine	Night Time Cold and FluRelief
dextromethorphan HBr/acetaminophen/doxylamine	Night Time Cold-Flu
dextromethorphan HBr/acetaminophen/doxylamine	Night Time Cold-Flu Relief
dextromethorphan HBr/acetaminophen/doxylamine	Nighttime Cold-Flu

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
dextromethorphan HBr/acetaminophen/doxylamine	Nighttime Cold-Flu Relief
dextromethorphan HBr/acetaminophen/doxylamine	Nite Time Cold-Flu
dextromethorphan HBr/acetaminophen/doxylamine	Nite Time Cold-Flu Relief
dextromethorphan HBr/acetaminophen/doxylamine	Nite-Time Cold-Flu
dextromethorphan HBr/acetaminophen/doxylamine	Nitetime Multi-Symptom
dextromethorphan HBr/acetaminophen/doxylamine	Robitussin Cold-Flu Night
dextromethorphan HBr/acetaminophen/doxylamine	Vicks Nature Fusion Cold-Flu
dextromethorphan HBr/acetaminophen/doxylamine	Vicks NyQuil Cold/FluLiquicap
dextromethorphan HBr/acetaminophen/doxylamine	Vicks Nyquil Nighttime Relief
dextromethorphan HBr/doxylamine succinate	Daytime-Nighttime Cough
dextromethorphan HBr/doxylamine succinate	NightTime Cough
dextromethorphan HBr/doxylamine succinate	Nite Time Cough
dextromethorphan HBr/doxylamine succinate	Nitetime Cough
dextromethorphan HBr/doxylamine succinate	Robitussin Nighttime CoughDM
dextromethorphan HBr/doxylamine succinate	SafeTussin PM
dextromethorphan HBr/doxylamine succinate	Tussin Nighttime Cough DM
dextromethorphan HBr/doxylamine succinate	Vicks NyQuil Cough
dextromethorphan HBr/phenylephrine HCl	Children's Cold-CoughDaytime
dextromethorphan HBr/phenylephrine HCl	Children's Sudafed PE Cough
dextromethorphan HBr/phenylephrine HCl	Cold and Cough (pe-dm)
dextromethorphan HBr/phenylephrine HCl	Triaminic Cold and Cough(PE)
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Cold Head CongestionDaytime
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Cold Multi-Symptom
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Cold-Flu Relief
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Day Multi-Symp Flu-SevereCold
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Day Time PE
dextromethorphan HBr/phenylephrine HCl/acetaminophen	DayTime
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Daytime Cold

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Daytime Cold-Flu
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Daytime Cold-Flu Relief (PE)
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Flu Relief Therapy Daytime
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Flu-Severe Cold-CoughDaytime
dextromethorphan HBr/phenylephrine HCl/acetaminophen	HerbioMed Body Aches-SinusM-S
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Mapap Cold Formula
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Mucinex Fast-MaxCongest-Head
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Mucinex Fast-MaxSevCold-Sinus
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Robitussin Cold-Flu Day
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Sudafed PEPressure-Pain-Cough
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Theraflu ExpressMax ColdDay
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Theraflu Multi-Symptom Cold
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Tylenol Cold Max Day
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Tylenol Cold Multi-SymptomDay
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Vicks DayQuil Cold-Flu Relief
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Vicks Nature Fusion
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Wal-Flu Severe Cold-Cough
dextromethorphan HBr/phenylephrine HCl/dexbrompheniramine	Alahist CF
dextromethorphan HBr/phenylephrine HCl/dexbrompheniramine	Alahist DM
dextromethorphan HBr/phenylephrine HCl/dexbrompheniramine	Bionatuss DXP
dextromethorphan HBr/phenylephrine HCl/dexbrompheniramine	G-P-Tuss DXP
dextromethorphan HBr/phenylephrine HCl/dexbrompheniramine	Supress A

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
dextromethorphan HBr/phenylephrine/acetaminophen/doxylamine	Alka-Seltzer PlusSin-Allg-Cgh
dextromethorphan HBr/phenylephrine/acetaminophen/doxylamine	Cold Multi-SymptomNightTime
dextromethorphan HBr/phenylephrine/acetaminophen/doxylamine	Cold and Flu Relief Plus (D/N)
dextromethorphan HBr/phenylephrine/acetaminophen/doxylamine	Cold-Flu Relief, Day/Night
dextromethorphan HBr/phenylephrine/acetaminophen/doxylamine	Daytime-Nighttime
dextromethorphan HBr/phenylephrine/acetaminophen/doxylamine	Daytime-Nighttime Cold-Flu
dextromethorphan HBr/phenylephrine/acetaminophen/doxylamine	Mucinex Fast-Max Nite (doxyl)
dextromethorphan HBr/phenylephrine/acetaminophen/doxylamine	Nite Time Cold-Flu Relief (PE)
dextromethorphan HBr/phenylephrine/acetaminophen/doxylamine	Severe Cold and FluNighttime
dextromethorphan HBr/phenylephrine/acetaminophen/doxylamine	Severe Sinus CongestAlrgy-Cgh
dextromethorphan HBr/phenylephrine/acetaminophen/doxylamine	Tylenol Cold Max Night
dextromethorphan HBr/phenylephrine/acetaminophen/doxylamine	Tylenol Cold Multi-SymptNight
dextromethorphan HBr/phenylephrine/acetaminophen/doxylamine	Vicks NyQuil Severe Cold-Flu
dextromethorphan HBr/pseudoephedrine HCl/acetaminophen	DAY-TIME
dextromethorphan HBr/pseudoephedrine HCl/acetaminophen	Daytime Cold and Flu Relief
dextromethorphan/phenylephrine/acetaminophen /diphenhydramine	HerbioMed Deep Cold-FluNight
dextromethorphan/phenylephrine/acetaminophen /diphenhydramine	Multi-Symptom SevereCold-Nt
dextromethorphan/pseudoephrine HCl/acetaminophen/doxylamine	Alka-Seltzer Plus Cold+Flu
dextromethorphan/pseudoephrine HCl/acetaminophen/doxylamine	Night Time Cold Medicine
dextromethorphan/pseudoephrine HCl/acetaminophen/doxylamine	Night Time Cold-Flu
dextromethorphan/pseudoephrine HCl/acetaminophen/doxylamine	Night Time Cold-Flu Relief
dextromethorphan/pseudoephrine HCl/acetaminophen/doxylamine	Nite Time
diclofenac sodium	diclofenac sodium

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
diphenhydramine HCl	Alka-Seltzer Plus Allergy
diphenhydramine HCl	Aller-G-Time
diphenhydramine HCl	Allergy
diphenhydramine HCl	Allergy (diphenhydramine)
diphenhydramine HCl	Allergy Medication
diphenhydramine HCl	Allergy Medicine
diphenhydramine HCl	AllergyRelief(diphenhydramin)
diphenhydramine HCl	Banophen
diphenhydramine HCl	Banophen Allergy
diphenhydramine HCl	Benadryl
diphenhydramine HCl	Benadryl Allergy
diphenhydramine HCl	Child Allergy Relief (diphen)
diphenhydramine HCl	Children's Allergy (diphenhyd)
diphenhydramine HCl	Children's Allergy Medicine
diphenhydramine HCl	Children's Benadryl Allergy
diphenhydramine HCl	Children's Diphenhydramine
diphenhydramine HCl	Children's Wal-Dryl Allergy
diphenhydramine HCl	Complete Allergy
diphenhydramine HCl	Complete Allergy Medicine
diphenhydramine HCl	Compoz
diphenhydramine HCl	Diphedryl
diphenhydramine HCl	Diphen
diphenhydramine HCl	Diphenhist
diphenhydramine HCl	EZ Nite Sleep
diphenhydramine HCl	Geri-Dryl
diphenhydramine HCl	Medi-Phedryl
diphenhydramine HCl	Naramin
diphenhydramine HCl	NightTime Sleep Aid (diphen)
diphenhydramine HCl	Nighttime Allergy Relief
diphenhydramine HCl	Ormir
diphenhydramine HCl	Pharbedryl
diphenhydramine HCl	Q-Dryl
diphenhydramine HCl	Quenalin
diphenhydramine HCl	Rest Simply Nighttime Sleep
diphenhydramine HCl	Restfully Sleep
diphenhydramine HCl	Siladryl SA
diphenhydramine HCl	Silphen Cough
diphenhydramine HCl	Simply Sleep
diphenhydramine HCl	Sleep
diphenhydramine HCl	Sleep Aid (diphenhydramine)
diphenhydramine HCl	Sleep Aid Max Str(diphenhydr)
diphenhydramine HCl	Sleep II
diphenhydramine HCl	Sleep Time
diphenhydramine HCl	Sleep-Tabs
diphenhydramine HCl	Sleeping
diphenhydramine HCl	Total Allergy Medicine

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
diphenhydramine HCl	Unisom SleepGels
diphenhydramine HCl	Unisom SleepMelts
diphenhydramine HCl	Valu-Dryl Allergy
diphenhydramine HCl	Vanamine PD
diphenhydramine HCl	Vicks QlearQuil Nighttime Rlf
diphenhydramine HCl	Wal-Dryl Allergy
diphenhydramine HCl	Wal-Sleep Z
diphenhydramine HCl	Wal-Som (diphenhydramine)
diphenhydramine HCl	Z-Sleep
diphenhydramine HCl	ZzzQuil
diphenhydramine HCl	diphenhydramine HCl
diphenhydramine HCl in 0.9 % sodium chloride	diphenhydramine-0.9 %sod.chlr
diphenhydramine HCl/hydrocortisone	HC Derma-Pax
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Adult Robitussin Night M-SCld
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Allergy M-S Nighttime
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Allergy Plus Severe Sinus HA
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Allergy Sinus Headache (PE)
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Allergy and Cold PE
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Child Delsym Cough+Cold
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Children Dimetapp M-SCold-Flu
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Children's Mucinex NightTime
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Cold and FluRelief(diphen-pe)
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Cough and Severe Cold
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Delsym Cough-ColdNightTime
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Flu Relief Therapy Nighttime
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Flu and Sore Throat Relief
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Flu-Severe Cold-Cough Night
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Herbiomed Allergy Cold-Sinus
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Mucinex Fast-Max NiteCold-Flu

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Mucinex Sinus-Max NiteCongest
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Severe Allergy-SinusHeadache
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Severe Cold Cough-Flu
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Severe Cold PE
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Theraflu ExpressMax ColdNight
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Theraflu Night SevereCold-Cgh
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Theraflu Nighttime PowerPod
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Wal-Dryl Severe Allergy-Sinus
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Wal-Flu Severe Cold andCough
diphenhydramine HCl/phenylephrine HCl/acetaminophen	Wal-phed PE Severe Cold
diphenhydramine HCl/phenylephrine HCl/dextromethorphan HBr	Child Cold-Cough Day-Night
diphenhydramine HCl/phenylephrine/acetaminophen/guaifenesin	Sinus Relief Max StrDay-Night
diphenhydramine/phenylephrin/dextromethorph /acetaminophen/GG	Children's M-S ColdDay-Night
diphenhydramine/phenylephrin/dextromethorph /acetaminophen/GG	Daytime-ColdNighttime-Cld-Flu
diphenhydramine/phenylephrin/dextromethorph /acetaminophen/GG	Mucinex Fast-Max Day-NiteCold
diphenhydramine/phenylephrin/dextromethorph /acetaminophen/GG	Mucinex Fast-Max Day-NiteCong
doxylamine succ/pseudoephedrine HCl/dextromethorphan Hbr	Glentuss
doxylamine succ/pseudoephedrine HCl/dextromethorphan Hbr	Lortuss DM
doxylamine succinate/phenylephrine HCl	Poly Hist Forte
doxylamine succinate/phenylephrine HCl	Poly Hist Forte (doxylamine)
doxylamine succinate/phenylephrine HCl	doxylamine-phenylephrine
doxylamine succinate/pseudoephedrine HCl	Lortuss LQ
doxylamine/phenylephrine/dextromethorphan /acetaminophen/GG	Day-Nite Severe Cold-Flu
doxylamine/phenylephrine/dextromethorphan /acetaminophen/GG	Mucinex Fast-MaxDay-Nt(doxyl)

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
doxylamine/phenylephrine/dextromethorphan /acetaminophen/GG	Mucinex Sinus-Max Dy-Nt(dxyl)
doxylamine/phenylephrine/dextromethorphan /acetaminophen/GG	Severe Cold andFlu(Day/Night)
dupilumab	Dupixent
dyphylline	Lufyllin
dyphylline	dyphylline (bulk)
emedastine difumarate	Emadine
ephedrine sulfate	ephedrine sulfate
ephedrine sulfate/guaifenesin	Bronkaid Dual Action
epinastine HCl	Elestat
epinastine HCl	epinastine
epinephrine	Adrenaclick
epinephrine	Adrenalin
epinephrine	Adyphren
epinephrine	Adyphren Amp
epinephrine	Adyphren Amp II
epinephrine	Adyphren II
epinephrine	Auvi-Q
epinephrine	Bronchial Mist
epinephrine	Bronchial Mist Refill
epinephrine	EPIsnap
epinephrine	EpiPen
epinephrine	EpiPen 2-Pak
epinephrine	EpiPen Jr
epinephrine	EpiPen Jr 2-Pak
epinephrine	EpinephrineSnap-EMS
epinephrine	EpinephrineSnap-V
epinephrine	Epy
epinephrine	Primatene Mist
epinephrine	Symjepi
epinephrine	epinephrine
epinephrine HCl/PF	epinephrine HCl (PF)
fexofenadine HCl	Allegra Allergy
fexofenadine HCl	Aller-Fex
fexofenadine HCl	Aller-ease
fexofenadine HCl	Allergy Relief (fexofenadine)
fexofenadine HCl	Children's Allegra Allergy
fexofenadine HCl	Children's Allergy Relief(fex)
fexofenadine HCl	Children's Wal-Fex
fexofenadine HCl	Mucinex Allergy
fexofenadine HCl	Wal-Fex Allergy
fexofenadine HCl	fexofenadine
fexofenadine HCl	fexofenadine (bulk)
fexofenadine HCl/pseudoephedrine HCl	Allegra-D 12 Hour
fexofenadine HCl/pseudoephedrine HCl	Allegra-D 24 Hour

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
fexofenadine HCl/pseudoephedrine HCl	Allergy Relief D
fexofenadine HCl/pseudoephedrine HCl	Allergy Relief-D(fexofenadine)
fexofenadine HCl/pseudoephedrine HCl	Allergy-CongestRelief-D(fexo)
fexofenadine HCl/pseudoephedrine HCl	Wal-Fex D 12 Hour
fexofenadine HCl/pseudoephedrine HCl	Wal-Fex D 24 Hour
fexofenadine HCl/pseudoephedrine HCl	fexofenadine-pseudoephedrine
fludrocortisone acetate	fludrocortisone
flunisolide	Aerospan
flunisolide	flunisolide
fluocinolone acetonide/emollient combination no.65	Synalar Cream Kit
fluocinolone acetonide/emollient combination no.65	Synalar Ointment Kit
fluocinolone acetonide/skin cleanser comb no.28	Synalar TS
fluocinolone acetonide/skin cleanser no.10/silicone, tape	Xilapak
fluocinolone acetonide/urea/silicone, adhesive	Noxipak
flurbiprofen	flurbiprofen
fluticasone furoate	Arnuity Ellipta
fluticasone furoate	Children's Flonase Sensimist
fluticasone furoate	Flonase Sensimist
fluticasone furoate	Veramyst
fluticasone furoate/umeclidinium bromide/vilanterol trifenat	Trelegy Ellipta
fluticasone furoate/vilanterol trifenatate	Breo Ellipta
fluticasone propionate	24 Hour Allergy Relief
fluticasone propionate	Aller-Flo
fluticasone propionate	Allergy Relief (fluticasone)
fluticasone propionate	ArmonAir RespiClick
fluticasone propionate	Children's Flonase Allergy Rlf
fluticasone propionate	Childrens 24 Hr Allergy Relief
fluticasone propionate	ClariSpray
fluticasone propionate	Flonase
fluticasone propionate	Flonase Allergy Relief
fluticasone propionate	Flovent Diskus
fluticasone propionate	Flovent HFA
fluticasone propionate	Xhance
fluticasone propionate	fluticasone propionate
fluticasone propionate	fluticasone propionate (bulk)
fluticasone propionate, micronized	fluticasone prop, micro (bulk)
fluticasone propionate/emollient combination no.65	Beser Kit
fluticasone propionate/salmeterol xinafoate	Advair Diskus
fluticasone propionate/salmeterol xinafoate	Advair HFA
fluticasone propionate/salmeterol xinafoate	AirDuo RespiClick
fluticasone propionate/salmeterol xinafoate	Wixela Inhub

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
fluticasone propionate/salmeterol xinafoate	fluticasone propion-salmeterol
fluticasone propionate/sodium chloride/sodium bicarbonate	Ticanase
fluticasone propionate/sodium chloride/sodium bicarbonate	Ticaspray
formoterol fumarate	Foradil Aerolizer
formoterol fumarate	Perforomist
formoterol fumarate	formoterol fumarate (bulk)
formoterol fumarate dihydrate, micronized	formoterol fum dihyd,mic(bulk)
glycopyrrolate	Seebri Neohaler
glycopyrrolate/formoterol fumarate	Bevespi Aerosphere
glycopyrrolate/nebulizer accessories	Lonhala Magnair Refill
glycopyrrolate/nebulizer and accessories	Lonhala Magnair Starter
guaifenesin/acetaminophen	Chest Congestion
guaifenesin/dextromethorphan HBr	Adt Robitussin Peak Cld DMMax
guaifenesin/dextromethorphan HBr	Adult Cough Formula DM Max
guaifenesin/dextromethorphan HBr	Adult Robitussin Peak ColdDM
guaifenesin/dextromethorphan HBr	Adult Tussin Cough CongestDM
guaifenesin/dextromethorphan HBr	Adult Tussin DM
guaifenesin/dextromethorphan HBr	Adult Wal-Tussin DM Max
guaifenesin/dextromethorphan HBr	Allfen DM
guaifenesin/dextromethorphan HBr	Biocotron
guaifenesin/dextromethorphan HBr	Biospec DMX
guaifenesin/dextromethorphan HBr	Chest Congestion Relief DM
guaifenesin/dextromethorphan HBr	Chest Congestion-CoughRelief
guaifenesin/dextromethorphan HBr	Child ChestCongestion-Cough
guaifenesin/dextromethorphan HBr	Child Cough-Chest CongestDM
guaifenesin/dextromethorphan HBr	Child Delsym Cough+ChestDM
guaifenesin/dextromethorphan HBr	Child Mucinex CoughMini-Melts
guaifenesin/dextromethorphan HBr	Child Mucus Relief Cough
guaifenesin/dextromethorphan HBr	Child TriaminicCough-Congest
guaifenesin/dextromethorphan HBr	Children's Cough
guaifenesin/dextromethorphan HBr	Children's Mucinex Cough
guaifenesin/dextromethorphan HBr	Chld Robitussin Cough-ChestDM
guaifenesin/dextromethorphan HBr	Coricidin HBP ChestCong-Cough
guaifenesin/dextromethorphan HBr	Cough Control DM
guaifenesin/dextromethorphan HBr	Cough Control DM Max
guaifenesin/dextromethorphan HBr	CoughSuppressant-Expectorant
guaifenesin/dextromethorphan HBr	Cough Syrup DM
guaifenesin/dextromethorphan HBr	Cough-Chest Congestion DM
guaifenesin/dextromethorphan HBr	DM Max
guaifenesin/dextromethorphan HBr	Daytime Mucus Relief DM
guaifenesin/dextromethorphan HBr	Delsym Cough-ChestCongest DM
guaifenesin/dextromethorphan HBr	Diabetic Siltussin-DM
guaifenesin/dextromethorphan HBr	Diabetic Siltussin-DM Max Str
guaifenesin/dextromethorphan HBr	Diabetic Tussin DM

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
guaifenesin/dextromethorphan HBr	Diabetic Tussin Max St
guaifenesin/dextromethorphan HBr	Double-Tussin DM
guaifenesin/dextromethorphan HBr	Expectorant DM
guaifenesin/dextromethorphan HBr	Fenesin DM IR
guaifenesin/dextromethorphan HBr	G-Fenesin DM
guaifenesin/dextromethorphan HBr	G-Tron
guaifenesin/dextromethorphan HBr	G-Zyncof
guaifenesin/dextromethorphan HBr	Geri-Tussin DM
guaifenesin/dextromethorphan HBr	Guaiasorb DM
guaifenesin/dextromethorphan HBr	Guaicon DMS
guaifenesin/dextromethorphan HBr	Guaifenesin-DM
guaifenesin/dextromethorphan HBr	Intense Cough
guaifenesin/dextromethorphan HBr	Intense Cough Reliever
guaifenesin/dextromethorphan HBr	Iophen DM-NR
guaifenesin/dextromethorphan HBr	Medi-Tussin DM
guaifenesin/dextromethorphan HBr	Medi-Tussin DM Diabetic
guaifenesin/dextromethorphan HBr	Mucinex DM
guaifenesin/dextromethorphan HBr	Mucinex Fast-Max DM Max
guaifenesin/dextromethorphan HBr	Mucosa DM
guaifenesin/dextromethorphan HBr	Mucus DM
guaifenesin/dextromethorphan HBr	Mucus DM Max ER
guaifenesin/dextromethorphan HBr	Mucus Relief Cough
guaifenesin/dextromethorphan HBr	Mucus Relief DM
guaifenesin/dextromethorphan HBr	Mucus Relief DM Cough
guaifenesin/dextromethorphan HBr	Mucus Relief DM Max
guaifenesin/dextromethorphan HBr	Mucus Relief ER DM-MAX
guaifenesin/dextromethorphan HBr	Mucus and Cough Relief
guaifenesin/dextromethorphan HBr	Neo-Tuss
guaifenesin/dextromethorphan HBr	Q-Tussin DM
guaifenesin/dextromethorphan HBr	Refenesen DM
guaifenesin/dextromethorphan HBr	Ri-Tussin DM
guaifenesin/dextromethorphan HBr	Robafen DM
guaifenesin/dextromethorphan HBr	Robafen DM Cough
guaifenesin/dextromethorphan HBr	Robafen DM Cough-ChestCongest
guaifenesin/dextromethorphan HBr	Robitussin Cough-ChestCong DM
guaifenesin/dextromethorphan HBr	Safe Tussin DM
guaifenesin/dextromethorphan HBr	Scot-Tussin Senior
guaifenesin/dextromethorphan HBr	Siltussin DM DAS
guaifenesin/dextromethorphan HBr	Siltussin-DM
guaifenesin/dextromethorphan HBr	Sorbugen NR
guaifenesin/dextromethorphan HBr	Supress DM
guaifenesin/dextromethorphan HBr	TRISPEC DMX
guaifenesin/dextromethorphan HBr	Tab Tussin DM
guaifenesin/dextromethorphan HBr	Tusnel Diabetic
guaifenesin/dextromethorphan HBr	Tussin Cough DM
guaifenesin/dextromethorphan HBr	Tussin Cough-ChestCongestion

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
guaifenesin/dextromethorphan HBr	Tussin DM
guaifenesin/dextromethorphan HBr	Tussin DM Clear
guaifenesin/dextromethorphan HBr	Tussin DM Cough
guaifenesin/dextromethorphan HBr	Tussin DM Cough and Chest
guaifenesin/dextromethorphan HBr	Tussin DM Max
guaifenesin/dextromethorphan HBr	Ultra DM Free and Clear
guaifenesin/dextromethorphan HBr	Ultra Tuss Safe
guaifenesin/dextromethorphan HBr	Wal-Tussin DM
guaifenesin/dextromethorphan HBr	Zyncof
guaifenesin/dextromethorphan HBr	dextromethorphan-guaifenesin
guaifenesin/dextromethorphan HBr/phenylephrine	Actidom DMX
guaifenesin/dextromethorphan HBr/phenylephrine	Adult Robitussin M-S Cold
guaifenesin/dextromethorphan HBr/phenylephrine	Adult Robitussin Peak ColdM-S
guaifenesin/dextromethorphan HBr/phenylephrine	Adult Tussin Multi-Symp Cold
guaifenesin/dextromethorphan HBr/phenylephrine	Altipres
guaifenesin/dextromethorphan HBr/phenylephrine	Altipres Pediatric
guaifenesin/dextromethorphan HBr/phenylephrine	Aquanaz
guaifenesin/dextromethorphan HBr/phenylephrine	Bio T Pres
guaifenesin/dextromethorphan HBr/phenylephrine	Bio T Pres Pediatric
guaifenesin/dextromethorphan HBr/phenylephrine	Bio-S-Pres Dx
guaifenesin/dextromethorphan HBr/phenylephrine	BioGtuss NF
guaifenesin/dextromethorphan HBr/phenylephrine	Biobron DX
guaifenesin/dextromethorphan HBr/phenylephrine	Biobron SF
guaifenesin/dextromethorphan HBr/phenylephrine	Biocotron-D
guaifenesin/dextromethorphan HBr/phenylephrine	Biodesp DM
guaifenesin/dextromethorphan HBr/phenylephrine	Biogil
guaifenesin/dextromethorphan HBr/phenylephrine	Broncotron PED
guaifenesin/dextromethorphan HBr/phenylephrine	Brontuss SF
guaifenesin/dextromethorphan HBr/phenylephrine	Child MucinexCongestion-Cough
guaifenesin/dextromethorphan HBr/phenylephrine	Child Multi-SymptomCold/Cough
guaifenesin/dextromethorphan HBr/phenylephrine	Child's Mucus Relief M-S Cold
guaifenesin/dextromethorphan HBr/phenylephrine	Children's MucinexMulti-Symp
guaifenesin/dextromethorphan HBr/phenylephrine	Cough Control CF (PE)
guaifenesin/dextromethorphan HBr/phenylephrine	Cough and Cold
guaifenesin/dextromethorphan HBr/phenylephrine	Cough and Cold Mucus ReliefCF
guaifenesin/dextromethorphan HBr/phenylephrine	Deconex DMX
guaifenesin/dextromethorphan HBr/phenylephrine	Desgen
guaifenesin/dextromethorphan HBr/phenylephrine	Desgen DM
guaifenesin/dextromethorphan HBr/phenylephrine	Despec DM-G
guaifenesin/dextromethorphan HBr/phenylephrine	Despec EDA Cough-ColdDrops
guaifenesin/dextromethorphan HBr/phenylephrine	Despec-DM(phenyleph-DM-guaif)
guaifenesin/dextromethorphan HBr/phenylephrine	Dometuss-DMX
guaifenesin/dextromethorphan HBr/phenylephrine	Duravent DM
guaifenesin/dextromethorphan HBr/phenylephrine	Endacon
guaifenesin/dextromethorphan HBr/phenylephrine	Exactuss
guaifenesin/dextromethorphan HBr/phenylephrine	Exactuss TR

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
guaifenesin/dextromethorphan HBr/phenylephrine	Fast Mucus RlfCongest-Cough
guaifenesin/dextromethorphan HBr/phenylephrine	G-Supress DX
guaifenesin/dextromethorphan HBr/phenylephrine	G-Tron PED
guaifenesin/dextromethorphan HBr/phenylephrine	G-Tusicof
guaifenesin/dextromethorphan HBr/phenylephrine	Giltuss
guaifenesin/dextromethorphan HBr/phenylephrine	Giltuss Cough-Cold
guaifenesin/dextromethorphan HBr/phenylephrine	Giltuss Pediatric
guaifenesin/dextromethorphan HBr/phenylephrine	Giltuss TR
guaifenesin/dextromethorphan HBr/phenylephrine	Maxiphen DM
guaifenesin/dextromethorphan HBr/phenylephrine	Mucinex Fast-MaxCongest-Cough
guaifenesin/dextromethorphan HBr/phenylephrine	Mucus ReliefCongestion-Cough
guaifenesin/dextromethorphan HBr/phenylephrine	NeoTuss-D (ImprovedFormula)
guaifenesin/dextromethorphan HBr/phenylephrine	Nivanex DMX
guaifenesin/dextromethorphan HBr/phenylephrine	Pres Gen
guaifenesin/dextromethorphan HBr/phenylephrine	Pres Gen Pediatric
guaifenesin/dextromethorphan HBr/phenylephrine	Relhist DMX
guaifenesin/dextromethorphan HBr/phenylephrine	Robafen CF (phenylephrine)
guaifenesin/dextromethorphan HBr/phenylephrine	Robitussin Cough and ColdCF
guaifenesin/dextromethorphan HBr/phenylephrine	Robitussin M-S Cold CF Max
guaifenesin/dextromethorphan HBr/phenylephrine	Severe Congestion andCoughMax
guaifenesin/dextromethorphan HBr/phenylephrine	Supress DX
guaifenesin/dextromethorphan HBr/phenylephrine	Tusicof
guaifenesin/dextromethorphan HBr/phenylephrine	Tusnel DM
guaifenesin/dextromethorphan HBr/phenylephrine	Tusnel DMPediatric(phenyleph)
guaifenesin/dextromethorphan HBr/phenylephrine	Tussi-Pres
guaifenesin/dextromethorphan HBr/phenylephrine	Tussi-Pres Pediatric
guaifenesin/dextromethorphan HBr/phenylephrine	Tussin CF (PE-DM-guaif)
guaifenesin/dextromethorphan HBr/phenylephrine	Tussin CF Cough-Cold
guaifenesin/dextromethorphan HBr/phenylephrine	Tussin CF MAX
guaifenesin/dextromethorphan HBr/phenylephrine	Tusslin
guaifenesin/dextromethorphan HBr/phenylephrine	VanaTab DM
guaifenesin/dextromethorphan HBr/phenylephrine	Vanacof DM
guaifenesin/dextromethorphan HBr/phenylephrine	Wal-Tussin Cough and ColdCF
guaifenesin/dextromethorphan HBr/phenylephrine	phenylephrine-DM-guaifenesin
guaifenesin/dextromethorphan HBr/potassium citrate	Sorbutuss
guaifenesin/dextromethorphan HBr/pseudoephedrine HCl	Actinel
guaifenesin/dextromethorphan HBr/pseudoephedrine HCl	Actinel Pediatric
guaifenesin/dextromethorphan HBr/pseudoephedrine HCl	Ambi 40PSE-400GFN-20DM
guaifenesin/dextromethorphan HBr/pseudoephedrine HCl	Bionel

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
guaifenesin/dextromethorphan HBr/pseudoephedrine HCl	Bionel Pediatric
guaifenesin/dextromethorphan HBr/pseudoephedrine HCl	Capmist DM
guaifenesin/dextromethorphan HBr/pseudoephedrine HCl	Desgen DM(pseudoephedrine)
guaifenesin/dextromethorphan HBr/pseudoephedrine HCl	Despec-DM(pseudoeph-DM-guaif)
guaifenesin/dextromethorphan HBr/pseudoephedrine HCl	Entex PAC
guaifenesin/dextromethorphan HBr/pseudoephedrine HCl	Entre-Cough
guaifenesin/dextromethorphan HBr/pseudoephedrine HCl	ExeFen DMX
guaifenesin/dextromethorphan HBr/pseudoephedrine HCl	Pecgen PSE
guaifenesin/dextromethorphan HBr/pseudoephedrine HCl	Poly-Vent DM
guaifenesin/dextromethorphan HBr/pseudoephedrine HCl	Robafen CF
guaifenesin/dextromethorphan HBr/pseudoephedrine HCl	TRISPEC PSE
guaifenesin/dextromethorphan HBr/pseudoephedrine HCl	Tusnel DMPediatric(pseudoeph)
guaifenesin/dextromethorphan HBr/pseudoephedrine HCl	Tusnel New Formula
guaifenesin/dextromethorphan HBr/pseudoephedrine HCl	Tusnel Pediatric
guaifenesin/dextromethorphan HBr/pseudoephedrine HCl	Tussin CF
guaifenesin/dextromethorphan HBr/pseudoephedrine HCl	Z-Cof 12 DM
guaifenesin/dyphylline	Difil-G 400
guaifenesin/ephedrine HCl	Primatene Asthma
guaifenesin/hydrocodone bitartrate	Flowtuss
guaifenesin/hydrocodone bitartrate	Obredon
guaifenesin/hydrocodone bitartrate	hydrocodone-guaifenesin
guaifenesin/phenylephrine HCl	Chest Congestion Relief PE
guaifenesin/phenylephrine HCl	Chest-Sinus CongestionRelief
guaifenesin/phenylephrine HCl	Child Mucinex StuffyNose-Chst
guaifenesin/phenylephrine HCl	Child Mucinex StuffyNose-Cold
guaifenesin/phenylephrine HCl	Children's Stuffy Nose-Cold
guaifenesin/phenylephrine HCl	Congest-Eze PE
guaifenesin/phenylephrine HCl	Deconex IR
guaifenesin/phenylephrine HCl	Despec

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
guaifenesin/phenylephrine HCl	Duravent PE
guaifenesin/phenylephrine HCl	ED Bron GP
guaifenesin/phenylephrine HCl	Entex LQ
guaifenesin/phenylephrine HCl	ExaPhex TR
guaifenesin/phenylephrine HCl	Fenesin PE IR
guaifenesin/phenylephrine HCl	Gilphex TR
guaifenesin/phenylephrine HCl	J-MAX
guaifenesin/phenylephrine HCl	Liquibid D-R
guaifenesin/phenylephrine HCl	Liquibid PD-R
guaifenesin/phenylephrine HCl	Maxiphen
guaifenesin/phenylephrine HCl	MucaphEd
guaifenesin/phenylephrine HCl	Mucus Relief D(phenylephrine)
guaifenesin/phenylephrine HCl	Mucus Relief PE
guaifenesin/phenylephrine HCl	Mucus Relief Sinus
guaifenesin/phenylephrine HCl	Refenesen PE
guaifenesin/phenylephrine HCl	RelCof IR
guaifenesin/phenylephrine HCl	Rescon-GG
guaifenesin/phenylephrine HCl	Supress-PE
guaifenesin/phenylephrine HCl	TL-DMX
guaifenesin/phenylephrine HCl/acetaminophen	Cold HeadCongest(gg-pe-acetm)
guaifenesin/phenylephrine HCl/acetaminophen	Mucinex Cold and Sinus
guaifenesin/phenylephrine HCl/acetaminophen	Mucinex Fast-Max Cold-Sinus
guaifenesin/phenylephrine HCl/acetaminophen	Mucinex Sinus-MaxPressur-Pain
guaifenesin/phenylephrine HCl/acetaminophen	Mucinex Sinus-Max SevCongestn
guaifenesin/phenylephrine HCl/acetaminophen	Mucus Relief Cold and Sinus
guaifenesin/phenylephrine HCl/acetaminophen	Mucus ReliefSinusPressur-Pain
guaifenesin/phenylephrine HCl/acetaminophen	Mucus Rlf Severe SinusCongest
guaifenesin/phenylephrine HCl/acetaminophen	Pressure-Pain PE Plus Mucus
guaifenesin/phenylephrine HCl/acetaminophen	Severe Congestion Relief
guaifenesin/phenylephrine HCl/acetaminophen	Severe Sinus
guaifenesin/phenylephrine HCl/acetaminophen	Sinus Congestion-Pain(guaif)
guaifenesin/phenylephrine HCl/acetaminophen	Sinus Relief Pressure andPain
guaifenesin/phenylephrine HCl/acetaminophen	Sinus Relief SevereCongestion
guaifenesin/phenylephrine HCl/acetaminophen	Sudafed PEPressure-Pain-Mucus
guaifenesin/phenylephrine HCl/acetaminophen	Tylenol Cold Head CongestSevr
guaifenesin/phenylephrine HCl/acetaminophen	Tylenol Sinus CongestionPain
guaifenesin/phenylephrine HCl/acetaminophen	Tylenol Sinus Severe
guaifenesin/pseudoephedrine HCl	Ambi 60PSE-400GFN
guaifenesin/pseudoephedrine HCl	Chest Congestion Relief D
guaifenesin/pseudoephedrine HCl	Congest-Eze
guaifenesin/pseudoephedrine HCl	Congestac
guaifenesin/pseudoephedrine HCl	Despec-Tab
guaifenesin/pseudoephedrine HCl	Entex T
guaifenesin/pseudoephedrine HCl	ExeFen-IR
guaifenesin/pseudoephedrine HCl	Maxifed
guaifenesin/pseudoephedrine HCl	Mucinex D

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
guaifenesin/pseudoephedrine HCl	Mucinex D Maximum Strength
guaifenesin/pseudoephedrine HCl	Mucus D
guaifenesin/pseudoephedrine HCl	Mucus Relief D(pseudoephed)
guaifenesin/pseudoephedrine HCl	Poly-Vent IR
guaifenesin/pseudoephedrine HCl	Respaire-30
guaifenesin/pseudoephedrine HCl	Triacting Expectorant
guaifenesin/pseudoephedrine HCl	Tusnel Pediatric
guaifenesin/pseudoephedrine HCl	pseudoephedrine-guaifenesin
halobetasol propionate/ammonium lactate	Halonate
halobetasol propionate/ammonium lactate	Halonate Pac
halobetasol propionate/ammonium lactate	Ultravate PAC
halobetasol propionate/lactic acid	Ultravate X
hydrocodone bitartrate/chlorpheniramine maleate	Vituz
hydrocodone bitartrate/homatropine methylbromide	Hydrocodone Compound
hydrocodone bitartrate/homatropine methylbromide	Hydromet
hydrocodone bitartrate/homatropine methylbromide	Tussigon
hydrocodone bitartrate/homatropine methylbromide	hydrocodone-homatropine
hydrocodone bitartrate/pseudoephedrine HCl/guaifenesin	Hycofenix
hydrocodone polistirex/chlorpheniramine polistirex	TussiCaps
hydrocodone polistirex/chlorpheniramine polistirex	Tussionex Pennkinetic ER
hydrocodone polistirex/chlorpheniramine polistirex	hydrocodone-chlorpheniramine
hydrocortisone	Cortef
hydrocortisone	hydrocortisone
hydrocortisone acetate/aloe vera	Nucort
hydrocortisone acetate/aloe vera	hydrocortisone acet-aloe vera
hydrocortisone acetate/pramoxine HCl	Analpram-HC
hydrocortisone acetate/pramoxine HCl	Epifoam
hydrocortisone acetate/pramoxine HCl	Mezparox-HC
hydrocortisone acetate/pramoxine HCl	Novacort
hydrocortisone acetate/pramoxine HCl	Pramosone
hydrocortisone acetate/pramoxine HCl	hydrocortisone-pramoxine
hydrocortisone acetate/pramoxine HCl/aloe polysaccharide	Novacort (with aloe)
hydrocortisone acetate/pramoxine HCl/emollient base	Pramosone E
hydrocortisone acetate/urea	U-Cort
hydrocortisone sod succinate	A-Hydrocort
hydrocortisone sod succinate	Solu-Cortef
hydrocortisone sodium succinate/PF	Solu-Cortef Act-O-Vial (PF)
hydrocortisone/aloe vera	Anti-Itch(hydrocortisone)-Aloe

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
hydrocortisone/aloe vera	Cortisone with Aloe
hydrocortisone/aloe vera	Cortizone-10 with aloe
hydrocortisone/aloe vera	Hydrocortisone Plus
hydrocortisone/aloe vera	Hydroskin with Aloe
hydrocortisone/aloe vera	hydrocortisone-aloe vera
hydrocortisone/aloe vera/vitamin E acetate/vitamins A and D	Anti-Itch (HC) with Aloe-Vit E
hydrocortisone/aloe vera/vitamin E acetate/vitamins A and D	Anti-Itch Plus
hydrocortisone/emollient combination no.45	Pediaderm HC
hydrocortisone/mineral oil/petrolatum,white	hydrocortisone-min oil-wht pet
hydrocortisone/skin cleanser combination no.25	Aqua Glycolic HC
hydrocortisone/skin cleanser combination no.35	Dermasorb HC Complete Kit
ibuprofen	Addaprin
ibuprofen	Children's Ibu-Drops
ibuprofen	Children's Ibuprofen
ibuprofen	Ibuprofen IB
ibuprofen	Ibuprofen Jr Strength
ibuprofen	Infant's Ibuprofen
ibuprofen	Infants Ibu-Drops
ibuprofen	Medi-Profen
ibuprofen	Wal-Profen
ibuprofen	ibuprofen
ibuprofen/diphenhydramine HCl	Ibuprofen PM
ibuprofen/diphenhydramine HCl	ibuprofen-diphenhydramineHCl
ibuprofen/diphenhydramine citrate	Ibuprofen PM
ibuprofen/phenylephrine HCl	Advil Congestion Relief
ibuprofen/phenylephrine HCl	Congestion Relief(ibuprof-PE)
ibuprofen/pseudoephedrine HCl	Advil Cold and Sinus
ibuprofen/pseudoephedrine HCl	Cold and Sinus Pain Relief
ibuprofen/pseudoephedrine HCl	Cold-Sinus Relief
ibuprofen/pseudoephedrine HCl	Ibuprofen Cold
ibuprofen/pseudoephedrine HCl	Ibuprofen Cold-Sinus(withPSE)
ibuprofen/pseudoephedrine HCl	Wal-Profen Cold-Sinus
ibuprofen/pseudoephedrine HCl	Wal-Profen D Cold and Sinus
indacaterol maleate	Arcapta Neohaler
indacaterol maleate/glycopyrrolate	Utibron Neohaler
ipratropium bromide	Atrovent HFA
ipratropium bromide	ipratropium bromide
ipratropium bromide/albuterol sulfate	Combivent Respimat
ipratropium bromide/albuterol sulfate	DuoNeb
ipratropium bromide/albuterol sulfate	ipratropium-albuterol
ketotifen fumarate	Alaway
ketotifen fumarate	Allergy Eye (ketotifen)
ketotifen fumarate	Antihistamine Eye Drops
ketotifen fumarate	Children's Alaway

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
ketotifen fumarate	Eye Itch Relief
ketotifen fumarate	Itchy Eye Drops
ketotifen fumarate	Wal-Zyr (ketotifen)
ketotifen fumarate	Zaditor
ketotifen fumarate	ketotifen fumarate
levalbuterol HCl	Xopenex
levalbuterol HCl	Xopenex Concentrate
levalbuterol HCl	levalbuterol HCl
levalbuterol HCl	levalbuterol HCl (bulk)
levalbuterol tartrate	Xopenex HFA
levalbuterol tartrate	levalbuterol tartrate
levocetirizine dihydrochloride	24HR Allergy Relief
levocetirizine dihydrochloride	Xyzal
levocetirizine dihydrochloride	levocetirizine
levocetirizine dihydrochloride	levocetirizine (bulk)
lodoxamide tromethamine	Alomide
loratadine	Alavert
loratadine	Allerclear
loratadine	Allergy Relief (loratadine)
loratadine	Children's Allergy Relief(lor)
loratadine	Children's Claritin
loratadine	Children's Loratadine
loratadine	Claritin
loratadine	Claritin Liqui-Gel
loratadine	Claritin RediTabs
loratadine	Loradamed
loratadine	Non-Drowsy Allergy
loratadine	Vicks QlearQuil Allergy
loratadine	Wal-itin
loratadine	loratadine
loratadine	loratadine (bulk)
loratadine, micronized	loratadine, micronized (bulk)
loratadine/pseudoephedrine sulfate	Alavert D-12 Allergy-Sinus
loratadine/pseudoephedrine sulfate	AllerClear D-12hr
loratadine/pseudoephedrine sulfate	AllerClear D-24hr
loratadine/pseudoephedrine sulfate	Allergy Relief D-24hr
loratadine/pseudoephedrine sulfate	Allergy Relief D12
loratadine/pseudoephedrine sulfate	Allergy Relief,NasalDecongest
loratadine/pseudoephedrine sulfate	Allergy Relief-D (loratadine)
loratadine/pseudoephedrine sulfate	Allergy and Congestion Relief
loratadine/pseudoephedrine sulfate	Allergy-Congestion Relief-D
loratadine/pseudoephedrine sulfate	Claritin-D 12 Hour
loratadine/pseudoephedrine sulfate	Claritin-D 24 Hour
loratadine/pseudoephedrine sulfate	Lorata-D
loratadine/pseudoephedrine sulfate	Loratadine-D
loratadine/pseudoephedrine sulfate	Wal-Itin D 12 Hour

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
loratadine/pseudoephedrine sulfate	Wal-itin D
loratadine/pseudoephedrine sulfate	lorata-dine D
loratadine/pseudoephedrine sulfate	loratadine-pseudoephedrine
meloxicam	Mobic
meloxicam	meloxicam
mepolizumab	Nucala
metaproterenol sulfate	metaproterenol
methylprednisolone	Medrol
methylprednisolone	Medrol (Pak)
methylprednisolone	Methylpred DP
methylprednisolone	methylprednisolone
methylprednisolone acetate	Depo-Medrol
methylprednisolone acetate	P-Care D40
methylprednisolone acetate	P-Care D80
methylprednisolone acetate	ReadySharpMethylprednisolone
methylprednisolone acetate	methylprednisolone acetate
methylprednisolone acetate in sodium chloride,iso-osmotic/PF	methylpredac(PF)-NaCl,iso-osm
methylprednisolone acetate in sterile water for injection	methylprednisoloneacet-water
methylprednisolone acetate/bupivacaine HCl	Physicians EZ Use M-Pred
methylprednisolone acetate/bupivacaine HCl in sterile water	methylprednisolac-bupivac-wat
methylprednisolone acetate/norflurane/HFC 245fa	Medroloan II SUIK
methylprednisolone acetate/norflurane/HFC 245fa	Medroloan SUIK
methylprednisolone acetate/norflurane/HFC 245fa	P-Care D40G
methylprednisolone acetate/norflurane/HFC 245fa	P-Care D80G
methylprednisolone sodium succinate	Solu-Medrol
methylprednisolone sodium succinate	methylprednisolone sodiumsucc
methylprednisolone sodium succinate/PF	Solu-Medrol (PF)
methylprednisolone, micronized	methylprednisolone, mic(bulk)
mometasone furoate	Asmanex HFA
mometasone furoate	Asmanex Twisthaler
mometasone furoate	Nasonex
mometasone furoate	mometasone
mometasone furoate	mometasone furoate (bulk)
mometasone furoate/ammonium lactate	Momexin
mometasone furoate/formoterol fumarate	Dulera
montelukast sodium	Singulair
montelukast sodium	montelukast
montelukast sodium	montelukast (bulk)
naproxen	naproxen
naproxen sodium	All Day Pain Relief
naproxen sodium	All Day Relief
naproxen sodium	Flanax (naproxen)
naproxen sodium	Midol (naproxen)

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
naproxen sodium	Wal-Proxen
naproxen sodium	naproxen sodium
naproxen sodium/pseudoephedrine HCl	Aleve Cold and Sinus
naproxen sodium/pseudoephedrine HCl	Aleve Sinus and Headache
naproxen sodium/pseudoephedrine HCl	All Day Pain Relief Sinus,Cold
naproxen sodium/pseudoephedrine HCl	Sinus and Cold-D
nedocromil sodium	Alocril
olodaterol HCl	Striverdi Respimat
olopatadine HCl	Pataday
olopatadine HCl	Patanase
olopatadine HCl	Patanol
olopatadine HCl	Pazeo
olopatadine HCl	olopatadine
omalizumab	Xolair
phenylephrine HCl/acetaminophen	AcetaminophenCongestion-Pain
phenylephrine HCl/acetaminophen	Contac Cold-Flu Day
phenylephrine HCl/acetaminophen	DayTime Sinus
phenylephrine HCl/acetaminophen	Daytime Sinus-Congestion
phenylephrine HCl/acetaminophen	Mapap Sinus Max Strength(PE)
phenylephrine HCl/acetaminophen	Non-Aspirin Sinus
phenylephrine HCl/acetaminophen	Pain Relief Sinus PE
phenylephrine HCl/acetaminophen	Pyrroxate Cold andCongestion
phenylephrine HCl/acetaminophen	Sinus Congestion and Pain
phenylephrine HCl/acetaminophen	Sinus Headache PE
phenylephrine HCl/acetaminophen	Sinus Maximum Strength
phenylephrine HCl/acetaminophen	Sinus Pain-Pressure (PE)
phenylephrine HCl/acetaminophen	Sinus Relief (Non-Drowsy)
phenylephrine HCl/acetaminophen	Sudafed PE Pressure-Pain
phenylephrine HCl/acetaminophen	Suphedrine PE SinusHeadache
phenylephrine HCl/acetaminophen	Tylenol Sinus CongestionPain
phenylephrine HCl/acetaminophen	Vicks Dayquil Sinex
phenylephrine HCl/acetaminophen	Vicks QlearQuil DaytimeSinus
phenylephrine HCl/acetaminophen	Vicks Sinex Daytime
phenylephrine HCl/acetaminophen	Wal-Phed PE SinusHeadache
phenylephrine HCl/acetaminophen/chlorpheniramine	Allergy Multi-Symptom
phenylephrine HCl/acetaminophen/chlorpheniramine	Allergy Relief Multi-Symptom
phenylephrine HCl/acetaminophen/chlorpheniramine	Allergy Relief(chlorphen-acet)
phenylephrine HCl/acetaminophen/chlorpheniramine	Allergy Sinus PE
phenylephrine HCl/acetaminophen/chlorpheniramine	Contac Cold-Flu Day andNight

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
phenylephrine HCl/acetaminophen/chlorpheniramine	Contac Cold-Flu Max Strength
phenylephrine HCl/acetaminophen/chlorpheniramine	Dristan Cold
phenylephrine HCl/acetaminophen/chlorpheniramine	Effervescent Cold Relief Plus
phenylephrine HCl/acetaminophen/chlorpheniramine	Medicidin-D
phenylephrine HCl/acetaminophen/chlorpheniramine	Norel AD
phenylephrine HCl/acetaminophen/chlorpheniramine	Sinus Congest-PainDay-Night
phenylephrine HCl/acetaminophen/chlorpheniramine	SinusCongestion-Pain(chlorph)
phenylephrine HCl/acetaminophen/chlorpheniramine	Sinutrol PE
phenylephrine HCl/acetaminophen/doxylamine succinate	DayTime and NiteTime Sinus
phenylephrine HCl/acetaminophen/doxylamine succinate	NightTime Sinus
phenylephrine HCl/acetaminophen/doxylamine succinate	Nighttime Sinus-Congestion
phenylephrine HCl/acetaminophen/doxylamine succinate	Sinus Daytime-Nightime
phenylephrine HCl/acetaminophen/doxylamine succinate	Vicks Nyquil Sinex
phenylephrine HCl/acetaminophen/doxylamine succinate	Vicks QlearQuil NightimeSinus
phenylephrine HCl/chlophedianol HCl/guaifenesin	Donatussin Pediatric
phenylephrine HCl/chlophedianol HCl/guaifenesin	Vanacof GPE
phenylephrine HCl/chlophedianol HCl/guaifenesin	phenylephrine-chlophedianol-GG
phenylephrine HCl/codeine phosphate/acetaminophen/guaifen	Phenflu CD
phenylephrine HCl/codeine phosphate/acetaminophen/guaifen	Phenflu CDX
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Children's Cold-Cough-Sore
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Children's MucinexCold-Fever
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Cold Head Congestion SeverDay
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Cold Severe Congestion
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Cold and Flu Severe

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Cold-Cough Sinus Relief PE
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Decorel Forte Plus
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Delsym Cough-Cold Daytime
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Dometuss G
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Fast Mucus Relief SevereCold
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Head Congestion Cold Relief
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Herbiomed Severe Cold-FluM-S
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Mucinex Cold,Flu,Sore Throat
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Mucinex Fast-MaxCold-Flu-Thrt
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Mucinex Fast-Max SevereCold
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Mucinex Sinus-MaxPressure-Cgh
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Mucinex Sinus-Max SevCong(DM)
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Mucus Relief Cold-Flu-SoreThr
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Mucus Relief Plus
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Mucus Relief SevCongest-Cold
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Mucus Relief Severe Cold
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Multi-Symptom Cold (PE)
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Non-Pseudo Cold Relief
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Pain Relief Cold
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Pressure-Pain PE Plus Cold
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Pressure-Pain-Cold
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Rompe Pecho Max MultiSymptoms

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Severe Cold
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Severe Cold Multi-Symptom
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Severe Cold and Flu (PE)
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Sudafed PEPressure-Pain-Cold
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Tussin CF Max Severe M-SCold
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Tylenol Cold and Flu Severe
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Vicks DayQuil SevereCold-Flu
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Wal-Phed PE Cold-Cough
phenylephrine HCl/dextromethorphan HBr/acetaminophen/guaifen	Wal-Phed PEPressure+Pain+Cold
phenylephrine HCl/diphenhydramine HCl	Aldex-CT
phenylephrine HCl/diphenhydramine HCl	Allergy and Sinus Relief
phenylephrine HCl/diphenhydramine HCl	Child Allergy Plus Congestion
phenylephrine HCl/diphenhydramine HCl	Child Benadryl PlusCongestion
phenylephrine HCl/diphenhydramine HCl	Child's Benadryl-D Allergy-Sin
phenylephrine HCl/diphenhydramine HCl	Children Night TimeCold-Cough
phenylephrine HCl/diphenhydramine HCl	Childs Triacting Cold-Cough
phenylephrine HCl/diphenhydramine HCl	Cold and Cough(diphenhydr-pe)
phenylephrine HCl/diphenhydramine HCl	Dimetapp Cold-Congestion
phenylephrine HCl/diphenhydramine HCl	Nighttime Cough-Cold
phenylephrine HCl/diphenhydramine HCl	Triaminic Cold andCoughNT(PE)
phenylephrine HCl/diphenhydramine HCl	diphenhydramine-phenylephrine
phenylephrine HCl/promethazine HCl	Promethazine VC
phenylephrine HCl/promethazine HCl	promethazine-phenylephrine
phenylephrine HCl/pyrilamine maleate	Aldex D
phenylephrine HCl/pyrilamine maleate	Glen PE
phenylephrine HCl/pyrilamine maleate	Poly Hist Forte (pyrilamine)
phenylephrine HCl/pyrilamine maleate	Pyril D
phenylephrine HCl/pyrilamine maleate	Vazotab (pyrilamine)
phenylephrine HCl/pyrilamine maleate	pyrilamine-phenylephrine
phenylephrine HCl/triprolidine HCl	Histex PE
phenylephrine HCl/triprolidine HCl	Sinus Nighttime
prednisolone	Millipred
prednisolone	Millipred DP
prednisolone	Prelone
prednisolone	prednisolone
prednisolone acetate	Flo-Pred

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
prednisolone acetate, micronized	prednisolone ac, micro (bulk)
prednisolone, micronized	prednisolone, micro (bulk)
prednisone	Deltasone
prednisone	Prednisone Intensol
prednisone	Rayos
prednisone	prednisone
prednisone micronized	prednisone micronized (bulk)
promethazine HCl	Phenadoz
promethazine HCl	Phenergan
promethazine HCl	Promethegan
promethazine HCl	promethazine
promethazine HCl	promethazine (bulk)
promethazine HCl in 0.9 % sodium chloride	promethazine in 0.9 % NaCl
promethazine HCl/codeine	promethazine-codeine
promethazine HCl/dextromethorphan HBr	promethazine-DM
promethazine/phenylephrine HCl/codeine	Promethazine VC-Codeine
promethazine/phenylephrine HCl/codeine	promethazine-phenyleph-codeine
pseudoephedrine HCl/acetaminophen	Nexafed Sinus Pressure-Pain
pseudoephedrine HCl/acetaminophen	Sinus HeadacheDegongestant
pseudoephedrine HCl/acetaminophen/chlorpheniramine	Allergy Sinus-D
pseudoephedrine HCl/acetaminophen/chlorpheniramine	Non-Aspirin Allergy Sinus
pseudoephedrine HCl/acetaminophen/chlorpheniramine	Non-Aspirin Child's Cold
pseudoephedrine HCl/acetaminophen/chlorpheniramine	Pain Reliever Allergy Sinus
pseudoephedrine HCl/acrivastine	Semprex-D
pseudoephedrine HCl/chlophedianol HCl	Rondec-D
pseudoephedrine HCl/chlophedianol HCl/guaifenesin	Certuss-D
pseudoephedrine HCl/chlophedianol HCl/guaifenesin	Vanacof DX
pseudoephedrine HCl/chlophedianol HCl/guaifenesin	Vanatab DX
pseudoephedrine HCl/chlorpheniramine maleate/bellad alk	Respa-AR
pseudoephedrine HCl/codeine phosphate	Codar D
pseudoephedrine HCl/codeine phosphate/acetaminophen/guaifen	Maxiflu CD
pseudoephedrine HCl/codeine phosphate/acetaminophen/guaifen	Maxiflu CDX
pseudoephedrine HCl/codeine phosphate/guaifenesin	Cheratussin DAC

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
pseudoephedrine HCl/codeine phosphate/guaifenesin	Coditussin DAC
pseudoephedrine HCl/codeine phosphate/guaifenesin	Guaifenesin DAC
pseudoephedrine HCl/codeine phosphate/guaifenesin	Lortuss EX
pseudoephedrine HCl/codeine phosphate/guaifenesin	Phenylhistine
pseudoephedrine HCl/codeine phosphate/guaifenesin	Tricode GF
pseudoephedrine HCl/codeine phosphate/guaifenesin	Tusnel C
pseudoephedrine HCl/codeine phosphate/guaifenesin	Virtussin DAC
pseudoephedrine HCl/codeine phosphate/guaifenesin	Zodryl DEC 25
pseudoephedrine HCl/codeine phosphate/guaifenesin	Zodryl DEC 30
pseudoephedrine HCl/codeine phosphate/guaifenesin	Zodryl DEC 35
pseudoephedrine HCl/codeine phosphate/guaifenesin	Zodryl DEC 40
pseudoephedrine HCl/codeine phosphate/guaifenesin	Zodryl DEC 50
pseudoephedrine HCl/codeine phosphate/guaifenesin	Zodryl DEC 60
pseudoephedrine HCl/codeine phosphate/guaifenesin	Zodryl DEC 80
pseudoephedrine HCl/codeine/chlorpheniramine	Phenylhistine DH
pseudoephedrine HCl/hydrocodone bitartrate	Rezira
pyrilamine maleate	pyrilamine maleate (bulk)
pyrilamine maleate/chlophedianol HCl	DayClear Allergy Relief
pyrilamine maleate/chlophedianol HCl	Ninjacof
pyrilamine maleate/chlophedianol HCl	VanaCof AC
pyrilamine maleate/chlophedianol HCl	VanaTab AC
pyrilamine maleate/chlophedianol HCl	Vanacof-8
pyrilamine maleate/chlophedianol HCl/acetaminophen	Ninjacof-A
pyrilamine maleate/dextromethorphan HBr	Capron DM
pyrilamine maleate/dextromethorphan HBr	Capron DMT
pyrilamine maleate/phenylephrine HCl/chlophedianol HCl	Pro-Chlo
pyrilamine maleate/phenylephrine HCl/dextromethorphan HBr	Codituss DM

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
pyrilamine maleate/pseudoephedrine HCl/chlophedianol HCl	Ninjacof-D
racepinephrine HCl	Asthmanefrin Refill
racepinephrine HCl	Asthmanefrin Starter Kit
racepinephrine HCl	S2 Racepinephrine
racepinephrine HCl	racepinephrine
racepinephrine HCl	racepinephrine (bulk)
reslizumab	Cinqair
revefenacin	Yupelri
roflumilast	Daliresp
salmeterol xinafoate	Serevent Diskus
terbutaline sulfate	terbutaline
theophylline anhydrous	Elixophyllin
theophylline anhydrous	Theo-24
theophylline anhydrous	Theochron
theophylline anhydrous	theophylline
thonzylamine HCl/chlophedianol HCl	POLY HIST PD
thonzylamine HCl/phenylephrine HCl	Nasopen PE
thonzylamine HCl/phenylephrine HCl/chlophedianol HCl	Vanacof APE
thonzylamine HCl/phenylephrine HCl/dextromethorphan HBr	Poly-Hist DM (thonzylamine)
tiotropium bromide	Spiriva Respimat
tiotropium bromide	Spiriva with HandiHaler
tiotropium bromide/olodaterol HCl	Stiolto Respimat
tranilast	tranilast (bulk)
triamcinolone acetonide	24 Hour Nasal Allergy
triamcinolone acetonide	Arze-Ject-A
triamcinolone acetonide	Children's Nasacort
triamcinolone acetonide	Kenalog
triamcinolone acetonide	Kenalog-80
triamcinolone acetonide	Nasacort
triamcinolone acetonide	Nasacort AQ
triamcinolone acetonide	Nasal Allergy
triamcinolone acetonide	P-Care K40
triamcinolone acetonide	P-Care K80
triamcinolone acetonide	Pod-Care 100K
triamcinolone acetonide	Pro-C-Dure 5
triamcinolone acetonide	Pro-C-Dure 6
triamcinolone acetonide	ReadySharp Triamcinolone
triamcinolone acetonide	Zilretta
triamcinolone acetonide	triamcinolone acetonide
triamcinolone acetonide	triamcinolone acetonide (bulk)
triamcinolone acetonide in 0.9 % sodium chloride	triamcinolone aceton-0.9%NaCl
triamcinolone acetonide/0.9% sodium chloride/PF	triamcinol ac (PF) in0.9%NaCl
triamcinolone acetonide/dimethicone	Ellzia Pak

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
triamcinolone acetonide/dimethicone/silicone, adhesive	DermaSilkRx SDS
triamcinolone acetonide/dimethicone/silicone, adhesive	DermaWerx SDS
triamcinolone acetonide/dimethicone/silicone, adhesive	DermacinRx SilaPak
triamcinolone acetonide/dimethicone/silicone, adhesive	NuTriaRx
triamcinolone acetonide/dimethicone/silicone, adhesive	SanaDermRx
triamcinolone acetonide/dimethicone/silicone, adhesive	Sure Result Tac Pak
triamcinolone acetonide/dimethicone/silicone, adhesive	Tri-Sila
triamcinolone acetonide/dimethicone/silicone, adhesive	Whytederm TDPak
triamcinolone acetonide/dimethicone/silicone, adhesive	Whytederm Trilasil Pak
triamcinolone acetonide/emollient combination no.45	Pediaderm TA
triamcinolone acetonide/emollient combination no.86	Dermasorb TA Complete Kit
triamcinolone acetonide/lidocaine HCl	EZ Use Joint-Tunnel-Trigger
triamcinolone acetonide/lidocaine HCl	Lidocilone I
triamcinolone acetonide/lidocaine/prilocaine	DermacinRx Cinlone-I CPI
triamcinolone diacetate in 0.9 % sodium chloride	triamcinolone diacet-0.9%NaCl
triamcinolone diacetate in 0.9 % sodium chloride/PF	triamcinolonedia(PF)-0.9%NaCl
triamcinolone hexacetonide	Aristospan Intra-Articular
triamcinolone hexacetonide	Aristospan Intralesional
triamcinolone hexacetonide	triamcinolone hexaceton(bulk)
triamcinolone hexacetonide, micronized	triamcin hexacet, micro (bulk)
triamcinolone/norflurane and pentafluoropropane (HFC 245fa)	P-Care K40G
triamcinolone/norflurane and pentafluoropropane (HFC 245fa)	P-Care K80G
triamcinolone/norflurane and pentafluoropropane (HFC 245fa)	Pod-Care 100KG
triamcinolone/norflurane and pentafluoropropane (HFC 245fa)	Triloan II SUIK
triamcinolone/norflurane and pentafluoropropane (HFC 245fa)	Triloan SUIK
trimeprazine tartrate	trimeprazine tartrate (bulk)
tripelennamine HCl	tripelennamine (bulk)
triprolidine HCl	Histex (triprolidine)

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
triprolidine HCl	Histex PD
triprolidine HCl	Histex PDX
triprolidine HCl	M-Hist PD
triprolidine HCl	VanaClear PD
triprolidine HCl	Vanahist PD
triprolidine HCl	triprolidine HCl
triprolidine HCl	triprolidine HCl (bulk)
triprolidine HCl/phenylephrine HCl/codeine phosphate	Histex-AC
triprolidine HCl/phenylephrine HCl/dextromethorphan HBr	Histex DM
triprolidine HCl/pseudoephedrine HCl	Aprodine
triprolidine HCl/pseudoephedrine HCl/chlophedianol HCl	Trymine CD
umeclidinium bromide	Incruse Ellipta
umeclidinium bromide/vilanterol trifenatate	Anoro Ellipta
zafirlukast	Accolate
zafirlukast	zafirlukast
zileuton	Zyflo
zileuton	Zyflo CR
zileuton	zileuton
Nonsteroidal Anti-Inflammatory Drugs	
CHLORPHENIRAMINE MALEATE/PHENYLEPHRINE HCL/IBUPROFEN	Advil Allergy-Congestion Rlf
CHLORPHENIRAMINE MALEATE/PSEUDOEPHEDRINE HCL/IBUPROFEN	Advil Allergy Sinus
HYDROCODONE/IBUPROFEN	Ibudone
HYDROCODONE/IBUPROFEN	Reprexain
HYDROCODONE/IBUPROFEN	Vicoprofen
HYDROCODONE/IBUPROFEN	Xylon 10
HYDROCODONE/IBUPROFEN	hydrocodone-ibuprofen
IBUPROFEN	Children's Ibuprofen
IBUPROFEN	ibuprofen
IBUPROFEN/OXYCODONE HCL	ibuprofen-oxycodone
IBUPROFEN/PHENYLEPHRINE HCL	Advil Congestion Relief
IBUPROFEN/PHENYLEPHRINE HCL	Congestion Relief(ibuprof-PE)
IBUPROFEN/PSEUDOEPHEDRINE HCL	Advil Cold and Sinus
IBUPROFEN/PSEUDOEPHEDRINE HCL	Cold and Sinus Pain Relief
IBUPROFEN/PSEUDOEPHEDRINE HCL	Cold-Sinus Relief
IBUPROFEN/PSEUDOEPHEDRINE HCL	Ibuprofen Cold
IBUPROFEN/PSEUDOEPHEDRINE HCL	Ibuprofen Cold-Sinus(withPSE)
IBUPROFEN/PSEUDOEPHEDRINE HCL	Wal-Profen Cold-Sinus
IBUPROFEN/PSEUDOEPHEDRINE HCL	Wal-Profen D Cold and Sinus
INDOMETHACIN	indomethacin

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
NAPROXEN SODIUM	naproxen sodium
NAPROXEN SODIUM/PSEUDOEPHEDRINE HCL	Aleve Cold and Sinus
NAPROXEN SODIUM/PSEUDOEPHEDRINE HCL	Aleve Sinus and Headache
NAPROXEN SODIUM/PSEUDOEPHEDRINE HCL	Aleve-D Sinus and Cold
NAPROXEN SODIUM/PSEUDOEPHEDRINE HCL	Aleve-D Sinus and Headache
NAPROXEN SODIUM/PSEUDOEPHEDRINE HCL	All Day Pain Relief Sinus,Cold
NAPROXEN SODIUM/PSEUDOEPHEDRINE HCL	Sinus and Cold-D
OXAPROZIN	oxaprozin
PIROXICAM	piroxicam
SUMATRIPTAN SUCCINATE/NAPROXEN SODIUM	Treximet
celecoxib	Celebrex
celecoxib	celecoxib
diclofenac potassium	Cambia
diclofenac potassium	Cataflam
diclofenac potassium	Zipsor
diclofenac potassium	diclofenac potassium
diclofenac sodium	Voltaren-XR
diclofenac sodium/misoprostol	Arthrotec 50
diclofenac sodium/misoprostol	Arthrotec 75
diclofenac sodium/misoprostol	diclofenac-misoprostol
diclofenac submicronized	Zorvolex
etodolac	Lodine
etodolac	etodolac
fenoprofen calcium	Fenortho
fenoprofen calcium	Nalfon
fenoprofen calcium	ProFeno
fenoprofen calcium	fenoprofen
flurbiprofen	Ansaid
ibuprofen	Advil
ibuprofen	Advil Liqui-Gel
ibuprofen	Advil Migraine
ibuprofen	Child Ibuprofen
ibuprofen	Children's Advil
ibuprofen	Children's Medi-Profen
ibuprofen	Children's Motrin
ibuprofen	Children's Profen IB
ibuprofen	I-Prin
ibuprofen	IBU

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
ibuprofen	IBU-200
ibuprofen	Ibu-Drops
ibuprofen	Infant's Advil
ibuprofen	Infant's Medi-Profen
ibuprofen	Infant's Motrin
ibuprofen	Infants ProfenIB
ibuprofen	Motrin IB
ibuprofen	Provil
ibuprofen/diphenhydramine HCl	Advil PM Liqui-Gels
ibuprofen/diphenhydramine citrate	Advil PM
ibuprofen/diphenhydramine citrate	Motrin PM
ibuprofen/diphenhydramine citrate	ibuprofen-diphenhydramine cit
ibuprofen/famotidine	Duexis
indomethacin	Indocin
indomethacin	indomethacin
indomethacin, submicronized	Tivorbex
ketoprofen	ketoprofen
ketorolac tromethamine	ketorolac
meclofenamate sodium	meclofenamate
mefenamic acid	Ponstel
mefenamic acid	mefenamic acid
meloxicam	Qmiiz ODT
meloxicam, submicronized	Vivlodex
nabumetone	nabumetone
naproxen	EC-Naprosyn
naproxen	EC-Naproxen
naproxen	Naprosyn
naproxen sodium	Aleve
naproxen sodium	Anaprox
naproxen sodium	Anaprox DS
naproxen sodium	Mediproxen
naproxen sodium	Naprelan CR
naproxen sodium/diphenhydramine HCl	Aleve PM
naproxen/esomeprazole magnesium	Vimovo
oxaprozin	Daypro
oxaprozin	oxaprozin
piroxicam	Feldene
piroxicam	piroxicam
sulindac	sulindac
tolmetin sodium	tolmetin
Diuretics (thiazides, potassium sparing, loop diuretics)	
amiloride HCl	amiloride
amiloride HCl/hydrochlorothiazide	amiloride-hydrochlorothiazide
bumetanide	bumetanide
chlorothiazide	Diuril
chlorothiazide	chlorothiazide

Appendix G. Generic and Brand Names of Medical Products Used to Define Covariates in this Request

Generic Name	Brand Name
chlorothiazide sodium	Diuril IV
chlorothiazide sodium	chlorothiazide sodium
chlorthalidone	chlorthalidone
eplerenone	Inspra
eplerenone	eplerenone
ethacrynate sodium	Sodium Edecrin
ethacrynate sodium	ethacrynate sodium
ethacrynic acid	Edecrin
ethacrynic acid	ethacrynic acid
furosemide	Lasix
furosemide	furosemide
furosemide	furosemide (bulk)
furosemide in 0.9 % sodium chloride	furosemide in 0.9 % NaCl
furosemide/dextrose 5 % in water	furosemide in dextrose 5 %
hydrochlorothiazide	Microzide
hydrochlorothiazide	hydrochlorothiazide
hydrochlorothiazide	hydrochlorothiazide (bulk)
indapamide	indapamide
methyclothiazide	methyclothiazide
metolazone	Zaroxolyn
metolazone	metolazone
spironolactone	Aldactone
spironolactone	CaroSpir
spironolactone	spironolactone
spironolactone	spironolactone (bulk)
spironolactone, micronized	spironolactone micro (bulk)
spironolactone/hydrochlorothiazide	Aldactazide
spironolactone/hydrochlorothiazide	spironolacton-hydrochlorothiaz
torsemide	Demadex
torsemide	torsemide
triamterene	Dyrenium
triamterene	triamterene
triamterene	triamterene (bulk)
triamterene/hydrochlorothiazide	Dyazide
triamterene/hydrochlorothiazide	Maxzide
triamterene/hydrochlorothiazide	Maxzide-25mg
triamterene/hydrochlorothiazide	triamterene-hydrochlorothiazid
trichlormethiazide	trichlormethiazide (bulk)
Everolimus	
everolimus	Afinitor
everolimus	Afinitor Disperz
everolimus	Zortress
Sirolimus	
sirolimus	Rapamune
sirolimus	sirolimus

Appendix H. Specifications Defining Parameters for this Request

This request executed the Cohort Identification and Descriptive Analysis (CIDA) and Propensity Score Analysis (PSA) tools, version 9.7.0, to assess the risk for angioedema associated with sacubitril/valsartan (SV) compared to angiotensin-converting enzyme inhibitors (ACEI) or to angiotensin II receptor blockers (ARBs) among heart failure patients in the Sentinel Distributed Database (SDD).

Query Period: July 7, 2015 - Februrary 29, 2020
Coverage Requirement: Medical and drug coverage
Enrollment Requirement: 183 days
Enrollment Gap: 45 days
Age Groups: 18-44, 45-54, 55-64, 65+ years
Output Requested: Attrition table, Kaplan-Meier curves

	No prior comparator use; angioedema				No prior comparator use; angioedema Gap sensitivity analysis				No prior comparator use; serious angioedema			
	Comparison 1		Comparison 2		Comparison 3		Comparison 4		Comparison 5		Comparison 6	
Drug/Exposure												
Exposure/ Comparator	Sacubitril/ Valsartan (SV)	Angiotensin-converting enzyme inhibitors (ACEI)	SV	Angiotensin II receptor blockers (ARBs)	SV	ACEI	SV	ARBs	SV	ACEI	SV	ARBs
Incident with Respect to:	ACEI, ARBs, SV		ACEI, ARBs, SV		ACEI, ARBs, SV		ACEI, ARBs, SV		ACEI, ARBs, SV		ACEI, ARBs, SV	
Incidence Assessment	Dispensing date or days supply		Dispensing date or days supply		Dispensing date or days supply		Dispensing date or days supply		Dispensing date or days supply		Dispensing date or days supply	
Washout (days)	183		183		183		183		183		183	
Cohort Definition	First valid incident exposure episode		First valid incident exposure episode		First valid incident exposure episode		First valid incident exposure episode		First valid incident exposure episode		First valid incident exposure episode	
Stockpiling overlapping claims	Default		Default		Default		Default		Default		Default	
Episode Gap (days)	14		14		7		7		14		14	
Episode Extension Period (days)	14		14		7		7		14		14	
Maximum Episode Duration (days)	365		365		365		365		365		365	

Appendix H. Specifications Defining Parameters for this Request

	No prior comparator use; angioedema				No prior comparator use; angioedema Gap sensitivity analysis				No prior comparator use; serious angioedema			
	Comparison 1		Comparison 2		Comparison 3		Comparison 4		Comparison 5		Comparison 6	
Censor Criteria	ACEI	SV	ARBs	SV	ACEI	SV	ARBs	SV	ACEI	SV	ARBs	SV
	ARBs, end of treatment, outcome occurrence, disenrollment, recorded death, data end date		ACEI, end of treatment, outcome occurrence, disenrollment, recorded death, data end date		ARBs, end of treatment, outcome occurrence, disenrollment, recorded death, data end date		ACEI, end of treatment, outcome occurrence, disenrollment, recorded death, data end date		ARBs, end of treatment, outcome occurrence, disenrollment, recorded death, data end date		ACEI, end of treatment, outcome occurrence, disenrollment, recorded death, data end date	
Inclusion/Exclusion												
Pre-Existing Condition	Heart failure		Heart failure		Heart failure		Heart failure		Heart failure		Heart failure	
Include/Exclude	Include		Include		Include		Include		Include		Include	
Lookback Period (days)	-183, 0		-183, 0		-183, 0		-183, 0		-183, 0		-183, 0	
Pre-Existing Condition	ACEI, ARBs	SV, ARBs	ACEI, ARBs	SV, ACEI	ACEI, ARBs	SV, ARBs	ACEI, ARBs	SV, ACEI	ACEI, ARBs	SV, ARBs	ACEI, ARBs	SV, ACEI
Include/Exclude	Exclude	Exclude	Exclude	Exclude	Exclude	Exclude	Exclude	Exclude	Exclude	Exclude	Exclude	Exclude
Care Setting/ Primary Diagnosis	Any	Any	Any	Any	Any	Any	Any	Any	Any	Any	Any	Any
Lookback Period (dyas)	0	0	0	0	0	0	0	0	0	0	0	0
Inclusion Assessment	Dispensing date	Dispensing date	Dispensing date	Dispensing date	Dispensing date	Dispensing date	Dispensing date	Dispensing date	Dispensing date	Dispensing date	Dispensing date	Dispensing date

Appendix H. Specifications Defining Parameters for this Request

	No prior comparator use; angioedema		No prior comparator use; angioedema Gap sensitivity analysis		No prior comparator use; serious angioedema	
	Comparison 1	**Comparison 2**	**Comparison 3**	**Comparison 4**	**Comparison 5**	**Comparison 6**
Event/Outcome						
Event/Outcome	Angioedema	Angioedema	Angioedema	Angioedema	Serious Angioedema	Serious Angioedema
Care Setting/ Primary Diagnosis	Inpatient, emergency department or outpatient	Inpatient, emergency department or outpatient	Inpatient, emergency department or outpatient	Inpatient, emergency department or outpatient	Inpatient or emergency department (ED) angioedema diagnosis requiring an intensive care unit admission, intubation, tracheostomy, or laryngoscopy occurring within 2 days of the date of hospital admission or ED visit	Inpatient or emergency department (ED) angioedema diagnosis requiring an intensive care unit admission, intubation, tracheostomy, or laryngoscopy occurring within 2 days of the date of hospital admission or ED visit
Washout (days)	0	0	0	0	0	0
Blackout Period (days)	0	0	0	0	0	0
Propensity Score (PS) Matching						
Covariates	See Appendix J	See Appendix J	See Appendix J	See Appendix J	See Appendix J	See Appendix J
Matching Ratio	1:1	1:1	1:1	1:1	1:1	1:1
Matching Caliper Settings	0.05	0.05	0.05	0.05	0.05	0.05
Analysis Type	Conditional and unconditional	Conditional and unconditional	Conditional and unconditional	Conditional and unconditional	Conditional and unconditional	Conditional and unconditional
Sensitivity Analysis	PS stratification with deciles	PS stratification with deciles	--	--	--	--
Subgroup Analyses						
Stratifying variable	Angioedema	Angioedema			Angioedema	Angioedema
Evaluation Window (days)	-183, -1	-183, -1			-183, -1	-183, -1

Appendix H. Specifications Defining Parameters for this Request

	No prior comparator use; angioedema		No prior comparator use; angioedema Gap sensitivity analysis		No prior comparator use; serious angioedema	
	Comparison 1	**Comparison 2**	**Comparison 3**	**Comparison 4**	**Comparison 5**	**Comparison 6**
Re-matching	Re-matching should be done with the matched cohort	Re-matching should be done with the matched cohort			Re-matching should be done with the matched cohort	Re-matching should be done with the matched cohort
Stratifying variable **Evaluation Window (days)** **Re-matching**	Angioedema Pre-index enrollment history, -1 Re-matching should be done with the matched cohort	Angioedema Pre-index enrollment history, -1 Re-matching should be done with the matched cohort			Angioedema Pre-index enrollment history, -1 Re-matching should be done with the matched	Angioedema Pre-index enrollment history, -1 Re-matching should be done with the matched
Stratifying variable **Evaluation Window (days)** **Re-matching**	Serious allergies -183, -1 Re-matching should be done with the matched cohort	Serious allergies -183, -1 Re-matching should be done with the matched cohort			Serious allergies -183, -1 Re-matching should be done with the matched	Serious allergies -183, -1 Re-matching should be done with the matched
Stratifying variable **Re-matching**	Age group Re-matching should be done with the matched cohort	Age group Re-matching should be done with the matched cohort			Age group Re-matching should be done with the matched	Age group Re-matching should be done with the matched
Stratifying variable **Re-matching**	Sex Re-matching should be done with the matched cohort	Sex Re-matching should be done with the matched cohort			Sex Re-matching should be done with the matched	Sex Re-matching should be done with the matched
Stratifying variable **Re-matching**	Race Re-matching should be done with the matched cohort	Race Re-matching should be done with the matched cohort			Race Re-matching should be done with the matched	Race Re-matching should be done with the matched

International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Edition, Clinical Modification (ICD-10-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) codes are provided by Optum360. National Drug Codes are checked against First Data Bank's "FDB MedKnowledge®" database.

Appendix I. Specifications Defining Parameters for Baseline Covariate Groups in this Request

Covariate	Covariate Evaluation Window
Demographic Characteristics	
Age (years, continuous)	Index date
Age-group	
18-44 years*	Index date
45-54 years*	Index date
55-64 years*	Index date
≥65 years*	Index date
Sex	
Male	Index date
Female	Index date
Race/ethnicity	
American Indian or Alaska Native	Index date
Asian	Index date
Black or African American	Index date
Native Hawaiian or Other Pacific Islander	Index date
White	Index date
Unknown	Index date
Year	
2015	Index date
2016	Index date
2017	Index date
2018	Index date
Combined comorbidity score	
Combined comorbidity score	-183 to 0
Health Conditions	
Angioedema	-183 to -1
Angioedema*	Ever to -1
Ambulatory allergies or allergy treatment*	-183 to -1
Serious allergies (inpatient hospital stays or emergency department vis	-183 to -1
Ambulatory allergies or treatment and not serious allergies	-183 to -1
Diabetes	-183 to 0
Ischemic heart disease	-183 to 0
Renal disorders	-183 to 0
Medications	
Diuretics (thiazides, potassium sparing, loop diuretics)	-183 to 0
Nonsteroidal anti-inflammatory drugs (NSAIDs)	-183 to 0
Sirolimus	-183 to 0
Everolimus	-183 to 0
Health care utilization	
Number of inpatient hospital stays	-183 to 0
Number of emergency department visits	-183 to 0
Numer of institutional stay visits	-183 to 0
Number of ambulatory visits	-183 to 0
Number of other ambulatory visits	-183 to 0

Appendix I. Specifications Defining Parameters for Baseline Covariate Groups in this Request

Covariate	Covariate Evaluation Window
Drug utilization	
Number of unique dispensings*	-183 to 0
Number of unique generics dispensed*	-183 to 0
Number of unique drug classes dispensed	-183 to 0

* Covariates followed by an asterisk (*) were not included in the adjusted Propensity Score (PS) model; only those covariates not followed by an asterisk (*) were included in the adjusted PS model.