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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Sentinel

Overview for Request: cder_mpl2p_wp032

Request ID: cder_mpl2p_wp032_nsdp_v01

Request Description: In this request, we assessed the risk of angioedema in patients diagnosed with heart failure associated with: 1) sacubitril/valsartan (SV) use comparing those with prior angiotensin-converting enzyme inhibitor (ACEI) use and those with prior angiotensin II receptor blockers (ARBs, not including SV) use; 2) SV use comparing those with and without prior ACEI use; and 3) SV use comparing those with and without prior ARB use. This request is a follow-up analysis to requests cder_mpl2r_wp016_nsdp_v01 and cder_mpl2p_wp021_nsdp_v01.

Sentinel Routine Querying Module: Type 2 Cohort Identification and Descriptive Analysis and Propensity Score (PS) Analysis modules, Query Request Package version 11.2.3, with ad hoc programming

Data Source: The query period spanned from July 7, 2015 through the end of Data Partner (DP)-specific data completeness at the time of execution of prior request, cder_mpl2p_wp021_nsdp_v01. We distributed the analytic package on January 18, 2022. This report contains aggregated data from five DPs which are a subset of the SDD. Data from Medicare patients having both fee-for-service medical coverage and Part D drug coverage are included. The propensity score estimation models converged across comparisons for all DPs. See Appendix A for the list of the query end dates specified for each DP in this query.

Study Design: We identified individuals with incident use of SV who were 18 years or older with a history of heart failure and evaluated occurrence of angioedema during the first qualifying (index) exposure episode. We then conducted pairwise, PS-matched comparisons between SV new users, SV new users with prior ACEI exposure, and SV new users with prior ARB exposure.

Exposure: We defined the exposure of interest using the National Drug Codes (NDCs) recorded in outpatient dispensing data. We defined new use using a 183-day washout period of no prior SV use. For a list of generic and brand names of medical products used to define the exposure drugs, please see Appendix B.

Outcomes of Interest: We defined our 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 outcomes using International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM). For a list of diagnosis codes used to define outcomes, please see Appendix C.

Cohort Eligibility Criteria: We required patients be enrolled in health plans with both medical and drug coverage for at least 183 days before index SV dispensing, during which gaps in coverage of up to 45 days were allowed. The following age groups were included in the cohort: 18-44, 45-54, 55-64 and 65+ years of age. We formed separate cohorts of SV new users, SV new users with ACEI use in the prior 183 days, SV new users with ARB use in the prior 183 days. We also performed sensitivity analyses for SV new users with ACEI use in the prior 14 days and SV new users with ARB use in the prior 14 days. For all SV new user cohorts, we required a diagnosis of heart failure in the 183 days prior to and including index date and no same-day dispensing of ACEI or ARB on the index date. We implemented additional exclusion criterion for each SV new user cohort: SV new users were required to have no ACEI or ARB use in the prior 183 days, SV new users with prior ACEI use were required to have no ARB use in the prior 183 days, and SV new users with prior ARB were required to have no ACEI use in the prior 183 days. Please see Appendix D for a list of generic and brand names of medical products to define inclusion/exclusion criteria in this request. Please see Appendix E for a list of ICD-9-CM and ICD-10-CM diagnosis codes used to define the heart failure inclusion condition for this request.

Follow-up: We determined follow-up time as-treated and based on the length of the exposure episode. We created exposure episodes using days supply recorded in the outpatient pharmacy dispensing data. We bridged together dispensings less than 14 days apart in covered days and added 14 days at the end of each exposure episode to create continuous treatment episodes. 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, including 365 days of continuous SV exposure, and initiation of ACEI or ARB; 3) disenrollment; 4) recorded death; 5) end of exposure episode; or 6) end of query period. Only the first valid exposure episode that occurred during the study period was included per patient.

Overview for Request: cder_mpl2p_wp032
Baseline Covariates: We summarized the following characteristics for individual SV new user cohorts: demographics as of the index date, including sex, race, Hispanic origin, age, and calendar year; pre-existing conditions or treatment use in the prior 183 days, including ambulatory allergies, ambulatory but not serious allergies, serious allergies, angioedema in the prior 183 days, angioedema throughout the past enrollment history; comorbidities or specific drug utilization in the prior 183 days or on the index date, including combined comorbidity score, diabetes, ischemic heart disease, renal disorders, diuretics, everolimus, nonsteroidal anti-inflammatory drugs, sirolimus; general health services and drug utilization in the prior 183 days or on the index date. Please refer to Appendices F, G, and I for a list of covariates, codes, and evaluation windows used to define covariates. **Propensity Score Estimation, Matching, and Analysis:** For each comparison, we fit a logistic regression model for PS estimation based on potential confounders and risk factors outlined in Appendix I. The matching ratio was 1:1 and the matching caliper was 0.05. Exposure and comparator episodes were nearest neighbor-matched without replacement. For each comparison, we used a risk set-based approach to estimate the hazard ratio and 95% confidence intervals for the site-adjusted analyses, unconditional, and conditional matched analyses. We also estimated period-specific risks separately for 0-30, 31-60, 61-90, 91-180, 181-270, and 271-365 days. Subgroup analyses for effect estimation included angioedema diagnosis in 183 days prior to index date and race. **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).

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

Amount Supplied - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing.
Blackout Period - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.
Care Setting - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency Department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or Missing (U). The Care Setting, along with the Principal Diagnosis Indicator (PDX), forms the Care Setting/PDX parameter.

- **Ambulatory Visit (AV) -** includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.
- **Emergency Department (ED) -** includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.
- **Inpatient Hospital Stay (IP) -** includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date.
- **Non-Acute Institutional Stay (IS) -** includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.
- **Other Ambulatory Visit (OA) -** includes other non overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone and email consultations.

Charlson/Elixhauser Combined Comorbidity Score - calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (e.g., in the 183 days prior to index).
Code Days - the minimum number of times the diagnosis must be found during the evaluation period in order to fulfill the algorithm to identify the corresponding patient characteristic.
Cohort Definition (drug/exposure) - indicates how the cohort will be defined: 01: Cohort includes only the first valid treatment episode during the query period; 02: Cohort includes all valid treatment episodes during the query period; 03: Cohort includes all valid treatment episodes during the query period until an event occurs.

Computed Start Marketing Date - represents the first observed dispensing date among all valid users within a GROUP (scenario) within each Data Partner site.
Days Supplied - number of days supplied for all dispensings in qualifying treatment episodes.
Eligible Members - number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.
Enrollment Gap - number of days allowed between two consecutive enrollment periods without breaking a “continuously enrolled” sequence.
Episodes - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the episode gap.
Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment episode.
Event Deduplication - specifies how events are counted by the Modular Program (MP) algorithm: 0: Counts all occurrences of a health outcome of interest (HOI) during an exposure episode; 1: de-duplicates occurrences of the same HOI code and code type on the same day; 2: de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

Exposure Episode Length - number of days after exposure initiation that is considered "exposed time."
Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extensions are added after any episode gaps have been bridged.
Lookback Period - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).

Maximum Episode Duration - truncates exposure episodes after a requester-specified number of exposed days. Applied after any gaps are bridged and extension days added to the length of the exposure episode.
Member-Years - sum of all days of enrollment with medical and drug coverage in the query period preceded by an exposure washout period all divided by 365.25.
Minimum Days Supplied - specifies a minimum number of days in length of the days supplied for the episode to be considered.
Minimum Episode Duration - specifies a minimum number of days in length of the episode for it to be considered. Applied after any gaps are bridged and extension days added to the length of the exposure episode.
Monitoring Period - used to define time periods of interest for both sequential analysis and simple cohort characterization requests.
Principal Diagnosis (PDX) - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.

Query Period - period in which the modular program looks for exposures and outcomes of interest.
Switch Evaluation Step Value - value used to differentiate evaluation step. Each switch pattern can support up to 2 evaluation steps (0 = switch pattern evaluation start; 1 = first evaluation; 2 = second evaluation).
Switch Gap Inclusion Indicator - indicator for whether gaps in treatment episodes that are included in a switch episode will be counted as part of the switch episode duration.
Switch Pattern Cohort Inclusion Date - indicates which date to use for inclusion into the switch pattern cohort of interest as well as optionally as the index date of the treatment episode initiating the switch pattern. Valid options are the product approval date, product marketing date, other requester defined date, or computed start marketing date.

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

Treatment Episode Truncation Indicator - indicates whether the exposure episode will be truncated at the occurrence of a requester-specified code.
Washout Period (drug/exposure) - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.
Washout Period (event/outcome) - number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.
Years at Risk - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

*all terms may not be used in this report

Sentinel

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

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

Sentinel

Table 1a. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, in Risk Assessment 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	
	ACEI-SV		ARB-SV			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	68,868	100.0%	48,406	100.0%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	70.2	11.2	72.6	10.7	-2.394	-0.218
Age						
18-44 years	*2,374*	*3.4%*	*1,136*	*2.3%*	*1.100*	*0.066*
45-54 years	*5,060*	*7.3%*	*2,588*	*5.3%*	*2.001*	*0.082*
55-64 years	*11,290*	*16.4%*	*5,863*	*12.1%*	*4.282*	*0.123*
65+ years	*50,144*	*72.8%*	*38,819*	*80.2%*	*-7.383*	*-0.175*
Sex						
Female	20,972	30.5%	18,939	39.1%	-8.673	-0.183
Male	47,896	69.5%	29,467	60.9%	8.673	0.183
Race						
American Indian or Alaska Native	237	0.3%	129	0.3%	0.078	0.014
Asian	662	1.0%	1,053	2.2%	-1.214	-0.098
Black or African American	8,897	12.9%	6,877	14.2%	-1.288	-0.038
Native Hawaiian or Other Pacific Islander	66	0.1%	59	0.1%	-0.026	-0.008
Unknown	11,340	16.5%	7,857	16.2%	0.235	0.006
White	47,666	69.2%	32,431	67.0%	2.216	0.048
Hispanic Origin	*1,336*	*1.9%*	*1,123*	*2.3%*	*-0.380*	*-0.026*
Year						
2015	1,336	1.9%	862	1.8%	0.159	0.012
2016	10,422	15.1%	6,619	13.7%	1.459	0.042
2017	16,688	24.2%	10,924	22.6%	1.664	0.039
2018	18,864	27.4%	13,385	27.7%	-0.260	-0.006
2019	21,239	30.8%	16,324	33.7%	-2.883	-0.062
2020	319	3.6%	292	4.9%	-1.349	-0.067
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[3]	5.2	2.7	5.4	2.7	-0.156	-0.059
Ambulatory allergies or allergy treatment	*33,387*	*48.5%*	*25,738*	*53.2%*	*-4.691*	*-0.094*
Ambulatory allergies or treatment and not serious	28,086	40.8%	21,351	44.1%	-3.326	-0.067
Angioedema (-183, -1)	83	0.1%	56	0.1%	0.005	0.001
Angioedema (ever, -1)	*492*	*0.7%*	*740*	*1.5%*	*-0.814*	*-0.077*
Diabetes	34,675	50.3%	25,720	53.1%	-2.784	-0.056
Ischemic heart disease	54,489	79.1%	37,775	78.0%	1.083	0.026
Renal disorders	27,082	39.3%	20,921	43.2%	-3.895	-0.079
Serious allergies	8,036	11.7%	6,440	13.3%	-1.635	-0.049

Table 1a. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, in Risk Assessment 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	
	ACEI-SV		ARB-SV			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	59,667	86.6%	42,247	87.3%	-0.637	-0.019
Everolimus	11	0.0%	16	0.0%	-0.017	-0.011
Nonsteroidal anti-inflammatory drugs (NSAIDs)	7,692	11.2%	5,540	11.4%	-0.276	-0.009
Sirolimus	*****	*****	*****	*****	-0.001	-0.001
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	17.8	13.7	19.2	14.8	-1.364	-0.096
Mean number of emergency room encounters	0.8	1.6	0.7	1.5	0.067	0.043
Mean number of inpatient hospital encounters	0.8	1.1	0.8	1.1	0.028	0.026
Mean number of non-acute institutional encounters	0.1	0.5	0.1	0.5	0.006	0.012
Mean number of other ambulatory encounters	8.2	12.5	8.1	11.9	0.071	0.006
Mean number of filled prescriptions	*31.2*	*19.6*	*32.3*	*20.8*	*-1.135*	*-0.056*
Mean number of generics	*13.1*	*5.1*	*13.8*	*5.4*	*-0.692*	*-0.131*
Mean number of unique drug classes	11.4	4.5	12.0	4.7	-0.602	-0.131

[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.

Sentinel

Table 1b. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, in Risk Assessment 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	
	ACEI-SV		ARB-SV			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	46,333	67.3%	46,333	95.7%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	72.2	10.6	72.2	10.7	-0.039	-0.004
Age						
18-44 years	*1,009*	*2.2%*	*1,132*	*2.4%*	*-0.265*	*-0.018*
45-54 years	*2,418*	*5.2%*	*2,572*	*5.6%*	*-0.332*	*-0.015*
55-64 years	*6,571*	*14.2%*	*5,796*	*12.5%*	*1.673*	*0.051*
65+ years	*36,335*	*78.4%*	*36,833*	*79.5%*	*-1.075*	*-0.028*
Sex						
Female	17,309	37.4%	17,308	37.4%	0.002	0.000
Male	29,024	62.6%	29,025	62.6%	-0.002	-0.000
Race						
American Indian or Alaska Native	138	0.3%	127	0.3%	0.024	0.004
Asian	633	1.4%	580	1.3%	0.114	0.010
Black or African American	6,363	13.7%	6,436	13.9%	-0.158	-0.005
Native Hawaiian or Other Pacific Islander	59	0.1%	56	0.1%	0.006	0.002
Unknown	7,557	16.3%	7,528	16.2%	0.063	0.003
White	31,583	68.2%	31,606	68.2%	-0.050	-0.001
Hispanic Origin	*1,039*	*2.2%*	*986*	*2.1%*	*0.114*	*0.008*
Year						
2015	846	1.8%	834	1.8%	0.026	0.002
2016	6,449	13.9%	6,469	14.0%	-0.043	-0.001
2017	10,566	22.8%	10,564	22.8%	0.004	0.000
2018	12,782	27.6%	12,823	27.7%	-0.088	-0.002
2019	15,424	33.3%	15,370	33.2%	0.117	0.002
2020	266	4.6%	273	4.7%	-0.120	-0.006
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[3]	5.4	2.7	5.4	2.7	0.010	0.004
Ambulatory allergies or allergy treatment	*24,258*	*52.4%*	*24,213*	*52.3%*	*0.097*	*0.002*
Ambulatory allergies or treatment and not serious	20,229	43.7%	20,146	43.5%	0.179	0.004
Angioedema (-183, -1)	55	0.1%	52	0.1%	0.006	0.002
Angioedema (ever, -1)	*340*	*0.7%*	*699*	*1.5%*	*-0.775*	*-0.074*
Diabetes	24,321	52.5%	24,306	52.5%	0.032	0.001
Ischemic heart disease	36,287	78.3%	36,318	78.4%	-0.067	-0.002
Renal disorders	19,739	42.6%	19,680	42.5%	0.127	0.003
Serious allergies	6,013	13.0%	6,029	13.0%	-0.035	-0.001

Table 1b. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, in Risk Assessment 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	
	ACEI-SV		ARB-SV			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	40,368	87.1%	40,436	87.3%	-0.147	-0.004
Everolimus	11	0.0%	12	0.0%	-0.002	-0.001
Nonsteroidal anti-inflammatory drugs (NSAIDs)	5,241	11.3%	5,186	11.2%	0.119	0.004
Sirolimus	*****	*****	*****	*****	0.002	0.002
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	18.9	14.6	18.8	14.1	0.047	0.003
Mean number of emergency room encounters	0.7	1.4	0.7	1.5	0.011	0.007
Mean number of inpatient hospital encounters	0.8	1.1	0.8	1.1	0.004	0.004
Mean number of non-acute institutional encounters	0.1	0.5	0.1	0.5	0.000	0.001
Mean number of other ambulatory encounters	8.1	11.8	8.1	12.0	0.037	0.003
Mean number of filled prescriptions	*32.4*	*20.2*	*31.7*	*20.0*	*0.689*	*0.034*
Mean number of generics	*13.6*	*5.2*	*13.6*	*5.2*	*-0.011*	*-0.002*
Mean number of unique drug classes	11.8	4.6	11.8	4.6	0.023	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 1c. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, in Risk Assessment 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	
	ACEI-SV		SV			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	68,829	100.0%	43,140	100.0%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	70.2	11.2	71.6	11.9	-1.410	-0.122
Age						
18-44 years	*2,373*	*3.4%*	*1,606*	*3.7%*	*-0.275*	*-0.015*
45-54 years	*5,058*	*7.3%*	*2,977*	*6.9%*	*0.448*	*0.017*
55-64 years	*11,281*	*16.4%*	*5,949*	*13.8%*	*2.600*	*0.073*
65+ years	*50,117*	*72.8%*	*32,608*	*75.6%*	*-2.773*	*-0.063*
Sex						
Female	20,959	30.5%	15,442	35.8%	-5.344	-0.114
Male	47,870	69.5%	27,698	64.2%	5.344	0.114
Race						
American Indian or Alaska Native	237	0.3%	139	0.3%	0.022	0.004
Asian	664	1.0%	531	1.2%	-0.266	-0.026
Black or African American	8,906	12.9%	5,806	13.5%	-0.519	-0.015
Native Hawaiian or Other Pacific Islander	66	0.1%	46	0.1%	-0.011	-0.003
Unknown	11,333	16.5%	7,114	16.5%	-0.025	-0.001
White	47,623	69.2%	29,504	68.4%	0.799	0.017
Hispanic Origin	*1,335*	*1.9%*	*738*	*1.7%*	*0.229*	*0.017*
Year						
2015	1,336	1.9%	429	1.0%	0.947	0.079
2016	10,421	15.1%	4,174	9.7%	5.465	0.166
2017	16,686	24.2%	9,113	21.1%	3.118	0.075
2018	18,848	27.4%	12,227	28.3%	-0.959	-0.021
2019	21,219	30.8%	16,854	39.1%	-8.240	-0.173
2020	319	3.6%	343	5.9%	-2.310	-0.109
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[3]	5.2	2.7	5.6	2.8	-0.390	-0.142
Ambulatory allergies or allergy treatment	*33,365*	*48.5%*	*21,201*	*49.1%*	*-0.669*	*-0.013*
Ambulatory allergies or treatment and not serious	28,067	40.8%	17,374	40.3%	0.504	0.010
Angioedema (-183, -1)	83	0.1%	59	0.1%	-0.016	-0.005
Angioedema (ever, -1)	*493*	*0.7%*	*612*	*1.4%*	*-0.702*	*-0.068*
Diabetes	34,669	50.4%	20,080	46.5%	3.824	0.077
Ischemic heart disease	54,462	79.1%	32,685	75.8%	3.362	0.080
Renal disorders	27,064	39.3%	19,253	44.6%	-5.308	-0.108
Serious allergies	8,028	11.7%	6,019	14.0%	-2.289	-0.069

Table 1c. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, in Risk Assessment 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	
	ACEI-SV		SV			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	59,637	86.6%	34,664	80.4%	6.293	0.170
Everolimus	11	0.0%	12	0.0%	-0.012	-0.008
Nonsteroidal anti-inflammatory drugs (NSAIDs)	7,692	11.2%	4,364	10.1%	1.060	0.034
Sirolimus	*****	*****	*****	*****	-0.012	-0.009
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	17.8	13.7	18.3	17.3	-0.529	-0.034
Mean number of emergency room encounters	0.8	1.6	0.8	1.6	0.001	0.001
Mean number of inpatient hospital encounters	0.8	1.1	0.8	1.1	-0.018	-0.016
Mean number of non-acute institutional encounters	0.1	0.5	0.2	0.6	-0.058	-0.104
Mean number of other ambulatory encounters	8.2	12.5	9.5	14.5	-1.280	-0.095
Mean number of filled prescriptions	*31.2*	*19.7*	*26.7*	*20.7*	*4.477*	*0.222*
Mean number of generics	*13.1*	*5.1*	*11.7*	*5.5*	*1.453*	*0.273*
Mean number of unique drug classes	11.4	4.5	11.0	4.9	0.386	0.082

[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.

Sentinel

Table 1d. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, in Risk Assessment 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	
	ACEI-SV		SV			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	41,518	60.3%	41,518	96.2%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	71.6	10.9	71.5	11.8	0.039	0.003
Age						
18-44 years	*1,179*	*2.8%*	*1,521*	*3.7%*	*-0.824*	*-0.047*
45-54 years	*2,555*	*6.2%*	*2,868*	*6.9%*	*-0.754*	*-0.031*
55-64 years	*6,074*	*14.6%*	*5,737*	*13.8%*	*0.812*	*0.024*
65+ years	*31,710*	*76.4%*	*31,392*	*75.6%*	*0.766*	*0.019*
Sex						
Female	14,510	34.9%	14,518	35.0%	-0.019	-0.000
Male	27,008	65.1%	27,000	65.0%	0.019	0.000
Race						
American Indian or Alaska Native	128	0.3%	132	0.3%	-0.010	-0.002
Asian	475	1.1%	482	1.2%	-0.017	-0.002
Black or African American	5,622	13.5%	5,550	13.4%	0.173	0.005
Native Hawaiian or Other Pacific Islander	37	0.1%	40	0.1%	-0.007	-0.002
Unknown	6,641	16.0%	6,668	16.1%	-0.065	-0.003
White	28,615	68.9%	28,646	69.0%	-0.075	-0.002
Hispanic Origin	*753*	*1.8%*	*708*	*1.7%*	*0.108*	*0.008*
Year						
2015	438	1.1%	428	1.0%	0.024	0.002
2016	4,083	9.8%	4,161	10.0%	-0.188	-0.006
2017	8,941	21.5%	9,013	21.7%	-0.173	-0.004
2018	11,903	28.7%	11,895	28.7%	0.019	0.000
2019	15,877	38.2%	15,743	37.9%	0.323	0.007
2020	276	5.0%	278	5.1%	-0.036	-0.002
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[3]	5.6	2.8	5.6	2.8	-0.005	-0.002
Ambulatory allergies or allergy treatment	*20,406*	*49.1%*	*20,374*	*49.1%*	*0.077*	*0.002*
Ambulatory allergies or treatment and not serious	16,688	40.2%	16,772	40.4%	-0.202	-0.004
Angioedema (-183, -1)	47	0.1%	55	0.1%	-0.019	-0.006
Angioedema (ever, -1)	*299*	*0.7%*	*592*	*1.4%*	*-0.706*	*-0.069*
Diabetes	19,584	47.2%	19,531	47.0%	0.128	0.003
Ischemic heart disease	31,745	76.5%	31,755	76.5%	-0.024	-0.001
Renal disorders	18,301	44.1%	18,268	44.0%	0.079	0.002
Serious allergies	5,707	13.7%	5,659	13.6%	0.116	0.003

Table 1d. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, in Risk Assessment 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	
	ACEI-SV		SV			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	34,073	82.1%	34,101	82.1%	-0.067	-0.002
Everolimus	*****	*****	*****	*****	-0.002	-0.002
Nonsteroidal anti-inflammatory drugs (NSAIDs)	4,302	10.4%	4,273	10.3%	0.070	0.002
Sirolimus	*****	*****	*****	*****	-0.010	-0.009
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	18.1	14.4	18.1	16.8	-0.035	-0.002
Mean number of emergency room encounters	0.8	1.6	0.8	1.6	0.009	0.006
Mean number of inpatient hospital encounters	0.8	1.1	0.8	1.1	0.000	0.000
Mean number of non-acute institutional encounters	0.2	0.6	0.2	0.6	-0.003	-0.005
Mean number of other ambulatory encounters	9.1	13.9	9.1	13.7	-0.041	-0.003
Mean number of filled prescriptions	*30.1*	*19.5*	*27.0*	*20.7*	*3.133*	*0.156*
Mean number of generics	*12.8*	*5.1*	*11.8*	*5.5*	*1.044*	*0.197*
Mean number of unique drug classes	11.1	4.5	11.1	4.9	0.019	0.004

[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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Sentinel

Table 1e. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, in Risk Assessment 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	
	ARB-SV		SV			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	48,455	100.0%	43,845	100.0%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	72.6	10.7	71.5	11.9	1.087	0.096
Age						
18-44 years	*1,136*	*2.3%*	*1,651*	*3.8%*	*-1.421*	*-0.083*
45-54 years	*2,592*	*5.3%*	*3,090*	*7.0%*	*-1.698*	*-0.070*
55-64 years	*5,868*	*12.1%*	*6,116*	*13.9%*	*-1.839*	*-0.055*
65+ years	*38,859*	*80.2%*	*32,988*	*75.2%*	*4.958*	*0.119*
Sex						
Female	18,947	39.1%	15,531	35.4%	3.680	0.076
Male	29,508	60.9%	28,314	64.6%	-3.680	-0.076
Race						
American Indian or Alaska Native	128	0.3%	144	0.3%	-0.064	-0.012
Asian	1,055	2.2%	525	1.2%	0.980	0.076
Black or African American	6,881	14.2%	5,888	13.4%	0.772	0.022
Native Hawaiian or Other Pacific Islander	59	0.1%	44	0.1%	0.021	0.006
Unknown	7,859	16.2%	7,214	16.5%	-0.234	-0.006
White	32,473	67.0%	30,030	68.5%	-1.474	-0.032
Hispanic Origin	*1,128*	*2.3%*	*752*	*1.7%*	*0.613*	*0.044*
Year						
2015	862	1.8%	429	1.0%	0.801	0.069
2016	6,622	13.7%	4,189	9.6%	4.112	0.129
2017	10,933	22.6%	9,229	21.0%	1.514	0.037
2018	13,394	27.6%	12,481	28.5%	-0.824	-0.018
2019	16,351	33.7%	17,169	39.2%	-5.414	-0.113
2020	293	4.9%	348	5.9%	-0.959	-0.042
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[3]	5.4	2.7	5.6	2.8	-0.223	-0.082
Ambulatory allergies or allergy treatment	*25,740*	*53.1%*	*21,467*	*49.0%*	*4.160*	*0.083*
Ambulatory allergies or treatment and not serious	21,353	44.1%	17,616	40.2%	3.890	0.079
Angioedema (-183, -1)	56	0.1%	59	0.1%	-0.019	-0.005
Angioedema (ever, -1)	*738*	*1.5%*	*596*	*1.4%*	*0.164*	*0.014*
Diabetes	25,762	53.2%	20,413	46.6%	6.610	0.132
Ischemic heart disease	37,818	78.0%	33,251	75.8%	2.210	0.052
Renal disorders	20,953	43.2%	19,524	44.5%	-1.287	-0.026
Serious allergies	6,441	13.3%	6,051	13.8%	-0.508	-0.015

Table 1e. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, in Risk Assessment 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	
	ARB-SV		SV			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	42,295	87.3%	35,247	80.4%	6.897	0.188
Everolimus	16	0.0%	12	0.0%	0.006	0.003
Nonsteroidal anti-inflammatory drugs (NSAIDs)	5,551	11.5%	4,401	10.0%	1.418	0.046
Sirolimus	*****	*****	*****	*****	-0.010	-0.008
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	19.2	14.8	18.3	17.3	0.904	0.056
Mean number of emergency room encounters	0.7	1.5	0.8	1.6	-0.062	-0.041
Mean number of inpatient hospital encounters	0.8	1.1	0.8	1.1	-0.042	-0.039
Mean number of non-acute institutional encounters	0.1	0.5	0.2	0.6	-0.062	-0.115
Mean number of other ambulatory encounters	8.1	11.9	9.4	14.5	-1.305	-0.099
Mean number of filled prescriptions	*32.4*	*20.8*	*26.7*	*20.7*	*5.643*	*0.272*
Mean number of generics	*13.8*	*5.4*	*11.7*	*5.5*	*2.162*	*0.397*
Mean number of unique drug classes	12.0	4.7	11.0	4.9	1.005	0.209

[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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Sentinel

Table 1f. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, in Risk Assessment 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	
	ARB-SV		SV			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	37,893	78.2%	37,893	86.4%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	72.2	10.9	72.3	11.5	-0.033	-0.003
Age						
18-44 years	*1,030*	*2.7%*	*1,096*	*2.9%*	*-0.174*	*-0.011*
45-54 years	*2,155*	*5.7%*	*2,436*	*6.4%*	*-0.742*	*-0.032*
55-64 years	*4,701*	*12.4%*	*5,046*	*13.3%*	*-0.910*	*-0.028*
65+ years	*30,007*	*79.2%*	*29,315*	*77.4%*	*1.826*	*0.048*
Sex						
Female	14,044	37.1%	13,990	36.9%	0.143	0.003
Male	23,849	62.9%	23,903	63.1%	-0.143	-0.003
Race						
American Indian or Alaska Native	113	0.3%	108	0.3%	0.013	0.002
Asian	546	1.4%	507	1.3%	0.103	0.009
Black or African American	5,167	13.6%	5,203	13.7%	-0.095	-0.003
Native Hawaiian or Other Pacific Islander	40	0.1%	41	0.1%	-0.003	-0.001
Unknown	5,825	15.4%	5,845	15.4%	-0.053	-0.002
White	26,202	69.1%	26,189	69.1%	0.034	0.001
Hispanic Origin	*693*	*1.8%*	*691*	*1.8%*	*0.005*	*0.000*
Year						
2015	477	1.3%	418	1.1%	0.156	0.014
2016	4,141	10.9%	4,055	10.7%	0.227	0.007
2017	8,295	21.9%	8,331	22.0%	-0.095	-0.002
2018	10,863	28.7%	10,851	28.6%	0.032	0.001
2019	13,870	36.6%	13,991	36.9%	-0.319	-0.007
2020	247	5.2%	247	5.2%	0.000	0.000
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[3]	5.5	2.7	5.5	2.7	0.009	0.003
Ambulatory allergies or allergy treatment	*19,321*	*51.0%*	*19,223*	*50.7%*	*0.259*	*0.005*
Ambulatory allergies or treatment and not serious	15,898	42.0%	15,890	41.9%	0.021	0.000
Angioedema (-183, -1)	46	0.1%	49	0.1%	-0.008	-0.002
Angioedema (ever, -1)	*568*	*1.5%*	*535*	*1.4%*	*0.087*	*0.007*
Diabetes	18,672	49.3%	18,546	48.9%	0.333	0.007
Ischemic heart disease	29,198	77.1%	29,183	77.0%	0.040	0.001
Renal disorders	16,721	44.1%	16,722	44.1%	-0.003	-0.000
Serious allergies	5,146	13.6%	5,148	13.6%	-0.005	-0.000

Table 1f. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, in Risk Assessment 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	
	ARB-SV		SV			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	32,102	84.7%	32,308	85.3%	-0.544	-0.015
Everolimus	12	0.0%	11	0.0%	0.003	0.002
Nonsteroidal anti-inflammatory drugs (NSAIDs)	4,032	10.6%	4,000	10.6%	0.084	0.003
Sirolimus	*****	*****	*****	*****	-0.003	-0.002
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	18.7	14.8	18.7	17.3	0.075	0.005
Mean number of emergency room encounters	0.7	1.6	0.7	1.4	-0.000	-0.000
Mean number of inpatient hospital encounters	0.8	1.1	0.8	1.1	0.000	0.000
Mean number of non-acute institutional encounters	0.1	0.5	0.1	0.5	0.002	0.004
Mean number of other ambulatory encounters	8.5	12.7	8.5	12.4	-0.027	-0.002
Mean number of filled prescriptions	*30.6*	*19.7*	*28.1*	*20.8*	*2.476*	*0.122*
Mean number of generics	*13.2*	*5.2*	*12.1*	*5.4*	*1.085*	*0.205*
Mean number of unique drug classes	11.5	4.5	11.5	4.9	0.020	0.004

[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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Sentinel

Table 1g. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, in Risk Assessment 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	
	ACEI-SV 14-day		ARB-SV 14-day			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	48,920	100.0%	35,084	100.0%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	70.5	11.1	72.8	10.6	-2.333	-0.216
Age						
18-44 years	*1,558*	*3.2%*	*752*	*2.1%*	*1.041*	*0.065*
45-54 years	*3,372*	*6.9%*	*1,738*	*5.0%*	*1.939*	*0.082*
55-64 years	*7,879*	*16.1%*	*4,166*	*11.9%*	*4.232*	*0.122*
65+ years	*36,111*	*73.8%*	*28,428*	*81.0%*	*-7.212*	*-0.173*
Sex						
Female	14,680	30.0%	13,653	38.9%	-8.907	-0.188
Male	34,240	70.0%	21,431	61.1%	8.907	0.188
Race						
American Indian or Alaska Native	160	0.3%	82	0.2%	0.093	0.018
Asian	525	1.1%	847	2.4%	-1.341	-0.103
Black or African American	5,967	12.2%	4,736	13.5%	-1.302	-0.039
Native Hawaiian or Other Pacific Islander	46	0.1%	45	0.1%	-0.034	-0.010
Unknown	7,922	16.2%	5,604	16.0%	0.221	0.006
White	34,300	70.1%	23,770	67.8%	2.363	0.051
Hispanic Origin	*973*	*2.0%*	*877*	*2.5%*	*-0.511*	*-0.034*
Year						
2015	940	1.9%	599	1.7%	0.214	0.016
2016	6,778	13.9%	4,410	12.6%	1.285	0.038
2017	11,541	23.6%	7,696	21.9%	1.656	0.039
2018	13,743	28.1%	9,952	28.4%	-0.273	-0.006
2019	15,681	32.1%	12,211	34.8%	-2.751	-0.058
2020	237	3.9%	216	5.3%	-1.410	-0.068
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[3]	5.1	2.6	5.3	2.6	-0.196	-0.076
Ambulatory allergies or allergy treatment	*23,587*	*48.2%*	*18,832*	*53.7%*	*-5.461*	*-0.109*
Ambulatory allergies or treatment and not serious	20,036	41.0%	15,807	45.1%	-4.098	-0.083
Angioedema (-183, -1)	46	0.1%	33	0.1%	-0.000	-0.000
Angioedema (ever, -1)	*330*	*0.7%*	*533*	*1.5%*	*-0.845*	*-0.081*
Diabetes	24,497	50.1%	18,695	53.3%	-3.211	-0.064
Ischemic heart disease	38,607	78.9%	27,363	78.0%	0.926	0.023
Renal disorders	18,569	38.0%	14,710	41.9%	-3.970	-0.081
Serious allergies	5,343	10.9%	4,442	12.7%	-1.739	-0.054

Table 1g. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, in Risk Assessment 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	
	ACEI-SV 14-day		ARB-SV 14-day			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	42,268	86.4%	30,596	87.2%	-0.806	-0.024
Everolimus	11	0.0%	11	0.0%	-0.009	-0.005
Nonsteroidal anti-inflammatory drugs (NSAIDs)	5,583	11.4%	4,097	11.7%	-0.265	-0.008
Sirolimus	*****	*****	*****	*****	-0.002	-0.002
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	17.5	13.4	19.0	14.7	-1.493	-0.106
Mean number of emergency room encounters	0.7	1.4	0.7	1.5	0.047	0.032
Mean number of inpatient hospital encounters	0.7	1.0	0.7	1.0	0.010	0.009
Mean number of non-acute institutional encounters	0.1	0.4	0.1	0.4	0.000	0.000
Mean number of other ambulatory encounters	7.3	10.9	7.4	10.6	-0.130	-0.012
Mean number of filled prescriptions	*31.7*	*20.1*	*33.2*	*21.6*	*-1.460*	*-0.070*
Mean number of generics	*13.2*	*5.1*	*14.0*	*5.4*	*-0.786*	*-0.150*
Mean number of unique drug classes	11.4	4.5	12.1	4.7	-0.678	-0.147

[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. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, in Risk Assessment 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	
	ACEI-SV 14-day		ARB-SV 14-day			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	33,383	68.2%	33,383	95.2%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	72.4	10.4	72.4	10.5	-0.044	-0.004
Age						
18-44 years	*623*	*1.9%*	*749*	*2.2%*	*-0.377*	*-0.027*
45-54 years	*1,679*	*5.0%*	*1,723*	*5.2%*	*-0.132*	*-0.006*
55-64 years	*4,704*	*14.1%*	*4,099*	*12.3%*	*1.812*	*0.055*
65+ years	*26,377*	*79.0%*	*26,812*	*80.3%*	*-1.303*	*-0.035*
Sex						
Female	12,303	36.9%	12,323	36.9%	-0.060	-0.001
Male	21,080	63.1%	21,060	63.1%	0.060	0.001
Race						
American Indian or Alaska Native	85	0.3%	82	0.2%	0.009	0.002
Asian	493	1.5%	471	1.4%	0.066	0.006
Black or African American	4,389	13.1%	4,387	13.1%	0.006	0.000
Native Hawaiian or Other Pacific Islander	37	0.1%	42	0.1%	-0.015	-0.004
Unknown	5,331	16.0%	5,327	16.0%	0.012	0.001
White	23,048	69.0%	23,074	69.1%	-0.078	-0.002
Hispanic Origin	*766*	*2.3%*	*762*	*2.3%*	*0.012*	*0.001*
Year						
2015	576	1.7%	583	1.7%	-0.021	-0.002
2016	4,297	12.9%	4,264	12.8%	0.099	0.003
2017	7,421	22.2%	7,401	22.2%	0.060	0.001
2018	9,432	28.3%	9,499	28.5%	-0.201	-0.004
2019	11,463	34.3%	11,436	34.3%	0.081	0.002
2020	194	4.8%	200	5.0%	-0.150	-0.007
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[3]	5.2	2.6	5.3	2.6	-0.009	-0.003
Ambulatory allergies or allergy treatment	*17,551*	*52.6%*	*17,515*	*52.5%*	*0.108*	*0.002*
Ambulatory allergies or treatment and not serious	14,788	44.3%	14,746	44.2%	0.126	0.003
Angioedema (-183, -1)	25	0.1%	28	0.1%	-0.009	-0.003
Angioedema (ever, -1)	*234*	*0.7%*	*495*	*1.5%*	*-0.782*	*-0.075*
Diabetes	17,520	52.5%	17,515	52.5%	0.015	0.000
Ischemic heart disease	26,098	78.2%	26,160	78.4%	-0.186	-0.005
Renal disorders	13,710	41.1%	13,718	41.1%	-0.024	-0.000
Serious allergies	4,100	12.3%	4,089	12.2%	0.033	0.001

Table 1h. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, in Risk Assessment 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	
	ACEI-SV 14-day		ARB-SV 14-day			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	29,121	87.2%	29,096	87.2%	0.075	0.002
Everolimus	*****	*****	*****	*****	0.003	0.002
Nonsteroidal anti-inflammatory drugs (NSAIDs)	3,825	11.5%	3,799	11.4%	0.078	0.002
Sirolimus	*****	*****	*****	*****	-0.006	-0.006
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	18.6	14.4	18.6	13.9	0.013	0.001
Mean number of emergency room encounters	0.7	1.3	0.7	1.5	0.002	0.002
Mean number of inpatient hospital encounters	0.7	1.0	0.7	1.0	-0.001	-0.001
Mean number of non-acute institutional encounters	0.1	0.4	0.1	0.4	-0.001	-0.003
Mean number of other ambulatory encounters	7.4	10.6	7.4	10.7	-0.006	-0.001
Mean number of filled prescriptions	*33.0*	*20.9*	*32.3*	*20.5*	*0.665*	*0.032*
Mean number of generics	*13.7*	*5.2*	*13.7*	*5.2*	*-0.037*	*-0.007*
Mean number of unique drug classes	11.9	4.6	11.9	4.6	0.010	0.002

[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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Sentinel

Table 1i. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, in Risk Assessment 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	
	ACEI-SV 14-day		SV			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	48,892	100.0%	44,050	100.0%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	70.5	11.1	71.6	11.9	-1.089	-0.095
Age						
18-44 years	*1,556*	*3.2%*	*1,658*	*3.8%*	*-0.581*	*-0.032*
45-54 years	*3,372*	*6.9%*	*3,056*	*6.9%*	*-0.041*	*-0.002*
55-64 years	*7,872*	*16.1%*	*6,127*	*13.9%*	*2.192*	*0.061*
65+ years	*36,092*	*73.8%*	*33,209*	*75.4%*	*-1.569*	*-0.036*
Sex						
Female	14,668	30.0%	15,715	35.7%	-5.675	-0.121
Male	34,224	70.0%	28,335	64.3%	5.675	0.121
Race						
American Indian or Alaska Native	160	0.3%	143	0.3%	0.003	0.000
Asian	525	1.1%	537	1.2%	-0.145	-0.014
Black or African American	5,969	12.2%	5,968	13.5%	-1.340	-0.040
Native Hawaiian or Other Pacific Islander	46	0.1%	47	0.1%	-0.013	-0.004
Unknown	7,919	16.2%	7,229	16.4%	-0.214	-0.006
White	34,273	70.1%	30,126	68.4%	1.709	0.037
Hispanic Origin	*972*	*2.0%*	*758*	*1.7%*	*0.267*	*0.020*
Year						
2015	940	1.9%	429	1.0%	0.949	0.079
2016	6,778	13.9%	4,188	9.5%	4.356	0.136
2017	11,538	23.6%	9,252	21.0%	2.596	0.062
2018	13,734	28.1%	12,543	28.5%	-0.384	-0.009
2019	15,665	32.0%	17,289	39.2%	-7.209	-0.151
2020	237	3.9%	349	5.9%	-2.015	-0.094
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[3]	5.1	2.6	5.6	2.8	-0.507	-0.188
Ambulatory allergies or allergy treatment	*23,570*	*48.2%*	*21,612*	*49.1%*	*-0.854*	*-0.017*
Ambulatory allergies or treatment and not serious	20,017	40.9%	17,732	40.3%	0.687	0.014
Angioedema (-183, -1)	46	0.1%	60	0.1%	-0.042	-0.012
Angioedema (ever, -1)	*331*	*0.7%*	*621*	*1.4%*	*-0.733*	*-0.072*
Diabetes	24,495	50.1%	20,551	46.7%	3.446	0.069
Ischemic heart disease	38,588	78.9%	33,377	75.8%	3.154	0.075
Renal disorders	18,565	38.0%	19,642	44.6%	-6.619	-0.135
Serious allergies	5,343	10.9%	6,110	13.9%	-2.942	-0.089

Table 1i. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, in Risk Assessment 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	
	ACEI-SV 14-day		SV			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	42,243	86.4%	35,414	80.4%	6.006	0.162
Everolimus	11	0.0%	12	0.0%	-0.005	-0.003
Nonsteroidal anti-inflammatory drugs (NSAIDs)	5,584	11.4%	4,435	10.1%	1.353	0.044
Sirolimus	*****	*****	*****	*****	-0.010	-0.008
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	17.5	13.4	18.3	17.3	-0.805	-0.052
Mean number of emergency room encounters	0.7	1.4	0.8	1.6	-0.053	-0.036
Mean number of inpatient hospital encounters	0.7	1.0	0.8	1.1	-0.083	-0.078
Mean number of non-acute institutional encounters	0.1	0.4	0.2	0.6	-0.094	-0.184
Mean number of other ambulatory encounters	7.3	10.9	9.4	14.5	-2.116	-0.165
Mean number of filled prescriptions	*31.7*	*20.1*	*26.7*	*20.7*	*5.044*	*0.247*
Mean number of generics	*13.2*	*5.1*	*11.7*	*5.5*	*1.520*	*0.287*
Mean number of unique drug classes	11.4	4.5	11.0	4.9	0.393	0.084

[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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Sentinel

Table 1j. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, in Risk Assessment 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	
	ACEI-SV 14-day		SV			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	38,268	78.3%	38,268	86.9%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	71.3	10.9	71.3	11.8	-0.010	-0.001
Age						
18-44 years	*1,127*	*2.9%*	*1,424*	*3.7%*	*-0.776*	*-0.044*
45-54 years	*2,354*	*6.2%*	*2,697*	*7.0%*	*-0.896*	*-0.037*
55-64 years	*5,729*	*15.0%*	*5,416*	*14.2%*	*0.818*	*0.024*
65+ years	*29,058*	*75.9%*	*28,731*	*75.1%*	*0.854*	*0.021*
Sex						
Female	12,707	33.2%	12,712	33.2%	-0.013	-0.000
Male	25,561	66.8%	25,556	66.8%	0.013	0.000
Race						
American Indian or Alaska Native	111	0.3%	115	0.3%	-0.010	-0.002
Asian	442	1.2%	453	1.2%	-0.029	-0.003
Black or African American	4,995	13.1%	4,986	13.0%	0.024	0.001
Native Hawaiian or Other Pacific Islander	42	0.1%	40	0.1%	0.005	0.002
Unknown	6,073	15.9%	6,076	15.9%	-0.008	-0.000
White	26,605	69.5%	26,598	69.5%	0.018	0.000
Hispanic Origin	*695*	*1.8%*	*681*	*1.8%*	*0.037*	*0.003*
Year						
2015	424	1.1%	424	1.1%	0.000	0.000
2016	4,000	10.5%	4,026	10.5%	-0.068	-0.002
2017	8,549	22.3%	8,525	22.3%	0.063	0.002
2018	11,112	29.0%	11,080	29.0%	0.084	0.002
2019	13,955	36.5%	13,978	36.5%	-0.060	-0.001
2020	228	4.6%	235	4.8%	-0.143	-0.007
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[3]	5.3	2.7	5.4	2.6	-0.013	-0.005
Ambulatory allergies or allergy treatment	*18,802*	*49.1%*	*18,681*	*48.8%*	*0.316*	*0.006*
Ambulatory allergies or treatment and not serious	15,710	41.1%	15,635	40.9%	0.196	0.004
Angioedema (-183, -1)	42	0.1%	44	0.1%	-0.005	-0.002
Angioedema (ever, -1)	*274*	*0.7%*	*528*	*1.4%*	*-0.664*	*-0.065*
Diabetes	18,299	47.8%	18,298	47.8%	0.003	0.000
Ischemic heart disease	29,508	77.1%	29,592	77.3%	-0.220	-0.005
Renal disorders	16,040	41.9%	15,968	41.7%	0.188	0.004
Serious allergies	4,716	12.3%	4,692	12.3%	0.063	0.002

Table 1j. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, in Risk Assessment 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	
	ACEI-SV 14-day		SV			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	32,038	83.7%	32,112	83.9%	-0.193	-0.005
Everolimus	*****	*****	*****	*****	-0.010	-0.007
Nonsteroidal anti-inflammatory drugs (NSAIDs)	4,076	10.7%	4,080	10.7%	-0.010	-0.000
Sirolimus	*****	*****	*****	*****	0.000	0.000
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	17.7	13.9	17.8	16.0	-0.026	-0.002
Mean number of emergency room encounters	0.7	1.4	0.7	1.5	0.003	0.002
Mean number of inpatient hospital encounters	0.8	1.0	0.8	1.1	-0.001	-0.001
Mean number of non-acute institutional encounters	0.1	0.4	0.1	0.4	-0.002	-0.005
Mean number of other ambulatory encounters	7.9	11.8	8.0	11.8	-0.063	-0.005
Mean number of filled prescriptions	*30.9*	*19.9*	*27.2*	*20.5*	*3.681*	*0.182*
Mean number of generics	*12.9*	*5.0*	*11.8*	*5.5*	*1.105*	*0.210*
Mean number of unique drug classes	11.2	4.4	11.2	4.9	0.005	0.001

[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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Sentinel

Table 1k. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, in Risk Assessment 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	
	ARB-SV 14-day		SV			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	35,088	100.0%	44,361	100.0%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	72.8	10.5	71.5	11.9	1.286	0.114
Age						
18-44 years	*750*	*2.1%*	*1,666*	*3.8%*	*-1.618*	*-0.096*
45-54 years	*1,741*	*5.0%*	*3,126*	*7.0%*	*-2.085*	*-0.088*
55-64 years	*4,166*	*11.9%*	*6,193*	*14.0%*	*-2.087*	*-0.062*
65+ years	*28,431*	*81.0%*	*33,376*	*75.2%*	*5.790*	*0.140*
Sex						
Female	13,649	38.9%	15,727	35.5%	3.447	0.071
Male	21,439	61.1%	28,634	64.5%	-3.447	-0.071
Race						
American Indian or Alaska Native	81	0.2%	145	0.3%	-0.096	-0.018
Asian	847	2.4%	532	1.2%	1.215	0.091
Black or African American	4,731	13.5%	5,990	13.5%	-0.020	-0.001
Native Hawaiian or Other Pacific Islander	45	0.1%	46	0.1%	0.025	0.007
Unknown	5,599	16.0%	7,272	16.4%	-0.436	-0.012
White	23,785	67.8%	30,376	68.5%	-0.688	-0.015
Hispanic Origin	*879*	*2.5%*	*754*	*1.7%*	*0.805*	*0.056*
Year						
2015	599	1.7%	429	1.0%	0.740	0.064
2016	4,411	12.6%	4,192	9.4%	3.122	0.100
2017	7,696	21.9%	9,295	21.0%	0.980	0.024
2018	9,949	28.4%	12,666	28.6%	-0.198	-0.004
2019	12,217	34.8%	17,427	39.3%	-4.466	-0.093
2020	216	5.3%	352	5.9%	-0.626	-0.027
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[3]	5.3	2.6	5.6	2.8	-0.307	-0.113
Ambulatory allergies or allergy treatment	*18,821*	*53.6%*	*21,702*	*48.9%*	*4.718*	*0.094*
Ambulatory allergies or treatment and not serious	15,800	45.0%	17,819	40.2%	4.861	0.098
Angioedema (-183, -1)	33	0.1%	60	0.1%	-0.041	-0.012
Angioedema (ever, -1)	*533*	*1.5%*	*608*	*1.4%*	*0.148*	*0.012*
Diabetes	18,696	53.3%	20,677	46.6%	6.672	0.134
Ischemic heart disease	27,367	78.0%	33,639	75.8%	2.165	0.051
Renal disorders	14,714	41.9%	19,754	44.5%	-2.596	-0.052
Serious allergies	4,439	12.7%	6,108	13.8%	-1.118	-0.033

Table 1k. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, in Risk Assessment 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	
	ARB-SV 14-day		SV			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	30,597	87.2%	35,674	80.4%	6.783	0.185
Everolimus	11	0.0%	12	0.0%	0.004	0.003
Nonsteroidal anti-inflammatory drugs (NSAIDs)	4,104	11.7%	4,447	10.0%	1.672	0.054
Sirolimus	*****	*****	*****	*****	-0.008	-0.006
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	19.0	14.7	18.3	17.3	0.710	0.044
Mean number of emergency room encounters	0.7	1.5	0.8	1.6	-0.099	-0.065
Mean number of inpatient hospital encounters	0.7	1.0	0.8	1.1	-0.091	-0.085
Mean number of non-acute institutional encounters	0.1	0.4	0.2	0.6	-0.093	-0.184
Mean number of other ambulatory encounters	7.4	10.6	9.4	14.4	-1.958	-0.154
Mean number of filled prescriptions	*33.2*	*21.6*	*26.7*	*20.7*	*6.520*	*0.308*
Mean number of generics	*14.0*	*5.4*	*11.6*	*5.5*	*2.314*	*0.425*
Mean number of unique drug classes	12.1	4.7	11.0	4.9	1.079	0.224

[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.

Sentinel

Table 1l. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, in Risk Assessment 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	
	ARB-SV 14-day		SV			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Patients (Number)	32,174	91.7%	32,174	72.5%	-	-
Demographics	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	72.6	10.6	72.7	11.3	-0.089	-0.008
Age						
18-44 years	*735*	*2.3%*	*797*	*2.5%*	*-0.193*	*-0.013*
45-54 years	*1,654*	*5.1%*	*1,881*	*5.8%*	*-0.706*	*-0.032*
55-64 years	*3,887*	*12.1%*	*4,200*	*13.1%*	*-0.973*	*-0.030*
65+ years	*25,898*	*80.5%*	*25,296*	*78.6%*	*1.871*	*0.050*
Sex						
Female	12,125	37.7%	12,141	37.7%	-0.050	-0.001
Male	20,049	62.3%	20,033	62.3%	0.050	0.001
Race						
American Indian or Alaska Native	80	0.2%	82	0.3%	-0.006	-0.001
Asian	521	1.6%	497	1.5%	0.075	0.006
Black or African American	4,348	13.5%	4,349	13.5%	-0.003	-0.000
Native Hawaiian or Other Pacific Islander	36	0.1%	34	0.1%	0.006	0.002
Unknown	4,900	15.2%	4,860	15.1%	0.124	0.005
White	22,289	69.3%	22,352	69.5%	-0.196	-0.005
Hispanic Origin	695	2.2%	636	2.0%	0.183	0.013
Year						
2015	431	1.3%	402	1.2%	0.090	0.008
2016	3,707	11.5%	3,657	11.4%	0.155	0.005
2017	7,013	21.8%	6,999	21.8%	0.044	0.001
2018	9,266	28.8%	9,270	28.8%	-0.012	-0.000
2019	11,554	35.9%	11,652	36.2%	-0.305	-0.006
2020	203	5.4%	194	5.1%	0.237	0.011
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score[3]	5.3	2.6	5.3	2.6	-0.002	-0.001
Ambulatory allergies or allergy treatment	*16,841*	*52.3%*	*16,741*	*52.0%*	*0.311*	*0.006*
Ambulatory allergies or treatment and not serious	14,056	43.7%	14,014	43.6%	0.131	0.003
Angioedema (-183, -1)	33	0.1%	34	0.1%	-0.003	-0.001
Angioedema (ever, -1)	*493*	*1.5%*	*457*	*1.4%*	*0.112*	*0.009*
Diabetes	16,478	51.2%	16,369	50.9%	0.339	0.007
Ischemic heart disease	24,964	77.6%	24,981	77.6%	-0.053	-0.001
Renal disorders	13,698	42.6%	13,783	42.8%	-0.264	-0.005
Serious allergies	4,136	12.9%	4,154	12.9%	-0.056	-0.002

Table 1l. Characteristics of New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, in Risk Assessment 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	
	ARB-SV 14-day		SV			
Characteristic[1,2]	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
History of Use:						
Diuretics (thiazides, potassium sparing, loop diuretics)	27,771	86.3%	27,925	86.8%	-0.479	-0.014
Everolimus	*****	*****	*****	*****	-0.003	-0.002
Nonsteroidal anti-inflammatory drugs (NSAIDs)	3,588	11.2%	3,534	11.0%	0.168	0.005
Sirolimus	*****	*****	*****	*****	0.000	0.000
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	18.8	14.6	18.7	17.1	0.048	0.003
Mean number of emergency room encounters	0.7	1.5	0.7	1.4	-0.005	-0.004
Mean number of inpatient hospital encounters	0.7	1.0	0.7	1.0	0.001	0.001
Mean number of non-acute institutional encounters	0.1	0.4	0.1	0.4	0.002	0.005
Mean number of other ambulatory encounters	7.6	10.9	7.5	10.5	0.055	0.005
Mean number of filled prescriptions	*32.0*	*20.4*	*29.0*	*21.0*	*2.985*	*0.144*
Mean number of generics	*13.6*	*5.2*	*12.4*	*5.4*	*1.150*	*0.217*
Mean number of unique drug classes	11.7	4.5	11.7	4.8	0.011	0.002

[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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Sentinel

Table 2. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Risk Window

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)[1]	Wald P-Value[1]
Overall											
Site-Adjusted Analysis											
ACEI-SV	68,868	*****	*****	*****	*****	2.15	*****	-0.47	*****	0.83 (0.55, 1.24)	0.356
ARB-SV	48,406	*****	*****	*****	*****	2.62	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	46,333	*****	*****	*****	*****	2.74	*****	-0.37	*****	0.88 (0.50, 1.56)	0.662
ARB-SV	46,333	*****	*****	*****	*****	3.11	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	46,333	*****	*****	*****	*****	2.11	*****	-0.49	*****	0.81 (0.52, 1.28)	0.369
ARB-SV	46,333	*****	*****	*****	*****	2.6	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV	68,868	*****	*****	*****	*****	3.5	*****	-0.38	*****	0.91 (0.45, 1.82)	0.784
ARB-SV	48,406	*****	*****	*****	*****	3.89	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	46,333	*****	*****	*****	*****	4.46	*****	0.32	*****	1.08 (0.51, 2.29)	0.847
ARB-SV	46,333	*****	*****	*****	*****	4.14	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	46,333	*****	*****	*****	*****	4.64	*****	0.88	*****	1.23 (0.59, 2.56)	0.575
ARB-SV	46,333	*****	*****	*****	*****	3.76	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV	55,636	*****	*****	*****	*****	3.18	*****	0.15	*****	1.06 (0.43, 2.59)	0.904
ARB-SV	38,892	*****	*****	*****	*****	3.02	*****				

Sentinel

Table 2. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	30,021	*****	*****	*****	*****	2.88	*****	-1.15	*****	0.71 (0.23, 2.25)	0.566
ARB-SV	30,021	*****	*****	*****	*****	4.03	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	37,183	*****	*****	*****	*****	2.37	*****	-0.77	*****	0.76 (0.26, 2.18)	0.604
ARB-SV	37,346	*****	*****	*****	*****	3.15	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV	37,553	*****	*****	*****	*****	2.5	*****	-1.07	*****	0.68 (0.24, 1.95)	0.477
ARB-SV	26,335	*****	*****	*****	*****	3.57	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	13,807	*****	*****	*****	*****	2.13	*****	-1.07	*****	0.67 (0.11, 3.99)	0.657
ARB-SV	13,807	*****	*****	*****	*****	3.2	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	25,121	*****	*****	*****	*****	1.61	*****	-2.11	*****	0.43 (0.11, 1.66)	0.219
ARB-SV	25,311	*****	*****	*****	*****	3.71	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV	30,181	*****	*****	*****	*****	0.52	*****	-1.72	*****	0.23 (0.06, 0.87)	0.029
ARB-SV	21,257	*****	*****	*****	*****	2.25	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	8,985	*****	*****	*****	*****	0.75	*****	0	*****	1.00 (0.06, 15.99)	1
ARB-SV	8,985	*****	*****	*****	*****	0.75	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	20,130	*****	*****	*****	*****	0.79	*****	-1.55	*****	0.34 (0.09, 1.24)	0.101
ARB-SV	20,464	*****	*****	*****	*****	2.33	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV	18,797	*****	*****	*****	*****	1.82	*****	0.3	*****	1.24 (0.36, 4.23)	0.734
ARB-SV	13,036	*****	*****	*****	*****	1.51	*****				

Sentinel

Table 2. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	3,442	*****	*****	*****	*****	0	*****	-1.72	*****	-	-
ARB-SV	3,442	*****	*****	*****	*****	1.72	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	12,497	*****	*****	*****	*****	1.57	*****	0	*****	1.01 (0.25, 4.03)	0.992
ARB-SV	12,557	*****	*****	*****	*****	1.57	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV	13,147	*****	*****	*****	*****	1.72	*****	0.7	*****	1.71 (0.33, 8.81)	0.522
ARB-SV	8,956	*****	*****	*****	*****	1.03	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	1,630	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	1,630	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	8,598	*****	*****	*****	*****	1.06	*****	0.53	*****	2.02 (0.18, 22.33)	0.565
ARB-SV	8,641	*****	*****	*****	*****	0.53	*****				

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

[2]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.

Sentinel

Table 3. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
No Angioedema (-183, -1)											
Overall											
Site-Adjusted Analysis											
ACEI-SV	68,785	*****	*****	*****	*****	2.07	*****	-0.2	*****	0.92 (0.61, 1.41)	0.71
ARB-SV	48,350	*****	*****	*****	*****	2.26	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	46,272	*****	*****	*****	*****	2.61	*****	0	*****	1.00 (0.55, 1.83)	1
ARB-SV	46,272	*****	*****	*****	*****	2.61	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	46,272	*****	*****	*****	*****	2.05	*****	-0.24	*****	0.90 (0.56, 1.43)	0.649
ARB-SV	46,272	*****	*****	*****	*****	2.29	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV	68,785	*****	*****	*****	*****	3.31	*****	0.81	*****	1.33 (0.59, 2.98)	0.49
ARB-SV	48,350	*****	*****	*****	*****	2.5	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	46,272	*****	*****	*****	*****	4.14	*****	1.28	*****	1.44 (0.62, 3.38)	0.396
ARB-SV	46,272	*****	*****	*****	*****	2.87	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	46,272	*****	*****	*****	*****	4.36	*****	1.75	*****	1.67 (0.73, 3.82)	0.224
ARB-SV	46,272	*****	*****	*****	*****	2.61	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV	55,566	*****	*****	*****	*****	2.91	*****	-0.11	*****	0.97 (0.39, 2.41)	0.944
ARB-SV	38,851	*****	*****	*****	*****	3.03	*****				

Sentinel

Table 3. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	29,989	*****	*****	*****	*****	2.88	*****	-1.15	*****	0.71 (0.23, 2.25)	0.566
ARB-SV	29,989	*****	*****	*****	*****	4.03	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	37,131	*****	*****	*****	*****	2.38	*****	-0.77	*****	0.76 (0.26, 2.18)	0.604
ARB-SV	37,302	*****	*****	*****	*****	3.15	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV	37,510	*****	*****	*****	*****	2.51	*****	-0.56	*****	0.81 (0.27, 2.42)	0.711
ARB-SV	26,307	*****	*****	*****	*****	3.07	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	13,790	*****	*****	*****	*****	2.13	*****	-1.07	*****	0.67 (0.11, 3.99)	0.657
ARB-SV	13,790	*****	*****	*****	*****	3.2	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	25,090	*****	*****	*****	*****	1.61	*****	-1.58	*****	0.50 (0.13, 2.02)	0.333
ARB-SV	25,283	*****	*****	*****	*****	3.19	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV	30,151	*****	*****	*****	*****	0.52	*****	-1.73	*****	0.23 (0.06, 0.86)	0.029
ARB-SV	21,233	*****	*****	*****	*****	2.25	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	8,981	*****	*****	*****	*****	0.75	*****	0	*****	1.00 (0.06, 15.99)	1
ARB-SV	8,981	*****	*****	*****	*****	0.75	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	20,107	*****	*****	*****	*****	0.79	*****	-1.55	*****	0.34 (0.09, 1.24)	0.101
ARB-SV	20,440	*****	*****	*****	*****	2.34	*****				

Sentinel

Table 3. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV	18,775	*****	*****	*****	*****	1.82	*****	0.3	*****	1.24 (0.36, 4.23)	0.734
ARB-SV	13,024	*****	*****	*****	*****	1.52	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	3,442	*****	*****	*****	*****	0	*****	-1.72	*****	-	-
ARB-SV	3,442	*****	*****	*****	*****	1.72	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	12,481	*****	*****	*****	*****	1.57	*****	0	*****	1.01 (0.25, 4.02)	0.993
ARB-SV	12,544	*****	*****	*****	*****	1.57	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV	13,130	*****	*****	*****	*****	1.72	*****	0.7	*****	1.71 (0.33, 8.81)	0.522
ARB-SV	8,947	*****	*****	*****	*****	1.03	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	1,631	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	1,631	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	8,587	*****	*****	*****	*****	1.06	0.23	0.53	*****	2.02 (0.18, 22.31)	0.565
ARB-SV	8,632	*****	*****	*****	*****	0.53	0.12				
Angioedema (-183, -1)											
Overall											
Site-Adjusted Analysis											
ACEI-SV	83	*****	*****	*****	*****	72.23	*****	-261.11	*****	0.26 (0.05, 1.33)	0.105
ARB-SV	56	*****	*****	*****	*****	333.33	*****				

Sentinel

Table 3. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	46	*****	*****	*****	*****	164.47	*****	-328.95	*****	0.33 (0.03, 3.20)	0.341
ARB-SV	46	*****	*****	*****	*****	493.42	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	46	*****	*****	*****	*****	64.77	*****	-143.57	*****	0.31 (0.03, 2.96)	0.308
ARB-SV	46	*****	*****	*****	*****	208.33	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV	83	*****	*****	*****	*****	156.99	*****	-1089.9	*****	0.13 (0.02, 1.11)	0.063
ARB-SV	56	*****	*****	*****	*****	1,246.88	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	46	*****	*****	*****	*****	332.23	*****	-664.45	*****	0.33 (0.03, 3.20)	0.341
ARB-SV	46	*****	*****	*****	*****	996.68	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	46	*****	*****	*****	*****	285.71	*****	-628.92	*****	0.31 (0.03, 2.96)	0.308
ARB-SV	46	*****	*****	*****	*****	914.63	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV	73	*****	*****	*****	*****	204.92	*****	204.92	*****	-	-
ARB-SV	45	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	31	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	31	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	40	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	36	*****	*****	*****	*****	0	*****				

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Table 3. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV	47	*****	*****	*****	*****	0	*****	-432.9	*****	-	-
ARB-SV	30	*****	*****	*****	*****	432.9	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	17	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	17	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	27	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	25	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV	33	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	26	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	11	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	11	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	21	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	21	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV	23	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	15	*****	*****	*****	*****	0	*****				

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Table 3. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	14	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	12	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV	18	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	13	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	*****	*****	*****	*****	*****	0	*****				

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

[2]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.

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Table 4. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Race: Unknown											
Overall											
Site-Adjusted Analysis											
ACEI-SV	11,340	*****	*****	*****	*****	1.28	*****	-0.22	*****	0.79 (0.21, 2.94)	0.723
ARB-SV	7,857	*****	*****	*****	*****	1.51	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	7,448	*****	*****	*****	*****	0.81	*****	-0.81	*****	0.50 (0.05, 5.51)	0.571
ARB-SV	7,448	*****	*****	*****	*****	1.62	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	7,448	*****	*****	*****	*****	1.2	*****	-0.38	*****	0.73 (0.16, 3.28)	0.686
ARB-SV	7,448	*****	*****	*****	*****	1.58	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV	11,340	*****	*****	*****	*****	1.21	*****	-2.29	*****	0.34 (0.03, 3.75)	0.376
ARB-SV	7,857	*****	*****	*****	*****	3.5	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	7,448	*****	*****	*****	*****	0	*****	-4.12	*****	-	-
ARB-SV	7,448	*****	*****	*****	*****	4.12	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	7,448	*****	*****	*****	*****	1.85	*****	-1.83	*****	0.50 (0.05, 5.52)	0.572
ARB-SV	7,448	*****	*****	*****	*****	3.68	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV	8,766	*****	*****	*****	*****	3.32	*****	3.32	*****	-	-
ARB-SV	6,039	*****	*****	*****	*****	0	*****				

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Table 4. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	4,446	*****	*****	*****	*****	3.84	*****	3.84	*****	-	-
ARB-SV	4,446	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	5,703	*****	*****	*****	*****	2.56	*****	2.56	*****	-	-
ARB-SV	5,747	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV	6,045	*****	*****	*****	*****	2.23	*****	-1.05	*****	0.59 (0.04, 9.43)	0.708
ARB-SV	4,105	*****	*****	*****	*****	3.29	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	2,097	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	2,097	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	3,919	*****	*****	*****	*****	0	*****	-3.45	*****	-	-
ARB-SV	3,904	*****	*****	*****	*****	3.45	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV	4,821	*****	*****	*****	*****	0	*****	-1.57	*****	-	-
ARB-SV	3,286	*****	*****	*****	*****	1.57	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	1,344	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	1,344	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	3,119	*****	*****	*****	*****	0	*****	-1.64	*****	-	-
ARB-SV	3,135	*****	*****	*****	*****	1.64	*****				

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Table 4. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV	3,040	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	2,080	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	552	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	552	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	1,935	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	1,991	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV	2,130	*****	*****	*****	*****	2.13	*****	2.13	*****	-	-
ARB-SV	1,422	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	249	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	249	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	1,333	*****	*****	*****	*****	3.45	*****	3.45	*****	-	-
ARB-SV	1,364	*****	*****	*****	*****	0	*****				
Race: American Indian											
Overall											
Site-Adjusted Analysis											
ACEI-SV	237	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	129	*****	*****	*****	*****	0	*****				

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Table 4. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	119	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	119	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	119	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	119	*****	*****	*****	*****	0	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV	237	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	129	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	119	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	119	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	119	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	119	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV	189	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	101	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	70	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	70	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	86	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	93	*****	*****	*****	*****	0	*****				

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Table 4. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV	121	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	64	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	27	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	27	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	56	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	60	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV	98	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	56	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	19	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	19	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	44	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	53	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV	56	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	33	*****	*****	*****	*****	0	*****				

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Table 4. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	24	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	32	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV	39	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	19	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	18	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	20	*****	*****	*****	*****	0	*****				
Race: Asian											
Overall											
Site-Adjusted Analysis											
ACEI-SV	662	*****	*****	*****	*****	0	*****	-2.93	*****	-	-
ARB-SV	1,053	*****	*****	*****	*****	2.93	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	569	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	569	*****	*****	*****	*****	0	*****				

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Table 4. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	569	*****	*****	*****	*****	0	*****	-5.17	*****	-	-
ARB-SV	569	*****	*****	*****	*****	5.17	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV	662	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	1,053	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	569	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	569	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	569	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	569	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV	509	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	774	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	336	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	336	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	442	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	434	*****	*****	*****	*****	0	*****				

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Table 4. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV	351	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	515	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	163	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	163	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	303	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	293	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV	267	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	411	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	99	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	99	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	231	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	234	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV	178	*****	*****	*****	*****	0	*****	-18.22	*****	-	-
ARB-SV	271	*****	*****	*****	*****	18.22	*****				

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Table 4. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	43	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	43	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	155	*****	*****	*****	*****	0	*****	-30.89	*****	-	-
ARB-SV	160	*****	*****	*****	*****	30.89	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV	126	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	183	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	20	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	20	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	114	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	107	*****	*****	*****	*****	0	*****				
Race: Black											
Overall											
Site-Adjusted Analysis											
ACEI-SV	8,897	*****	*****	*****	*****	5.61	*****	0.76	*****	1.15 (0.52, 2.57)	0.727
ARB-SV	6,877	*****	*****	*****	*****	4.86	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	6,301	*****	*****	*****	*****	11.7	*****	7.44	*****	2.75 (0.88, 8.64)	0.083
ARB-SV	6,301	*****	*****	*****	*****	4.25	*****				

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Table 4. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	6,301	*****	*****	*****	*****	6.76	*****	2	*****	1.43 (0.61, 3.35)	0.407
ARB-SV	6,301	*****	*****	*****	*****	4.76	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV	8,897	*****	*****	*****	*****	12.08	*****	6.2	*****	2.07 (0.55, 7.79)	0.284
ARB-SV	6,877	*****	*****	*****	*****	5.88	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	6,301	*****	*****	*****	*****	16.47	*****	9.41	*****	2.33 (0.60, 9.02)	0.22
ARB-SV	6,301	*****	*****	*****	*****	7.06	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	6,301	*****	*****	*****	*****	14.96	*****	8.54	*****	2.34 (0.60, 9.05)	0.218
ARB-SV	6,301	*****	*****	*****	*****	6.42	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV	7,131	*****	*****	*****	*****	10.81	*****	5.21	*****	1.91 (0.37, 9.86)	0.438
ARB-SV	5,471	*****	*****	*****	*****	5.61	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	4,007	*****	*****	*****	*****	13.74	*****	9.16	*****	3.00 (0.31, 28.84)	0.341
ARB-SV	4,007	*****	*****	*****	*****	4.58	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	5,035	*****	*****	*****	*****	12.15	*****	6.03	*****	1.99 (0.37, 10.88)	0.426
ARB-SV	5,012	*****	*****	*****	*****	6.12	*****				

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Table 4. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV	4,319	*****	*****	*****	*****	0	*****	-8.17	*****	-	-
ARB-SV	3,357	*****	*****	*****	*****	8.17	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	1,556	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	1,556	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	3,121	*****	*****	*****	*****	0	*****	-8.92	*****	-	-
ARB-SV	3,074	*****	*****	*****	*****	8.92	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV	3,257	*****	*****	*****	*****	1.69	*****	-0.5	*****	0.76 (0.05, 12.20)	0.848
ARB-SV	2,566	*****	*****	*****	*****	2.19	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	881	*****	*****	*****	*****	8.04	*****	8.04	*****	-	-
ARB-SV	881	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	2,362	*****	*****	*****	*****	2.32	*****	-0.06	*****	0.97 (0.06, 15.57)	0.985
ARB-SV	2,353	*****	*****	*****	*****	2.38	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV	1,845	*****	*****	*****	*****	2.7	*****	-0.8	*****	0.77 (0.05, 12.24)	0.85
ARB-SV	1,418	*****	*****	*****	*****	3.5	*****				

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Table 4. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	299	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	299	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	1,348	*****	*****	*****	*****	3.68	*****	-0.12	*****	0.98 (0.06, 15.61)	0.986
ARB-SV	1,310	*****	*****	*****	*****	3.8	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV	1,243	*****	*****	*****	*****	0	*****	-4.89	*****	-	-
ARB-SV	962	*****	*****	*****	*****	4.89	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	133	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	133	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	908	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	886	*****	*****	*****	*****	0	*****				
Race: Pacific Islander											
Overall											
Site-Adjusted Analysis											
ACEI-SV	66	*****	*****	*****	*****	52.19	*****	52.19	*****	-	-
ARB-SV	59	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
ACEI-SV	50	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	50	*****	*****	*****	*****	0	*****				

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Table 4. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	50	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	50	*****	*****	*****	*****	0	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV	66	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	59	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
ACEI-SV	50	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	50	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	50	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	50	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV	53	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	51	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
ACEI-SV	37	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	37	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	40	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	44	*****	*****	*****	*****	0	*****				

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Table 4. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV	37	*****	*****	*****	*****	364.96	*****	364.96	*****	-	-
ARB-SV	34	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
ACEI-SV	16	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	16	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	27	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	31	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV	31	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	22	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
ACEI-SV	11	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	11	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	24	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	18	*****	*****	*****	*****	0	*****				

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Table 4. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV	16	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	13	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
ACEI-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	12	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	*****	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
ACEI-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	*****	*****	*****	*****	*****	0	*****				
Race: White											
Overall											
Site-Adjusted Analysis											
ACEI-SV	47,666	*****	*****	*****	*****	1.79	*****	-0.69	*****	0.73 (0.44, 1.21)	0.218
ARB-SV	32,431	*****	*****	*****	*****	2.48	*****				

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Table 4. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
ACEI-SV	31,449	*****	*****	*****	*****	2.09	*****	-0.52	*****	0.80 (0.37, 1.71)	0.565
ARB-SV	31,449	*****	*****	*****	*****	2.62	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	31,449	*****	*****	*****	*****	1.6	*****	-0.87	*****	0.65 (0.36, 1.17)	0.151
ARB-SV	31,449	*****	*****	*****	*****	2.46	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV	47,666	*****	*****	*****	*****	2.52	*****	-1.19	*****	0.69 (0.27, 1.73)	0.425
ARB-SV	32,431	*****	*****	*****	*****	3.7	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
ACEI-SV	31,449	*****	*****	*****	*****	3.71	*****	0.46	*****	1.14 (0.41, 3.15)	0.796
ARB-SV	31,449	*****	*****	*****	*****	3.25	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	31,449	*****	*****	*****	*****	3.4	*****	0.01	*****	1.00 (0.38, 2.67)	0.996
ARB-SV	31,449	*****	*****	*****	*****	3.39	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV	38,991	*****	*****	*****	*****	1.88	*****	-1.43	*****	0.56 (0.17, 1.83)	0.338
ARB-SV	26,458	*****	*****	*****	*****	3.3	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[1]											
ACEI-SV	20,913	*****	*****	*****	*****	0.82	*****	-3.27	*****	0.20 (0.02, 1.71)	0.142
ARB-SV	20,913	*****	*****	*****	*****	4.08	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	25,564	*****	*****	*****	*****	0.57	*****	-2.83	*****	0.17 (0.02, 1.40)	0.099
ARB-SV	25,704	*****	*****	*****	*****	3.4	*****				

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Table 4. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV	26,687	*****	*****	*****	*****	2.5	*****	-0.42	*****	0.85 (0.23, 3.18)	0.815
ARB-SV	18,263	*****	*****	*****	*****	2.93	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	9,915	*****	*****	*****	*****	2.94	*****	0	*****	1.00 (0.14, 7.10)	1
ARB-SV	9,915	*****	*****	*****	*****	2.94	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	17,489	*****	*****	*****	*****	2.3	*****	-0.71	*****	0.76 (0.17, 3.41)	0.723
ARB-SV	17,761	*****	*****	*****	*****	3.01	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV	21,713	*****	*****	*****	*****	0.48	*****	-2	*****	0.20 (0.04, 0.95)	0.043
ARB-SV	14,919	*****	*****	*****	*****	2.48	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	6,608	*****	*****	*****	*****	1	*****	0	*****	1.00 (0.06, 15.99)	1
ARB-SV	6,608	*****	*****	*****	*****	1	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	14,197	*****	*****	*****	*****	0.74	*****	-1.81	*****	0.29 (0.06, 1.40)	0.123
ARB-SV	14,521	*****	*****	*****	*****	2.55	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV	13,670	*****	*****	*****	*****	2.14	*****	1.07	*****	2.02 (0.41, 10.01)	0.389
ARB-SV	9,226	*****	*****	*****	*****	1.07	*****				

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Table 4. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	2,617	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	2,617	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	8,929	*****	*****	*****	*****	1.65	*****	0.55	*****	1.51 (0.25, 9.04)	0.651
ARB-SV	8,979	*****	*****	*****	*****	1.1	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV	9,611	*****	*****	*****	*****	1.88	*****	1.16	*****	2.65 (0.30, 23.71)	0.383
ARB-SV	6,362	*****	*****	*****	*****	0.72	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	1,254	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV	1,254	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	6,159	*****	*****	*****	*****	0.74	*****	0	*****	1.01 (0.06, 16.07)	0.997
ARB-SV	6,198	*****	*****	*****	*****	0.74	*****				

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

[2]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.

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Table 5. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Risk Window

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)[1]	Wald P-Value[1]
Overall											
Site-Adjusted Analysis											
ACEI-SV	68,829	*****	*****	*****	*****	2.15	*****	0.78	*****	1.60 (0.96, 2.66)	0.069
SV	43,140	*****	*****	*****	*****	1.36	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	41,518	*****	*****	*****	*****	2.91	*****	1.59	*****	2.20 (1.04, 4.65)	0.039
SV	41,518	*****	*****	*****	*****	1.32	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	41,518	*****	*****	*****	*****	2.06	*****	0.79	*****	1.62 (0.91, 2.89)	0.103
SV	41,518	*****	*****	*****	*****	1.27	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV	68,829	*****	*****	*****	*****	3.5	*****	2.33	*****	2.98 (1.01, 8.80)	0.048
SV	43,140	*****	*****	*****	*****	1.17	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	41,518	*****	*****	*****	*****	3.68	*****	2.34	*****	2.75 (0.88, 8.64)	0.083
SV	41,518	*****	*****	*****	*****	1.34	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	41,518	*****	*****	*****	*****	3.56	*****	2.34	*****	2.92 (0.93, 9.18)	0.066
SV	41,518	*****	*****	*****	*****	1.21	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV	55,600	*****	*****	*****	*****	3.18	*****	1.66	*****	2.10 (0.68, 6.50)	0.2
SV	39,259	*****	*****	*****	*****	1.52	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	30,516	*****	*****	*****	*****	3.44	*****	1.72	*****	2.00 (0.50, 8.00)	0.327
SV	30,516	*****	*****	*****	*****	1.72	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	33,361	*****	*****	*****	*****	3.1	*****	1.53	*****	1.96 (0.57, 6.69)	0.284
SV	37,889	*****	*****	*****	*****	1.57	*****				

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Table 5. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV	37,527	*****	*****	*****	*****	2.5	*****	0.43	*****	1.21 (0.35, 4.12)	0.766
SV	25,725	*****	*****	*****	*****	2.07	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	13,424	*****	*****	*****	*****	1.09	*****	0	*****	1.00 (0.06, 15.99)	1
SV	13,424	*****	*****	*****	*****	1.09	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	22,364	*****	*****	*****	*****	1.81	*****	-0.33	*****	0.84 (0.19, 3.75)	0.82
SV	24,864	*****	*****	*****	*****	2.14	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV	30,162	*****	*****	*****	*****	0.52	*****	-1.11	*****	0.33 (0.08, 1.30)	0.113
SV	20,877	*****	*****	*****	*****	1.63	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	8,688	*****	*****	*****	*****	1.66	*****	0.83	*****	2.00 (0.18, 22.06)	0.571
SV	8,688	*****	*****	*****	*****	0.83	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	17,798	*****	*****	*****	*****	0.6	*****	-0.52	*****	0.53 (0.10, 2.90)	0.465
SV	20,213	*****	*****	*****	*****	1.12	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV	18,794	*****	*****	*****	*****	1.82	*****	0.91	*****	1.97 (0.41, 9.47)	0.399
SV	11,373	*****	*****	*****	*****	0.91	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	2,885	*****	*****	*****	*****	0	*****	-2.12	*****	-	-
SV	2,885	*****	*****	*****	*****	2.12	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	10,722	*****	*****	*****	*****	1.39	*****	0.46	*****	1.46 (0.24, 8.72)	0.681
SV	11,071	*****	*****	*****	*****	0.93	*****				

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Table 5. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Risk Window

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)[1]	Wald P-Value[1]
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV	13,146	*****	*****	*****	*****	1.72	*****	1.06	*****	2.57 (0.30, 21.97)	0.39
SV	7,133	*****	*****	*****	*****	0.66	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	1,270	*****	*****	*****	*****	8.45	*****	8.45	*****	-	-
SV	1,270	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	7,231	*****	*****	*****	*****	1.91	*****	1.24	*****	2.76 (0.29, 26.50)	0.38
SV	6,972	*****	*****	*****	*****	0.67	*****				

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

[2]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.

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Table 6. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
No Angioedema (-183, -1)											
Overall											
Site-Adjusted Analysis											
ACEI-SV	68,746	*****	*****	*****	*****	2.07	*****	0.96	*****	1.90 (1.09, 3.29)	0.023
SV	43,081	*****	*****	*****	*****	1.11	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	41,454	*****	*****	*****	*****	2.91	*****	1.99	*****	3.14 (1.34, 7.36)	0.008
SV	41,454	*****	*****	*****	*****	0.93	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	41,454	*****	*****	*****	*****	2.06	*****	1.06	*****	2.05 (1.10, 3.82)	0.024
SV	41,454	*****	*****	*****	*****	1.01	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV	68,746	*****	*****	*****	*****	3.31	*****	2.73	*****	5.61 (1.30, 24.29)	0.021
SV	43,081	*****	*****	*****	*****	0.59	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	41,454	*****	*****	*****	*****	3.68	*****	3.01	*****	5.50 (1.22, 24.81)	0.027
SV	41,454	*****	*****	*****	*****	0.67	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	41,454	*****	*****	*****	*****	3.56	*****	2.96	*****	5.83 (1.29, 26.32)	0.022
SV	41,454	*****	*****	*****	*****	0.61	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV	55,530	*****	*****	*****	*****	2.92	*****	1.4	*****	1.92 (0.61, 6.03)	0.264
SV	39,207	*****	*****	*****	*****	1.52	*****				

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Table 6. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	30,472	*****	*****	*****	*****	3.45	*****	1.72	*****	2.00 (0.50, 8.00)	0.327
SV	30,472	*****	*****	*****	*****	1.72	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	33,309	*****	*****	*****	*****	3.1	*****	1.53	*****	1.96 (0.57, 6.69)	0.284
SV	37,832	*****	*****	*****	*****	1.57	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV	37,484	*****	*****	*****	*****	2.51	*****	0.95	*****	1.61 (0.42, 6.22)	0.491
SV	25,688	*****	*****	*****	*****	1.56	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	13,401	*****	*****	*****	*****	1.1	*****	0	*****	1.00 (0.06, 15.99)	1
SV	13,401	*****	*****	*****	*****	1.1	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	22,332	*****	*****	*****	*****	1.81	*****	0.2	*****	1.12 (0.23, 5.55)	0.89
SV	24,823	*****	*****	*****	*****	1.61	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV	30,132	*****	*****	*****	*****	0.52	*****	-0.84	*****	0.39 (0.09, 1.65)	0.201
SV	20,847	*****	*****	*****	*****	1.36	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	8,674	*****	*****	*****	*****	1.66	*****	1.66	*****	-	-
SV	8,674	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	17,773	*****	*****	*****	*****	0.6	*****	-0.24	*****	0.71 (0.12, 4.25)	0.708
SV	20,180	*****	*****	*****	*****	0.84	*****				

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Table 6. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV	18,772	*****	*****	*****	*****	1.82	*****	0.91	*****	1.97 (0.41, 9.46)	0.399
SV	11,356	*****	*****	*****	*****	0.91	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	2,887	*****	*****	*****	*****	0	*****	-2.11	*****	-	-
SV	2,887	*****	*****	*****	*****	2.11	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	10,707	*****	*****	*****	*****	1.39	*****	0.46	*****	1.46 (0.24, 8.72)	0.681
SV	11,052	*****	*****	*****	*****	0.93	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV	13,129	*****	*****	*****	*****	1.72	*****	1.06	*****	2.56 (0.30, 21.95)	0.39
SV	7,122	*****	*****	*****	*****	0.66	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	1,269	*****	*****	*****	*****	8.46	*****	8.46	*****	-	-
SV	1,269	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	7,219	*****	*****	*****	*****	1.91	*****	1.24	*****	2.75 (0.29, 26.48)	0.38
SV	6,959	*****	*****	*****	*****	0.67	*****				
Angioedema (-183, -1)											
Overall											
Site-Adjusted Analysis											
ACEI-SV	83	*****	*****	*****	*****	72.23	*****	-105.31	*****	0.40 (0.07, 2.17)	0.287
SV	59	*****	*****	*****	*****	177.54	*****				

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Table 6. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	38	*****	*****	*****	*****	0	*****	-133.51	*****	-	-
SV	38	*****	*****	*****	*****	133.51	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	38	*****	*****	*****	*****	0	*****	-131.41	*****	-	-
SV	38	*****	*****	*****	*****	131.41	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV	83	*****	*****	*****	*****	155.04	*****	-274.15	*****	0.36 (0.03, 3.98)	0.405
SV	59	*****	*****	*****	*****	429.18	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	38	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	38	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	38	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	38	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV	74	*****	*****	*****	*****	186.22	*****	186.22	*****	-	-
SV	54	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	32	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	32	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	34	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	36	*****	*****	*****	*****	0	*****				

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Table 6. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV	47	*****	*****	*****	*****	0	*****	-348.43	*****	-	-
SV	39	*****	*****	*****	*****	348.43	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	27	*****	*****	*****	*****	0	*****	-757.58	*****	-	-
SV	27	*****	*****	*****	*****	757.58	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	23	*****	*****	*****	*****	0	*****	-480.77	*****	-	-
SV	29	*****	*****	*****	*****	480.77	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV	34	*****	*****	*****	*****	0	*****	-159.24	*****	-	-
SV	31	*****	*****	*****	*****	159.24	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	12	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	12	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	19	*****	*****	*****	*****	0	*****	-228.31	*****	-	-
SV	22	*****	*****	*****	*****	228.31	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV	23	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	20	*****	*****	*****	*****	0	*****				

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Table 6. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	12	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	16	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV	19	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	14	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	11	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	11	*****	*****	*****	*****	0	*****				

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

[2]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.

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Table 7. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Race: Unknown											
Overall											
Site-Adjusted Analysis											
ACEI-SV	11,333	*****	*****	*****	*****	1.28	*****	0.52	*****	1.75 (0.34, 9.03)	0.504
SV	7,114	*****	*****	*****	*****	0.76	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	6,597	*****	*****	*****	*****	1.67	*****	0.84	*****	2.00 (0.18, 22.06)	0.571
SV	6,597	*****	*****	*****	*****	0.84	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	6,597	*****	*****	*****	*****	1.37	*****	0.97	*****	3.43 (0.36, 33.01)	0.286
SV	6,597	*****	*****	*****	*****	0.41	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV	11,333	*****	*****	*****	*****	1.21	*****	1.21	*****	-	-
SV	7,114	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	6,597	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	6,597	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	6,597	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	6,597	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV	8,756	*****	*****	*****	*****	3.33	*****	3.33	*****	-	-
SV	6,412	*****	*****	*****	*****	0	*****				

Table 7. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	4,632	*****	*****	*****	*****	3.69	*****	3.69	*****	-	-
SV	4,632	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	5,084	*****	*****	*****	*****	5.75	*****	5.75	*****	-	-
SV	5,989	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV	6,037	*****	*****	*****	*****	2.23	*****	-0.85	*****	0.71 (0.04, 11.29)	0.805
SV	4,335	*****	*****	*****	*****	3.08	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	2,148	*****	*****	*****	*****	6.89	*****	0	*****	1.00 (0.06, 15.99)	1
SV	2,148	*****	*****	*****	*****	6.89	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	3,481	*****	*****	*****	*****	3.9	*****	0.61	*****	1.19 (0.07, 19.05)	0.902
SV	4,056	*****	*****	*****	*****	3.29	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV	4,815	*****	*****	*****	*****	0	*****	-1.56	*****	-	-
SV	3,512	*****	*****	*****	*****	1.56	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	1,367	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	1,367	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	2,731	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	3,285	*****	*****	*****	*****	0	*****				

Sentinel

Table 7. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV	3,039	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	2,015	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	488	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	488	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	1,668	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	1,901	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV	2,127	*****	*****	*****	*****	2.13	*****	2.13	*****	-	-
SV	1,276	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	217	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	217	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	1,130	244.26	78.95	0.22	0	0	*****	0	*****	-	-
SV	1,212	260.05	78.37	0.21	0	0	*****				
Race: American Indian											
Overall											
Site-Adjusted Analysis											
ACEI-SV	237	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	139	*****	*****	*****	*****	0	*****				

Table 7. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	117	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	117	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	117	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	117	*****	*****	*****	*****	0	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV	237	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	139	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	117	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	117	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	117	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	117	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV	188	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	121	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	84	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	84	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	97	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	101	*****	*****	*****	*****	0	*****				

Sentinel

Table 7. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV	121	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	83	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	34	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	34	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	57	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	66	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV	98	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	62	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	21	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	21	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	45	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	53	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV	55	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	33	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	22	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	30	*****	*****	*****	*****	0	*****				

Sentinel

Table 7. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV	39	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	18	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	15	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	16	*****	*****	*****	*****	0	*****				
Race: Asian											
Overall											
Site-Adjusted Analysis											
ACEI-SV	664	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	531	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	459	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	459	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	459	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	459	*****	*****	*****	*****	0	*****				

Sentinel

Table 7. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV	664	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	531	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	459	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	459	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	459	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	459	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV	511	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	490	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	325	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	325	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	354	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	422	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV	352	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	333	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	150	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	150	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	247	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	285	*****	*****	*****	*****	0	*****				

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Table 7. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV	268	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	254	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	93	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	93	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	195	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	222	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV	178	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	138	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	35	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	35	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	126	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	123	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV	127	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	89	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	17	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	17	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	88	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	79	*****	*****	*****	*****	0	*****				

Table 7. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Race: Black											
Overall											
Site-Adjusted Analysis											
ACEI-SV	8,906	*****	*****	*****	*****	5.61	*****	1.55	*****	1.43 (0.58, 3.51)	0.434
SV	5,806	*****	*****	*****	*****	4.06	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	5,469	*****	*****	*****	*****	5.99	*****	1.2	*****	1.25 (0.34, 4.65)	0.739
SV	5,469	*****	*****	*****	*****	4.79	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	5,469	*****	*****	*****	*****	3.77	*****	0.11	*****	1.06 (0.34, 3.29)	0.919
SV	5,469	*****	*****	*****	*****	3.66	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV	8,906	*****	*****	*****	*****	12.07	*****	9.9	*****	5.44 (0.68, 43.51)	0.11
SV	5,806	*****	*****	*****	*****	2.17	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	5,469	*****	*****	*****	*****	10.15	*****	7.61	*****	4.00 (0.45, 35.79)	0.215
SV	5,469	*****	*****	*****	*****	2.54	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	5,469	*****	*****	*****	*****	9.81	*****	7.51	*****	4.23 (0.47, 37.88)	0.197
SV	5,469	*****	*****	*****	*****	2.31	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV	7,138	*****	*****	*****	*****	10.8	*****	7.82	*****	3.71 (0.43, 31.76)	0.231
SV	5,277	*****	*****	*****	*****	2.98	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	4,000	*****	*****	*****	*****	4.75	*****	4.75	*****	-	-
SV	4,000	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	4,389	*****	*****	*****	*****	7.06	*****	3.91	*****	2.35 (0.21, 25.95)	0.485
SV	4,983	*****	*****	*****	*****	3.15	*****				

Sentinel

Table 7. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV	4,325	*****	*****	*****	*****	0	*****	-4.49	*****	-	-
SV	3,036	*****	*****	*****	*****	4.49	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	1,369	*****	*****	*****	*****	0	*****	-11.12	*****	-	-
SV	1,369	*****	*****	*****	*****	11.12	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	2,635	*****	*****	*****	*****	0	*****	-4.74	*****	-	-
SV	2,874	*****	*****	*****	*****	4.74	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV	3,259	*****	*****	*****	*****	1.69	*****	-3.72	*****	0.30 (0.03, 3.36)	0.332
SV	2,303	*****	*****	*****	*****	5.41	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	789	*****	*****	*****	*****	0	*****	-10.52	*****	-	-
SV	789	*****	*****	*****	*****	10.52	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	1,962	*****	*****	*****	*****	0	*****	-2.83	*****	-	-
SV	2,190	*****	*****	*****	*****	2.83	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV	1,846	*****	*****	*****	*****	2.69	*****	-7.3	*****	0.27 (0.02, 3.00)	0.287
SV	1,053	*****	*****	*****	*****	10	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	201	*****	*****	*****	*****	0	*****	-30.81	*****	-	-
SV	201	*****	*****	*****	*****	30.81	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	1,072	*****	*****	*****	*****	0	*****	-10.37	*****	-	-
SV	1,015	*****	*****	*****	*****	10.37	*****				

Sentinel

Table 7. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV	1,245	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	653	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	83	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	83	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	698	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	629	*****	*****	*****	*****	0	*****				

Sentinel

Table 7. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Race: Pacific Islander											
Overall											
Site-Adjusted Analysis											
ACEI-SV	66	*****	*****	*****	*****	52.19	*****	52.19	*****	-	-
SV	46	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	32	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	32	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	32	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	32	*****	*****	*****	*****	0	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV	66	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	46	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	32	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	32	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	32	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	32	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV	53	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	42	*****	*****	*****	*****	0	*****				

Sentinel

Table 7. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	24	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	24	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	25	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	30	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV	36	*****	*****	*****	*****	370.37	*****	370.37	*****	-	-
SV	28	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	11	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	11	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	15	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	19	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV	31	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	24	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	12	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	17	*****	*****	*****	*****	0	*****				

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Table 7. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV	16	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	15	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Race: White											
Overall											
Site-Adjusted Analysis											
ACEI-SV	47,623	*****	*****	*****	*****	1.79	*****	0.68	*****	1.62 (0.83, 3.16)	0.155
SV	29,504	*****	*****	*****	*****	1.11	*****				

Table 7. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	28,510	*****	*****	*****	*****	2.78	*****	1.85	*****	3.00 (1.09, 8.25)	0.033
SV	28,510	*****	*****	*****	*****	0.93	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	28,510	*****	*****	*****	*****	2	*****	0.86	*****	1.74 (0.85, 3.56)	0.129
SV	28,510	*****	*****	*****	*****	1.15	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV	47,623	*****	*****	*****	*****	2.52	*****	1.24	*****	1.98 (0.54, 7.32)	0.305
SV	29,504	*****	*****	*****	*****	1.28	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	28,510	*****	*****	*****	*****	3.39	*****	1.93	*****	2.33 (0.60, 9.02)	0.22
SV	28,510	*****	*****	*****	*****	1.45	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	28,510	*****	*****	*****	*****	3.28	*****	1.96	*****	2.48 (0.64, 9.58)	0.189
SV	28,510	*****	*****	*****	*****	1.32	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV	38,957	*****	*****	*****	*****	1.88	*****	0.23	*****	1.13 (0.27, 4.75)	0.863
SV	26,919	*****	*****	*****	*****	1.65	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	21,212	*****	*****	*****	*****	2.45	*****	0.82	*****	1.50 (0.25, 8.98)	0.657
SV	21,212	*****	*****	*****	*****	1.63	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	23,154	*****	*****	*****	*****	1.9	*****	0.2	*****	1.10 (0.22, 5.46)	0.906
SV	26,064	*****	*****	*****	*****	1.7	*****				

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Table 7. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV	26,664	*****	*****	*****	*****	2.51	*****	1.02	*****	1.69 (0.33, 8.72)	0.53
SV	17,919	*****	*****	*****	*****	1.48	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	9,627	*****	*****	*****	*****	1.51	*****	1.51	*****	-	-
SV	9,627	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	15,760	*****	*****	*****	*****	1.7	*****	0.18	*****	1.11 (0.16, 7.88)	0.917
SV	17,368	*****	*****	*****	*****	1.53	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV	21,696	*****	*****	*****	*****	0.48	*****	-0.67	*****	0.42 (0.07, 2.53)	0.347
SV	14,724	*****	*****	*****	*****	1.15	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	6,407	*****	*****	*****	*****	2.22	*****	2.22	*****	-	-
SV	6,407	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	12,722	*****	*****	*****	*****	0.84	*****	-0.34	*****	0.71 (0.12, 4.24)	0.706
SV	14,288	*****	*****	*****	*****	1.18	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV	13,667	*****	*****	*****	*****	2.14	*****	2.14	*****	-	-
SV	8,126	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	2,209	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	2,209	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	7,751	*****	*****	*****	*****	1.92	*****	1.92	*****	-	-
SV	7,921	*****	*****	*****	*****	0	*****				

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Table 7. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV	9,609	*****	*****	*****	*****	1.88	*****	0.95	*****	1.97 (0.22, 17.64)	0.544
SV	5,092	*****	*****	*****	*****	0.93	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV	989	*****	*****	*****	*****	10.84	*****	10.84	*****	-	-
SV	989	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV	5,248	*****	*****	*****	*****	2.63	*****	1.69	*****	2.71 (0.28, 26.10)	0.387
SV	4,991	*****	*****	*****	*****	0.94	*****				

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

[2]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 New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Risk Window

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)[1]	Wald P-Value[1]
Overall											
Site-Adjusted Analysis											
ARB-SV	48,455	*****	*****	*****	*****	2.62	*****	1.33	*****	2.10 (1.24, 3.57)	0.006
SV	43,845	*****	*****	*****	*****	1.28	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	37,893	*****	*****	*****	*****	4.02	*****	2.44	*****	2.55 (1.27, 5.11)	0.009
SV	37,893	*****	*****	*****	*****	1.58	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	37,893	*****	*****	*****	*****	2.76	*****	1.38	*****	2.03 (1.16, 3.54)	0.013
SV	37,893	*****	*****	*****	*****	1.38	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ARB-SV	48,455	*****	*****	*****	*****	3.88	*****	2.73	*****	3.36 (1.11, 10.22)	0.033
SV	43,845	*****	*****	*****	*****	1.15	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	37,893	*****	*****	*****	*****	4.03	*****	2.56	*****	2.75 (0.88, 8.64)	0.083
SV	37,893	*****	*****	*****	*****	1.46	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	37,893	*****	*****	*****	*****	3.9	*****	2.57	*****	2.93 (0.93, 9.20)	0.066
SV	37,893	*****	*****	*****	*****	1.33	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ARB-SV	38,929	*****	*****	*****	*****	3.02	*****	1.53	*****	2.00 (0.60, 6.65)	0.257
SV	39,911	*****	*****	*****	*****	1.49	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	27,896	*****	*****	*****	*****	4.38	*****	2.5	*****	2.33 (0.60, 9.02)	0.22
SV	27,896	*****	*****	*****	*****	1.88	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	30,495	*****	*****	*****	*****	3.38	*****	1.66	*****	1.97 (0.58, 6.72)	0.281
SV	34,703	*****	*****	*****	*****	1.71	*****				

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Table 8. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ARB-SV	26,362	*****	*****	*****	*****	3.57	*****	1.53	*****	1.79 (0.52, 6.14)	0.354
SV	26,165	*****	*****	*****	*****	2.04	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	12,369	*****	*****	*****	*****	7.11	*****	4.74	*****	3.00 (0.61, 14.86)	0.178
SV	12,369	*****	*****	*****	*****	2.37	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	20,601	*****	*****	*****	*****	3.92	*****	1.59	*****	1.71 (0.48, 6.07)	0.405
SV	22,846	*****	*****	*****	*****	2.33	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ARB-SV	21,280	*****	*****	*****	*****	2.24	*****	0.63	*****	1.43 (0.51, 4.05)	0.496
SV	21,227	*****	*****	*****	*****	1.61	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	8,114	*****	*****	*****	*****	2.66	*****	0.89	*****	1.50 (0.25, 8.98)	0.657
SV	8,114	*****	*****	*****	*****	1.77	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	16,557	*****	*****	*****	*****	2.25	*****	0.73	*****	1.46 (0.46, 4.60)	0.518
SV	18,643	*****	*****	*****	*****	1.52	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ARB-SV	13,053	*****	*****	*****	*****	1.51	*****	1.06	*****	3.25 (0.36, 29.12)	0.291
SV	11,473	*****	*****	*****	*****	0.45	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	2,718	*****	*****	*****	*****	2.24	*****	2.24	*****	-	-
SV	2,718	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	10,071	*****	*****	*****	*****	1.97	*****	1.47	*****	3.89 (0.43, 34.76)	0.225
SV	10,185	*****	*****	*****	*****	0.5	*****				

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Table 8. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Risk Window

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)[1]	Wald P-Value[1]
271 - 365 Days											
Site-Adjusted Analysis											
ARB-SV	8,961	*****	*****	*****	*****	1.03	*****	0.37	*****	1.50 (0.14, 16.58)	0.739
SV	7,184	*****	*****	*****	*****	0.66	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	1,204	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	1,204	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	6,844	*****	*****	*****	*****	0.68	*****	-0.05	*****	0.92 (0.06, 14.79)	0.956
SV	6,480	*****	*****	*****	*****	0.72	*****				

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

[2]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.

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Table 9. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
No Angioedema (-183, -1)											
Overall											
Site-Adjusted Analysis											
ARB-SV	48,399	*****	*****	*****	*****	2.26	*****	1.23	*****	2.26 (1.26, 4.05)	0.006
SV	43,786	*****	*****	*****	*****	1.03	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	37,832	*****	*****	*****	*****	3.3	*****	2.01	*****	2.56 (1.18, 5.52)	0.017
SV	37,832	*****	*****	*****	*****	1.29	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	37,832	*****	*****	*****	*****	2.38	*****	1.29	*****	2.20 (1.19, 4.08)	0.012
SV	37,832	*****	*****	*****	*****	1.1	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ARB-SV	48,399	*****	*****	*****	*****	2.5	*****	1.92	*****	4.39 (0.95, 20.33)	0.059
SV	43,786	*****	*****	*****	*****	0.58	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	37,832	*****	*****	*****	*****	2.57	*****	1.83	*****	3.50 (0.73, 16.85)	0.118
SV	37,832	*****	*****	*****	*****	0.73	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	37,832	*****	*****	*****	*****	2.48	*****	1.82	*****	3.76 (0.78, 18.09)	0.099
SV	37,832	*****	*****	*****	*****	0.67	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ARB-SV	38,888	*****	*****	*****	*****	3.02	*****	1.53	*****	2.00 (0.60, 6.65)	0.257
SV	39,859	*****	*****	*****	*****	1.49	*****				

Sentinel

Table 9. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	27,861	*****	*****	*****	*****	4.38	*****	2.5	*****	2.33 (0.60, 9.02)	0.22
SV	27,861	*****	*****	*****	*****	1.88	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	30,449	*****	*****	*****	*****	3.38	*****	1.67	*****	1.97 (0.58, 6.72)	0.281
SV	34,650	*****	*****	*****	*****	1.71	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ARB-SV	26,334	*****	*****	*****	*****	3.06	*****	1.53	*****	1.96 (0.49, 7.85)	0.34
SV	26,128	*****	*****	*****	*****	1.53	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	12,358	*****	*****	*****	*****	5.94	*****	3.56	*****	2.50 (0.49, 12.89)	0.273
SV	12,358	*****	*****	*****	*****	2.37	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	20,567	*****	*****	*****	*****	3.28	*****	1.53	*****	1.85 (0.44, 7.73)	0.401
SV	22,808	*****	*****	*****	*****	1.75	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ARB-SV	21,256	*****	*****	*****	*****	2.25	*****	0.9	*****	1.73 (0.58, 5.20)	0.326
SV	21,197	*****	*****	*****	*****	1.34	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	8,097	*****	*****	*****	*****	2.66	*****	0.89	*****	1.50 (0.25, 8.98)	0.657
SV	8,097	*****	*****	*****	*****	1.78	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	16,526	*****	*****	*****	*****	2.26	*****	1.04	*****	1.83 (0.54, 6.25)	0.336
SV	18,613	*****	*****	*****	*****	1.22	*****				

Sentinel

Table 9. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
181 - 270 Days											
Site-Adjusted Analysis											
ARB-SV	13,041	*****	*****	*****	*****	1.51	*****	1.06	*****	3.25 (0.36, 29.11)	0.291
SV	11,456	*****	*****	*****	*****	0.45	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	2,716	*****	*****	*****	*****	2.24	*****	2.24	*****	-	-
SV	2,716	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	10,057	*****	*****	*****	*****	1.97	*****	1.47	*****	3.88 (0.43, 34.76)	0.225
SV	10,168	*****	*****	*****	*****	0.5	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ARB-SV	8,952	*****	*****	*****	*****	1.03	*****	0.37	*****	1.50 (0.14, 16.57)	0.74
SV	7,173	*****	*****	*****	*****	0.66	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	1,209	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	1,209	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	6,834	*****	*****	*****	*****	0.68	*****	-0.05	*****	0.92 (0.06, 14.78)	0.956
SV	6,468	*****	*****	*****	*****	0.72	*****				
Angioedema (-183, -1)											
Overall											
Site-Adjusted Analysis											
ARB-SV	56	*****	*****	*****	*****	333.33	*****	156.19	*****	1.64 (0.46, 5.84)	0.444
SV	59	*****	*****	*****	*****	177.15	*****				

Sentinel

Table 9. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	36	*****	*****	*****	*****	663.35	*****	331.67	*****	2.00 (0.37, 10.92)	0.423
SV	36	*****	*****	*****	*****	331.67	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	36	*****	*****	*****	*****	368.32	*****	75.71	*****	1.09 (0.27, 4.35)	0.907
SV	36	*****	*****	*****	*****	292.61	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ARB-SV	56	*****	*****	*****	*****	1,253.13	*****	824.87	*****	2.84 (0.55, 14.73)	0.213
SV	59	*****	*****	*****	*****	428.27	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	36	*****	*****	*****	*****	1,666.67	*****	833.33	*****	2.00 (0.37, 10.92)	0.423
SV	36	*****	*****	*****	*****	833.33	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	36	*****	*****	*****	*****	1,593.63	*****	891.87	*****	2.22 (0.41, 12.15)	0.357
SV	36	*****	*****	*****	*****	701.75	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ARB-SV	44	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	54	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	23	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	23	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	27	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	32	*****	*****	*****	*****	0	*****				

Sentinel

Table 9. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ARB-SV	31	*****	*****	*****	*****	413.22	*****	84.28	*****	1.05 (0.07, 16.78)	0.973
SV	41	*****	*****	*****	*****	328.95	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	11	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	11	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	18	*****	*****	*****	*****	0	*****	-571.43	*****	-	-
SV	24	*****	*****	*****	*****	571.43	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ARB-SV	27	*****	*****	*****	*****	0	*****	-155.52	*****	-	-
SV	34	*****	*****	*****	*****	155.52	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	17	*****	*****	*****	*****	0	*****	-280.9	*****	-	-
SV	19	*****	*****	*****	*****	280.9	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ARB-SV	13	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	21	*****	*****	*****	*****	0	*****				

Sentinel

Table 9. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	11	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	11	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ARB-SV	11	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	14	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				

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

[2]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 10. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Race: Unknown											
Overall											
Site-Adjusted Analysis											
ARB-SV	7,859	*****	*****	*****	*****	1.51	*****	0.75	*****	2.31 (0.41, 12.85)	0.34
SV	7,214	*****	*****	*****	*****	0.75	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	5,722	*****	*****	*****	*****	1.91	*****	1.91	*****	-	-
SV	5,722	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	5,722	*****	*****	*****	*****	1.03	*****	0.57	*****	2.43 (0.22, 26.98)	0.469
SV	5,722	*****	*****	*****	*****	0.46	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ARB-SV	7,859	*****	*****	*****	*****	3.5	*****	3.5	*****	-	-
SV	7,214	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	5,722	*****	*****	*****	*****	2.49	*****	2.49	*****	-	-
SV	5,722	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	5,722	*****	*****	*****	*****	2.4	*****	2.4	*****	-	-
SV	5,722	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ARB-SV	6,039	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	6,505	*****	*****	*****	*****	0	*****				

Table 10. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	4,004	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	4,004	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	4,398	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	5,207	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ARB-SV	4,107	*****	*****	*****	*****	3.29	*****	0.24	*****	1.11 (0.07, 18.45)	0.943
SV	4,385	*****	*****	*****	*****	3.05	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	1,829	*****	*****	*****	*****	8.04	*****	8.04	*****	-	-
SV	1,829	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	3,001	*****	*****	*****	*****	4.5	*****	0.72	*****	1.32 (0.08, 21.19)	0.845
SV	3,524	*****	*****	*****	*****	3.77	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ARB-SV	3,285	*****	*****	*****	*****	1.57	*****	0.02	*****	1.51 (0.09, 24.24)	0.769
SV	3,544	*****	*****	*****	*****	1.55	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	1,203	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	1,203	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	2,412	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	2,870	*****	*****	*****	*****	0	*****				

Table 10. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
181 - 270 Days											
Site-Adjusted Analysis											
ARB-SV	2,082	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	2,021	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	448	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	448	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	1,531	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	1,666	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ARB-SV	1,422	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	1,284	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	208	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	208	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	1,039	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	1,075	*****	*****	*****	*****	0	*****				
Race: American Indian											
Overall											
Site-Adjusted Analysis											
ARB-SV	128	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	144	*****	*****	*****	*****	0	*****				

Table 10. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	95	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	95	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	95	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	95	*****	*****	*****	*****	0	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ARB-SV	128	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	144	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	95	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	95	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	95	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	95	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ARB-SV	99	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	128	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	66	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	66	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	73	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	85	*****	*****	*****	*****	0	*****				

Table 10. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ARB-SV	63	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	86	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	33	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	33	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	51	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	57	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ARB-SV	54	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	66	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	25	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	25	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	45	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	49	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ARB-SV	34	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	32	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	28	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	26	*****	*****	*****	*****	0	*****				

Table 10. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
271 - 365 Days											
Site-Adjusted Analysis											
ARB-SV	23	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	18	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	18	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	14	*****	*****	*****	*****	0	*****				
Race: Asian											
Overall											
Site-Adjusted Analysis											
ARB-SV	1,055	*****	*****	*****	*****	2.92	*****	2.92	*****	-	-
SV	525	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	475	*****	*****	*****	*****	11.79	*****	11.79	*****	-	-
SV	475	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	475	*****	*****	*****	*****	6.44	*****	6.44	*****	-	-
SV	475	*****	*****	*****	*****	0	*****				

Table 10. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
0 - 30 Days											
Site-Adjusted Analysis											
ARB-SV	1,055	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	525	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	475	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	475	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	475	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	475	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ARB-SV	776	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	483	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	328	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	328	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	352	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	437	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ARB-SV	518	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	329	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	147	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	147	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	235	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	303	*****	*****	*****	*****	0	*****				

Table 10. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
91 - 180 Days											
Site-Adjusted Analysis											
ARB-SV	413	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	254	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	92	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	92	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	187	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	236	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ARB-SV	272	*****	*****	*****	*****	18.14	*****	18.14	*****	-	-
SV	138	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	40	*****	*****	*****	*****	133.87	*****	133.87	*****	-	-
SV	40	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	131	*****	*****	*****	*****	39.49	*****	39.49	*****	-	-
SV	129	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ARB-SV	184	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	88	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	21	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	21	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	79	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	83	*****	*****	*****	*****	0	*****				
Race: Black											

Table 10. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Overall											
Site-Adjusted Analysis											
ARB-SV	6,881	*****	*****	*****	*****	4.85	*****	1.42	*****	1.42 (0.52, 3.93)	0.494
SV	5,888	*****	*****	*****	*****	3.44	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	5,016	*****	*****	*****	*****	3.85	*****	1.28	*****	1.50 (0.25, 8.98)	0.657
SV	5,016	*****	*****	*****	*****	2.57	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	5,016	*****	*****	*****	*****	4.06	*****	0.76	*****	1.26 (0.38, 4.12)	0.707
SV	5,016	*****	*****	*****	*****	3.3	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ARB-SV	6,881	*****	*****	*****	*****	5.88	*****	3.73	*****	2.62 (0.27, 25.23)	0.404
SV	5,888	*****	*****	*****	*****	2.14	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	5,016	*****	*****	*****	*****	5.55	*****	2.77	*****	2.00 (0.18, 22.06)	0.571
SV	5,016	*****	*****	*****	*****	2.77	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	5,016	*****	*****	*****	*****	5.37	*****	2.86	*****	2.09 (0.19, 23.03)	0.548
SV	5,016	*****	*****	*****	*****	2.51	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ARB-SV	5,477	*****	*****	*****	*****	5.6	*****	2.67	*****	1.96 (0.18, 21.58)	0.584
SV	5,357	*****	*****	*****	*****	2.93	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	3,664	*****	*****	*****	*****	5.15	*****	5.15	*****	-	-
SV	3,664	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	4,003	*****	*****	*****	*****	3.84	*****	0.44	*****	1.13 (0.07, 18.12)	0.93
SV	4,589	*****	*****	*****	*****	3.41	*****				

Table 10. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ARB-SV	3,358	*****	*****	*****	*****	8.17	*****	3.74	*****	1.80 (0.16, 19.84)	0.633
SV	3,088	*****	*****	*****	*****	4.42	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	1,291	*****	*****	*****	*****	0	*****	-11.78	*****	-	-
SV	1,291	*****	*****	*****	*****	11.78	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	2,443	*****	*****	*****	*****	5.65	*****	0.54	*****	1.12 (0.07, 17.90)	0.936
SV	2,666	*****	*****	*****	*****	5.11	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ARB-SV	2,565	*****	*****	*****	*****	2.18	*****	-3.16	*****	0.41 (0.04, 4.53)	0.468
SV	2,339	*****	*****	*****	*****	5.34	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	748	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	748	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	1,838	*****	*****	*****	*****	3.09	*****	0.03	*****	1.01 (0.06, 16.15)	0.994
SV	2,036	*****	*****	*****	*****	3.06	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ARB-SV	1,421	*****	*****	*****	*****	3.49	*****	-1.47	*****	0.73 (0.05, 11.69)	0.825
SV	1,062	*****	*****	*****	*****	4.96	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	206	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	206	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	995	*****	*****	*****	*****	4.97	*****	-0.64	*****	0.94 (0.06, 14.99)	0.964
SV	940	*****	*****	*****	*****	5.61	*****				
271 - 365 Days											

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Table 10. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Site-Adjusted Analysis											
ARB-SV	963	*****	*****	*****	*****	4.88	*****	4.88	*****	-	-
SV	655	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	88	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	88	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	672	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	575	*****	*****	*****	*****	0	*****				

Table 10. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Race: Pacific Islander											
Overall											
Site-Adjusted Analysis											
ARB-SV	59	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	44	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	34	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	34	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	34	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	34	*****	*****	*****	*****	0	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ARB-SV	59	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	44	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	34	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	34	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	34	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	34	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ARB-SV	51	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	41	*****	*****	*****	*****	0	*****				

Table 10. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	28	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	28	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	29	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	33	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ARB-SV	34	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	26	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	15	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	15	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	16	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	21	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ARB-SV	23	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	23	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	11	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	20	*****	*****	*****	*****	0	*****				

Table 10. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
181 - 270 Days											
Site-Adjusted Analysis											
ARB-SV	14	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	14	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	12	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ARB-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Race: White											
Overall											
Site-Adjusted Analysis											
ARB-SV	32,473	*****	*****	*****	*****	2.48	*****	1.38	*****	2.33 (1.19, 4.57)	0.014
SV	30,030	*****	*****	*****	*****	1.1	*****				

Table 10. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	25,922	*****	*****	*****	*****	4.44	*****	3.23	*****	3.67 (1.49, 9.04)	0.005
SV	25,922	*****	*****	*****	*****	1.21	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	25,922	*****	*****	*****	*****	2.93	*****	1.78	*****	2.62 (1.30, 5.27)	0.007
SV	25,922	*****	*****	*****	*****	1.14	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ARB-SV	32,473	*****	*****	*****	*****	3.7	*****	2.44	*****	2.93 (0.79, 10.84)	0.106
SV	30,030	*****	*****	*****	*****	1.26	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	25,922	*****	*****	*****	*****	4.25	*****	2.66	*****	2.67 (0.71, 10.05)	0.147
SV	25,922	*****	*****	*****	*****	1.59	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	25,922	*****	*****	*****	*****	4.12	*****	2.66	*****	2.85 (0.76, 10.74)	0.122
SV	25,922	*****	*****	*****	*****	1.46	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ARB-SV	26,489	*****	*****	*****	*****	3.3	*****	1.68	*****	2.07 (0.52, 8.28)	0.304
SV	27,401	*****	*****	*****	*****	1.62	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	19,386	*****	*****	*****	*****	5.31	*****	4.43	*****	6.00 (0.72, 49.84)	0.097
SV	19,386	*****	*****	*****	*****	0.89	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	21,150	*****	*****	*****	*****	4.14	*****	2.9	*****	3.36 (0.68, 16.64)	0.138
SV	23,783	*****	*****	*****	*****	1.24	*****				

Table 10. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ARB-SV	18,288	*****	*****	*****	*****	2.93	*****	1.47	*****	2.02 (0.37, 11.04)	0.417
SV	18,258	*****	*****	*****	*****	1.45	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	8,987	*****	*****	*****	*****	6.46	*****	4.85	*****	4.00 (0.45, 35.79)	0.215
SV	8,987	*****	*****	*****	*****	1.62	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	14,548	*****	*****	*****	*****	3.69	*****	2.03	*****	2.21 (0.40, 12.06)	0.36
SV	15,922	*****	*****	*****	*****	1.66	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ARB-SV	14,942	*****	*****	*****	*****	2.48	*****	1.35	*****	2.15 (0.56, 8.30)	0.268
SV	15,009	*****	*****	*****	*****	1.13	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	6,020	*****	*****	*****	*****	4.81	*****	4.81	*****	-	-
SV	6,020	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	11,819	*****	*****	*****	*****	2.7	*****	1.41	*****	2.09 (0.52, 8.35)	0.298
SV	13,166	*****	*****	*****	*****	1.29	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ARB-SV	9,236	*****	*****	*****	*****	1.07	*****	1.07	*****	-	-
SV	8,209	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	2,003	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	2,003	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	7,240	*****	*****	*****	*****	1.37	*****	1.37	*****	-	-
SV	7,263	*****	*****	*****	*****	0	*****				

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Table 10. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
271 - 365 Days											
Site-Adjusted Analysis											
ARB-SV	6,365	*****	*****	*****	*****	0.72	*****	-0.2	*****	0.78 (0.05, 12.55)	0.864
SV	5,135	*****	*****	*****	*****	0.92	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV	899	*****	*****	*****	*****	0	*****	-6.08	*****	-	-
SV	899	*****	*****	*****	*****	6.08	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV	4,940	*****	*****	*****	*****	0.94	*****	-0.08	*****	0.92 (0.06, 14.75)	0.955
SV	4,627	*****	*****	*****	*****	1.01	*****				

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

[2]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.

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Table 11. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Risk Window

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)[1]	Wald P-Value[1]
Overall											
Site-Adjusted Analysis											
ACEI-SV 14-day	48,920	*****	*****	*****	*****	2.44	*****	-0.84	*****	0.75 (0.48, 1.17)	0.208
ARB-SV 14-day	35,084	*****	*****	*****	*****	3.28	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	33,383	*****	*****	*****	*****	3.78	*****	-0.94	*****	0.80 (0.44, 1.44)	0.457
ARB-SV 14-day	33,383	*****	*****	*****	*****	4.72	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	33,383	*****	*****	*****	*****	2.63	*****	-0.61	*****	0.81 (0.50, 1.33)	0.405
ARB-SV 14-day	33,383	*****	*****	*****	*****	3.24	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	48,920	*****	*****	*****	*****	3.94	*****	-1.17	*****	0.77 (0.36, 1.64)	0.495
ARB-SV 14-day	35,084	*****	*****	*****	*****	5.11	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	33,383	*****	*****	*****	*****	5.1	*****	-0.46	*****	0.92 (0.40, 2.08)	0.835
ARB-SV 14-day	33,383	*****	*****	*****	*****	5.57	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	33,383	*****	*****	*****	*****	5.38	*****	0.43	*****	1.09 (0.50, 2.38)	0.835
ARB-SV 14-day	33,383	*****	*****	*****	*****	4.94	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	37,299	*****	*****	*****	*****	3.96	*****	0.09	*****	1.03 (0.39, 2.70)	0.954
ARB-SV 14-day	26,670	*****	*****	*****	*****	3.87	*****				

Table 11. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	19,392	*****	*****	*****	*****	3.59	*****	-0.9	*****	0.80 (0.21, 2.98)	0.739
ARB-SV 14-day	19,392	*****	*****	*****	*****	4.49	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	25,261	*****	*****	*****	*****	3.5	*****	0.05	*****	1.01 (0.33, 3.14)	0.985
ARB-SV 14-day	25,535	*****	*****	*****	*****	3.46	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	25,081	*****	*****	*****	*****	2.7	*****	-1.08	*****	0.72 (0.21, 2.47)	0.597
ARB-SV 14-day	17,938	*****	*****	*****	*****	3.78	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	8,804	*****	*****	*****	*****	0	*****	-3.41	*****	-	-
ARB-SV 14-day	8,804	*****	*****	*****	*****	3.41	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	16,973	*****	*****	*****	*****	1.6	*****	-2.33	*****	0.41 (0.08, 2.10)	0.282
ARB-SV 14-day	17,220	*****	*****	*****	*****	3.93	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	19,871	*****	*****	*****	*****	0.78	*****	-1.79	*****	0.31 (0.08, 1.18)	0.086
ARB-SV 14-day	14,260	*****	*****	*****	*****	2.57	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	5,539	*****	*****	*****	*****	2.38	*****	-1.19	*****	0.67 (0.11, 3.99)	0.657
ARB-SV 14-day	5,539	*****	*****	*****	*****	3.57	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	13,385	*****	*****	*****	*****	1.16	*****	-1.51	*****	0.43 (0.11, 1.67)	0.224
ARB-SV 14-day	13,703	*****	*****	*****	*****	2.67	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	12,720	*****	*****	*****	*****	1.91	*****	-0.28	*****	0.90 (0.24, 3.35)	0.875
ARB-SV 14-day	8,967	*****	*****	*****	*****	2.19	*****				

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Table 11. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	2,226	*****	*****	*****	*****	7.77	*****	0	*****	1.00 (0.20, 4.95)	1
ARB-SV 14-day	2,226	*****	*****	*****	*****	7.77	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	8,531	*****	*****	*****	*****	2.86	*****	0.59	*****	1.27 (0.34, 4.72)	0.724
ARB-SV 14-day	8,631	*****	*****	*****	*****	2.27	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	9,007	*****	*****	*****	*****	1.5	*****	0.03	*****	1.03 (0.17, 6.15)	0.977
ARB-SV 14-day	6,248	*****	*****	*****	*****	1.47	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	1,131	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	1,131	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	5,967	*****	*****	*****	*****	0	*****	-1.53	*****	-	-
ARB-SV 14-day	6,021	*****	*****	*****	*****	1.53	*****				

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

[2]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.

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Table 12. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
No Angioedema (-183, -1)											
Overall											
Site-Adjusted Analysis											
ACEI-SV 14-day	48,874	*****	*****	*****	*****	2.38	*****	-0.56	*****	0.82 (0.52, 1.30)	0.393
ARB-SV 14-day	35,051	*****	*****	*****	*****	2.94	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	33,350	*****	*****	*****	*****	3.78	*****	-0.38	*****	0.91 (0.50, 1.67)	0.758
ARB-SV 14-day	33,350	*****	*****	*****	*****	4.16	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	33,350	*****	*****	*****	*****	2.63	*****	-0.34	*****	0.89 (0.54, 1.46)	0.637
ARB-SV 14-day	33,350	*****	*****	*****	*****	2.97	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	48,874	*****	*****	*****	*****	3.94	*****	0.4	*****	1.11 (0.48, 2.56)	0.811
ARB-SV 14-day	35,051	*****	*****	*****	*****	3.54	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	33,350	*****	*****	*****	*****	5.11	*****	0.93	*****	1.22 (0.51, 2.95)	0.655
ARB-SV 14-day	33,350	*****	*****	*****	*****	4.18	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	33,350	*****	*****	*****	*****	5.38	*****	1.67	*****	1.45 (0.62, 3.39)	0.391
ARB-SV 14-day	33,350	*****	*****	*****	*****	3.71	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	37,263	*****	*****	*****	*****	3.56	*****	-0.31	*****	0.92 (0.34, 2.48)	0.877
ARB-SV 14-day	26,649	*****	*****	*****	*****	3.87	*****				

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Table 12. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	19,382	*****	*****	*****	*****	3.59	*****	-0.9	*****	0.80 (0.21, 2.98)	0.739
ARB-SV 14-day	19,382	*****	*****	*****	*****	4.49	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	25,235	*****	*****	*****	*****	3.51	*****	0.05	*****	1.01 (0.33, 3.14)	0.984
ARB-SV 14-day	25,514	*****	*****	*****	*****	3.46	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	25,060	*****	*****	*****	*****	2.7	*****	-1.08	*****	0.72 (0.21, 2.47)	0.597
ARB-SV 14-day	17,924	*****	*****	*****	*****	3.78	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	8,797	*****	*****	*****	*****	0	*****	-3.41	*****	-	-
ARB-SV 14-day	8,797	*****	*****	*****	*****	3.41	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	16,955	*****	*****	*****	*****	1.6	*****	-2.33	*****	0.41 (0.08, 2.10)	0.282
ARB-SV 14-day	17,204	*****	*****	*****	*****	3.93	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	19,858	*****	*****	*****	*****	0.78	*****	-1.79	*****	0.31 (0.08, 1.18)	0.086
ARB-SV 14-day	14,248	*****	*****	*****	*****	2.57	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	5,535	*****	*****	*****	*****	2.38	*****	-1.19	*****	0.67 (0.11, 3.99)	0.657
ARB-SV 14-day	5,535	*****	*****	*****	*****	3.57	*****				

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Table 12. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	13,372	*****	*****	*****	*****	1.16	*****	-1.51	*****	0.43 (0.11, 1.67)	0.224
ARB-SV 14-day	13,691	*****	*****	*****	*****	2.68	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	12,710	*****	*****	*****	*****	1.91	*****	-0.28	*****	0.90 (0.24, 3.35)	0.874
ARB-SV 14-day	8,960	*****	*****	*****	*****	2.19	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	2,226	*****	*****	*****	*****	7.77	*****	0	*****	1.00 (0.20, 4.95)	1
ARB-SV 14-day	2,226	*****	*****	*****	*****	7.77	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	8,522	*****	*****	*****	*****	2.86	*****	0.59	*****	1.27 (0.34, 4.72)	0.724
ARB-SV 14-day	8,625	*****	*****	*****	*****	2.27	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	8,999	*****	*****	*****	*****	1.5	*****	0.03	*****	1.03 (0.17, 6.14)	0.978
ARB-SV 14-day	6,241	*****	*****	*****	*****	1.47	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	1,133	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	1,133	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	5,962	*****	*****	*****	*****	0	*****	-1.53	*****	-	-
ARB-SV 14-day	6,016	*****	*****	*****	*****	1.53	*****				

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Table 12. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
Angioedema (-183, -1)											
Overall											
Site-Adjusted Analysis											
ACEI-SV 14-day	46	*****	*****	*****	*****	77.34	*****	-313.29	*****	0.15 (0.02, 1.52)	0.109
ARB-SV 14-day	33	*****	*****	*****	*****	390.63	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	20	*****	*****	*****	*****	0	*****	-436.68	*****	-	-
ARB-SV 14-day	20	*****	*****	*****	*****	436.68	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	20	*****	*****	*****	*****	0	*****	-145.56	*****	-	-
ARB-SV 14-day	20	*****	*****	*****	*****	145.56	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	46	*****	*****	*****	*****	0	*****	-1851.85	*****	-	-
ARB-SV 14-day	33	*****	*****	*****	*****	1,851.85	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	20	*****	*****	*****	*****	0	*****	-746.27	*****	-	-
ARB-SV 14-day	20	*****	*****	*****	*****	746.27	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	20	*****	*****	*****	*****	0	*****	-729.93	*****	-	-
ARB-SV 14-day	20	*****	*****	*****	*****	729.93	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	38	*****	*****	*****	*****	392.16	*****	392.16	*****	-	-
ARB-SV 14-day	23	*****	*****	*****	*****	0	*****				

Table 12. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	15	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	15	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	17	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	16	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	26	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	14	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	11	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	11	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	18	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	12	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****				

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Table 12. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	14	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	13	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****				

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

[2]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.

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Table 13. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Race: Unknown											
Overall											
Site-Adjusted Analysis											
ACEI-SV 14-day	7,922	*****	*****	*****	*****	1.58	*****	-0.13	*****	0.86 (0.19, 3.87)	0.848
ARB-SV 14-day	5,604	*****	*****	*****	*****	1.71	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	5,241	*****	*****	*****	*****	2.57	*****	-1.29	*****	0.67 (0.11, 3.99)	0.657
ARB-SV 14-day	5,241	*****	*****	*****	*****	3.86	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	5,241	*****	*****	*****	*****	1.21	*****	-0.6	*****	0.65 (0.11, 3.90)	0.638
ARB-SV 14-day	5,241	*****	*****	*****	*****	1.81	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	7,922	*****	*****	*****	*****	1.79	*****	-3.29	*****	0.35 (0.03, 3.85)	0.388
ARB-SV 14-day	5,604	*****	*****	*****	*****	5.08	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	5,241	*****	*****	*****	*****	3.13	*****	-3.13	*****	0.50 (0.05, 5.51)	0.571
ARB-SV 14-day	5,241	*****	*****	*****	*****	6.26	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	5,241	*****	*****	*****	*****	2.72	*****	-2.69	*****	0.50 (0.05, 5.50)	0.57
ARB-SV 14-day	5,241	*****	*****	*****	*****	5.41	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	5,650	*****	*****	*****	*****	2.59	*****	2.59	*****	-	-
ARB-SV 14-day	3,986	*****	*****	*****	*****	0	*****				

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Table 13. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	2,660	*****	*****	*****	*****	6.42	*****	6.42	*****	-	-
ARB-SV 14-day	2,660	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	3,695	*****	*****	*****	*****	3.94	*****	3.94	*****	-	-
ARB-SV 14-day	3,758	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	3,867	*****	*****	*****	*****	3.52	*****	3.52	*****	-	-
ARB-SV 14-day	2,678	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	1,257	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	1,257	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	2,538	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	2,530	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	3,028	*****	*****	*****	*****	0	*****	-2.42	*****	-	-
ARB-SV 14-day	2,116	*****	*****	*****	*****	2.42	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	794	*****	*****	*****	*****	0	*****	-8.02	*****	-	-
ARB-SV 14-day	794	*****	*****	*****	*****	8.02	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	1,969	*****	*****	*****	*****	0	*****	-2.54	*****	-	-
ARB-SV 14-day	2,012	*****	*****	*****	*****	2.54	*****				

Table 13. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	1,954	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	1,357	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	341	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	341	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	1,268	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	1,290	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	1,381	*****	*****	*****	*****	3.25	*****	3.25	*****	-	-
ARB-SV 14-day	933	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	186	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	186	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	896	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	885	*****	*****	*****	*****	0	*****				
Race: American Indian											
Overall											
Site-Adjusted Analysis											
ACEI-SV 14-day	160	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	82	*****	*****	*****	*****	0	*****				

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Table 13. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	72	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	72	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	72	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	72	*****	*****	*****	*****	0	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	160	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	82	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	72	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	72	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	72	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	72	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	121	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	59	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	39	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	39	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	55	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	51	*****	*****	*****	*****	0	*****				

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Table 13. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	77	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	34	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	17	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	17	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	34	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	28	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	61	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	31	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	13	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	13	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	26	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	27	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	38	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	16	*****	*****	*****	*****	0	*****				

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Table 13. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	14	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	14	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	28	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	11	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	11	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****				
Race: Asian											
Overall											
Site-Adjusted Analysis											
ACEI-SV 14-day	525	*****	*****	*****	*****	0	*****	-3.86	*****	-	-
ARB-SV 14-day	847	*****	*****	*****	*****	3.86	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	455	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	455	*****	*****	*****	*****	0	*****				

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Table 13. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	455	*****	*****	*****	*****	0	*****	-6.89	*****	-	-
ARB-SV 14-day	455	*****	*****	*****	*****	6.89	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	525	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	847	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	455	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	455	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	455	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	455	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	380	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	587	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	247	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	247	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	331	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	329	*****	*****	*****	*****	0	*****				

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Table 13. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	260	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	392	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	116	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	116	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	228	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	223	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	195	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	309	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	74	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	74	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	174	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	180	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	135	*****	*****	*****	*****	0	*****	-24.17	*****	-	-
ARB-SV 14-day	207	*****	*****	*****	*****	24.17	*****				

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Table 13. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	34	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	34	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	119	*****	*****	*****	*****	0	*****	-42.54	*****	-	-
ARB-SV 14-day	118	*****	*****	*****	*****	42.54	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	101	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	134	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	19	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	19	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	89	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	73	*****	*****	*****	*****	0	*****				
Race: Black											
Overall											
Site-Adjusted Analysis											
ACEI-SV 14-day	5,967	*****	*****	*****	*****	6.92	*****	1.78	*****	1.36 (0.53, 3.45)	0.521
ARB-SV 14-day	4,736	*****	*****	*****	*****	5.14	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	4,255	*****	*****	*****	*****	10.41	*****	6.94	*****	3.00 (0.61, 14.86)	0.178
ARB-SV 14-day	4,255	*****	*****	*****	*****	3.47	*****				

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Table 13. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	4,255	*****	*****	*****	*****	8.11	*****	4.05	*****	2.01 (0.69, 5.87)	0.204
ARB-SV 14-day	4,255	*****	*****	*****	*****	4.06	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	5,967	*****	*****	*****	*****	13.97	*****	5.17	*****	1.61 (0.40, 6.44)	0.5
ARB-SV 14-day	4,736	*****	*****	*****	*****	8.8	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	4,255	*****	*****	*****	*****	14.85	*****	7.42	*****	2.00 (0.37, 10.92)	0.423
ARB-SV 14-day	4,255	*****	*****	*****	*****	7.42	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	4,255	*****	*****	*****	*****	16.4	*****	9.87	*****	2.51 (0.49, 12.92)	0.272
ARB-SV 14-day	4,255	*****	*****	*****	*****	6.53	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	4,444	*****	*****	*****	*****	13.8	*****	9.48	*****	3.16 (0.35, 28.24)	0.304
ARB-SV 14-day	3,528	*****	*****	*****	*****	4.32	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	2,355	*****	*****	*****	*****	7.7	*****	7.7	*****	-	-
ARB-SV 14-day	2,355	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	3,150	*****	*****	*****	*****	14.5	*****	14.5	*****	-	-
ARB-SV 14-day	3,171	*****	*****	*****	*****	0	*****				

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Table 13. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	2,740	*****	*****	*****	*****	0	*****	-6.3	*****	-	-
ARB-SV 14-day	2,194	*****	*****	*****	*****	6.3	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	960	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	960	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	1,978	*****	*****	*****	*****	0	*****	-6.97	*****	-	-
ARB-SV 14-day	1,983	*****	*****	*****	*****	6.97	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	2,051	*****	*****	*****	*****	2.61	*****	2.61	*****	-	-
ARB-SV 14-day	1,656	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	534	*****	*****	*****	*****	13.52	*****	13.52	*****	-	-
ARB-SV 14-day	534	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	1,469	*****	*****	*****	*****	3.63	*****	3.63	*****	-	-
ARB-SV 14-day	1,498	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	1,235	*****	*****	*****	*****	4	*****	-1.2	*****	0.76 (0.05, 12.15)	0.846
ARB-SV 14-day	943	*****	*****	*****	*****	5.2	*****				

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Table 13. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	168	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	168	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	890	*****	*****	*****	*****	5.64	*****	-0.06	*****	0.99 (0.06, 15.82)	0.994
ARB-SV 14-day	860	*****	*****	*****	*****	5.7	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	837	*****	*****	*****	*****	0	*****	-7.12	*****	-	-
ARB-SV 14-day	658	*****	*****	*****	*****	7.12	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	86	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	86	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	584	*****	*****	*****	*****	0	*****	-7.77	*****	-	-
ARB-SV 14-day	601	*****	*****	*****	*****	7.77	*****				
Race: Pacific Islander											
Overall											
Site-Adjusted Analysis											
ACEI-SV 14-day	46	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	45	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	35	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	35	*****	*****	*****	*****	0	*****				

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Table 13. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	35	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	35	*****	*****	*****	*****	0	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	46	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	45	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	35	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	35	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	35	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	35	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	33	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	37	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	21	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	21	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	25	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	29	*****	*****	*****	*****	0	*****				

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Table 13. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	23	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	22	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	17	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	18	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	20	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	14	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	14	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	11	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	13	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****				

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Table 13. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****				
Race: White											
Overall											
Site-Adjusted Analysis											
ACEI-SV 14-day	34,300	*****	*****	*****	*****	2.02	*****	-1.28	*****	0.62 (0.36, 1.07)	0.084
ARB-SV 14-day	23,770	*****	*****	*****	*****	3.3	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	22,933	*****	*****	*****	*****	3.12	*****	-1.3	*****	0.71 (0.34, 1.48)	0.356
ARB-SV 14-day	22,933	*****	*****	*****	*****	4.43	*****				

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Table 13. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	22,933	*****	*****	*****	*****	2.17	*****	-1.11	*****	0.66 (0.36, 1.22)	0.183
ARB-SV 14-day	22,933	*****	*****	*****	*****	3.28	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	34,300	*****	*****	*****	*****	2.78	*****	-1.81	*****	0.61 (0.22, 1.69)	0.342
ARB-SV 14-day	23,770	*****	*****	*****	*****	4.59	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	22,933	*****	*****	*****	*****	4.64	*****	0	*****	1.00 (0.35, 2.85)	1
ARB-SV 14-day	22,933	*****	*****	*****	*****	4.64	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	22,933	*****	*****	*****	*****	4.17	*****	0.01	*****	1.00 (0.35, 2.86)	0.994
ARB-SV 14-day	22,933	*****	*****	*****	*****	4.16	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	26,674	*****	*****	*****	*****	2.75	*****	-2	*****	0.57 (0.17, 1.87)	0.354
ARB-SV 14-day	18,475	*****	*****	*****	*****	4.76	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	13,860	*****	*****	*****	*****	2.48	*****	-2.48	*****	0.50 (0.09, 2.73)	0.423
ARB-SV 14-day	13,860	*****	*****	*****	*****	4.97	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	17,726	*****	*****	*****	*****	1.66	*****	-3.25	*****	0.34 (0.07, 1.66)	0.181
ARB-SV 14-day	17,896	*****	*****	*****	*****	4.91	*****				

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Table 13. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	18,122	*****	*****	*****	*****	2.98	*****	-1.3	*****	0.69 (0.17, 2.77)	0.601
ARB-SV 14-day	12,620	*****	*****	*****	*****	4.28	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	6,482	*****	*****	*****	*****	2.3	*****	-2.3	*****	0.50 (0.05, 5.51)	0.571
ARB-SV 14-day	6,482	*****	*****	*****	*****	4.59	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	12,007	*****	*****	*****	*****	2.25	*****	-2.16	*****	0.51 (0.09, 2.77)	0.433
ARB-SV 14-day	12,247	*****	*****	*****	*****	4.41	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	14,521	*****	*****	*****	*****	0.71	*****	-2.38	*****	0.23 (0.05, 1.16)	0.076
ARB-SV 14-day	10,137	*****	*****	*****	*****	3.09	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	4,171	*****	*****	*****	*****	0	*****	-4.74	*****	-	-
ARB-SV 14-day	4,171	*****	*****	*****	*****	4.74	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	9,599	*****	*****	*****	*****	1.08	*****	-2.1	*****	0.34 (0.07, 1.69)	0.187
ARB-SV 14-day	9,832	*****	*****	*****	*****	3.18	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	9,359	*****	*****	*****	*****	2.07	*****	0.55	*****	1.37 (0.25, 7.49)	0.715
ARB-SV 14-day	6,444	*****	*****	*****	*****	1.52	*****				

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Table 13. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	1,693	*****	*****	*****	*****	6.79	*****	3.39	*****	2.00 (0.18, 22.06)	0.571
ARB-SV 14-day	1,693	*****	*****	*****	*****	3.39	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	6,156	*****	*****	*****	*****	3.17	*****	1.61	*****	2.01 (0.37, 10.97)	0.421
ARB-SV 14-day	6,269	*****	*****	*****	*****	1.56	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	6,661	*****	*****	*****	*****	1.35	*****	0.33	*****	1.35 (0.12, 14.90)	0.806
ARB-SV 14-day	4,510	*****	*****	*****	*****	1.02	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	870	*****	*****	*****	*****	0	*****	0	*****	-	-
ARB-SV 14-day	870	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	4,321	*****	*****	*****	*****	0	*****	-1.04	*****	-	-
ARB-SV 14-day	4,396	*****	*****	*****	*****	1.04	*****				

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

[2]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 New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Risk Window

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)[1]	Wald P-Value[1]
Overall											
Site-Adjusted Analysis											
ACEI-SV 14-day	48,892	*****	*****	*****	*****	2.44	*****	1.1	*****	1.86 (1.09, 3.15)	0.022
SV	44,050	*****	*****	*****	*****	1.34	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	38,268	*****	*****	*****	*****	3.4	*****	2.07	*****	2.56 (1.18, 5.52)	0.017
SV	38,268	*****	*****	*****	*****	1.33	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	38,268	*****	*****	*****	*****	2.56	*****	1.26	*****	1.98 (1.11, 3.53)	0.02
SV	38,268	*****	*****	*****	*****	1.3	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	48,892	*****	*****	*****	*****	3.94	*****	2.8	*****	3.40 (1.12, 10.34)	0.031
SV	44,050	*****	*****	*****	*****	1.15	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	38,268	*****	*****	*****	*****	4.83	*****	3.34	*****	3.25 (1.06, 9.97)	0.039
SV	38,268	*****	*****	*****	*****	1.49	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	38,268	*****	*****	*****	*****	4.68	*****	3.37	*****	3.55 (1.16, 10.89)	0.027
SV	38,268	*****	*****	*****	*****	1.31	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	37,272	*****	*****	*****	*****	3.96	*****	2.47	*****	2.65 (0.83, 8.46)	0.099
SV	40,092	*****	*****	*****	*****	1.49	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	26,730	*****	*****	*****	*****	4.59	*****	2.62	*****	2.33 (0.60, 9.02)	0.22
SV	26,730	*****	*****	*****	*****	1.97	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	29,086	*****	*****	*****	*****	4.07	*****	2.8	*****	3.16 (0.84, 11.93)	0.089
SV	35,104	*****	*****	*****	*****	1.27	*****				

Table 14. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	25,060	*****	*****	*****	*****	2.7	*****	0.67	*****	1.32 (0.35, 4.91)	0.681
SV	26,220	*****	*****	*****	*****	2.03	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	11,751	*****	*****	*****	*****	0	*****	-1.26	*****	-	-
SV	11,751	*****	*****	*****	*****	1.26	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	19,427	*****	*****	*****	*****	1.4	*****	-0.33	*****	0.80 (0.13, 4.79)	0.807
SV	23,009	*****	*****	*****	*****	1.73	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	19,855	*****	*****	*****	*****	0.78	*****	-0.82	*****	0.49 (0.12, 1.98)	0.319
SV	21,275	*****	*****	*****	*****	1.6	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	7,579	*****	*****	*****	*****	1.85	*****	1.85	*****	-	-
SV	7,579	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	15,292	*****	*****	*****	*****	1.02	*****	-0.48	*****	0.70 (0.17, 2.93)	0.622
SV	18,774	*****	*****	*****	*****	1.5	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	12,717	*****	*****	*****	*****	1.91	*****	1.01	*****	2.06 (0.40, 10.63)	0.387
SV	11,517	*****	*****	*****	*****	0.9	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	2,696	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	2,696	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	9,596	*****	*****	*****	*****	1.53	*****	0.54	*****	1.50 (0.25, 8.99)	0.656
SV	10,345	*****	*****	*****	*****	0.99	*****				

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Table 14. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Risk Window

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)[1]	Wald P-Value[1]
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	9,003	*****	*****	*****	*****	1.5	*****	0.85	*****	2.30 (0.24, 22.11)	0.472
SV	7,202	*****	*****	*****	*****	0.65	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	1,234	*****	*****	*****	*****	4.49	*****	0	*****	1.00 (0.06, 15.99)	1
SV	1,234	*****	*****	*****	*****	4.49	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	6,637	*****	*****	*****	*****	2.07	*****	1.36	*****	2.89 (0.30, 27.76)	0.359
SV	6,565	*****	*****	*****	*****	0.71	*****				

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

[2]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.

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Table 15. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
No Angioedema (-183, -1)											
Overall											
Site-Adjusted Analysis											
ACEI-SV 14-day	48,846	*****	*****	*****	*****	2.38	*****	1.29	*****	2.23 (1.26, 3.94)	0.006
SV	43,990	*****	*****	*****	*****	1.09	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	38,210	*****	*****	*****	*****	3.26	*****	2.37	*****	3.67 (1.49, 9.04)	0.005
SV	38,210	*****	*****	*****	*****	0.89	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	38,210	*****	*****	*****	*****	2.48	*****	1.47	*****	2.46 (1.31, 4.63)	0.005
SV	38,210	*****	*****	*****	*****	1.01	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	48,846	*****	*****	*****	*****	3.95	*****	3.37	*****	6.79 (1.54, 29.86)	0.011
SV	43,990	*****	*****	*****	*****	0.57	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	38,210	*****	*****	*****	*****	4.83	*****	4.09	*****	6.50 (1.47, 28.80)	0.014
SV	38,210	*****	*****	*****	*****	0.74	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	38,210	*****	*****	*****	*****	4.69	*****	4.03	*****	7.08 (1.60, 31.39)	0.01
SV	38,210	*****	*****	*****	*****	0.66	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	37,236	*****	*****	*****	*****	3.57	*****	2.08	*****	2.38 (0.73, 7.74)	0.148
SV	40,039	*****	*****	*****	*****	1.49	*****				

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Table 15. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	26,690	*****	*****	*****	*****	3.94	*****	1.97	*****	2.00 (0.50, 8.00)	0.327
SV	26,690	*****	*****	*****	*****	1.97	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	29,046	*****	*****	*****	*****	3.57	*****	2.29	*****	2.76 (0.71, 10.67)	0.141
SV	35,052	*****	*****	*****	*****	1.27	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	25,039	*****	*****	*****	*****	2.7	*****	1.18	*****	1.76 (0.42, 7.35)	0.44
SV	26,182	*****	*****	*****	*****	1.53	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	11,731	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	11,731	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	19,402	*****	*****	*****	*****	1.4	*****	0.24	*****	1.20 (0.17, 8.52)	0.855
SV	22,969	*****	*****	*****	*****	1.16	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	19,842	*****	*****	*****	*****	0.78	*****	-0.56	*****	0.60 (0.14, 2.51)	0.481
SV	21,244	*****	*****	*****	*****	1.34	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	7,574	*****	*****	*****	*****	1.85	*****	1.85	*****	-	-
SV	7,574	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	15,278	*****	*****	*****	*****	1.03	*****	-0.18	*****	0.88 (0.20, 3.95)	0.868
SV	18,743	*****	*****	*****	*****	1.21	*****				

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Table 15. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	12,707	*****	*****	*****	*****	1.91	*****	1.01	*****	2.06 (0.40, 10.62)	0.388
SV	11,500	*****	*****	*****	*****	0.9	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	2,698	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	2,698	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	9,587	*****	*****	*****	*****	1.54	*****	0.54	*****	1.50 (0.25, 8.98)	0.657
SV	10,330	*****	*****	*****	*****	1	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	8,995	*****	*****	*****	*****	1.5	*****	0.85	*****	2.29 (0.24, 22.09)	0.473
SV	7,191	*****	*****	*****	*****	0.66	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	1,234	*****	*****	*****	*****	4.48	*****	0	*****	1.00 (0.06, 15.99)	1
SV	1,234	*****	*****	*****	*****	4.48	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	6,631	*****	*****	*****	*****	2.07	*****	1.36	*****	2.88 (0.30, 27.73)	0.359
SV	6,557	*****	*****	*****	*****	0.71	*****				
Angioedema (-183, -1)											
Overall											
Site-Adjusted Analysis											
ACEI-SV 14-day	46	*****	*****	*****	*****	77.34	*****	-97.95	*****	0.52 (0.06, 4.73)	0.563
SV	60	*****	*****	*****	*****	175.28	*****				

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Table 15. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	30	*****	*****	*****	*****	239.23	*****	-239.23	*****	0.50 (0.05, 5.51)	0.571
SV	30	*****	*****	*****	*****	478.47	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	30	*****	*****	*****	*****	138.12	*****	-171.24	*****	0.44 (0.05, 4.14)	0.47
SV	30	*****	*****	*****	*****	309.36	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	46	*****	*****	*****	*****	0	*****	-421.94	*****	-	-
SV	60	*****	*****	*****	*****	421.94	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	30	*****	*****	*****	*****	0	*****	-952.38	*****	-	-
SV	30	*****	*****	*****	*****	952.38	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	30	*****	*****	*****	*****	0	*****	-854.7	*****	-	-
SV	30	*****	*****	*****	*****	854.7	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	39	*****	*****	*****	*****	371.75	*****	371.75	*****	-	-
SV	55	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	21	*****	*****	*****	*****	645.16	*****	645.16	*****	-	-
SV	21	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	24	*****	*****	*****	*****	574.71	*****	574.71	*****	-	-
SV	26	*****	*****	*****	*****	0	*****				

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Table 15. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	25	*****	*****	*****	*****	0	*****	-336.7	*****	-	-
SV	40	*****	*****	*****	*****	336.7	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	18	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	18	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	20	*****	*****	*****	*****	0	*****	-564.97	*****	-	-
SV	26	*****	*****	*****	*****	564.97	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	17	*****	*****	*****	*****	0	*****	-157.48	*****	-	-
SV	32	*****	*****	*****	*****	157.48	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	11	*****	*****	*****	*****	0	*****	-260.42	*****	-	-
SV	19	*****	*****	*****	*****	260.42	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	11	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	21	*****	*****	*****	*****	0	*****				

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Table 15. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				

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

[2]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 New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Race: Unknown											
Overall											
Site-Adjusted Analysis											
ACEI-SV 14-day	7,919	*****	*****	*****	*****	1.58	*****	0.83	*****	2.18 (0.40, 11.95)	0.369
SV	7,229	*****	*****	*****	*****	0.75	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	5,986	*****	*****	*****	*****	0.99	*****	0.99	*****	-	-
SV	5,986	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	5,986	*****	*****	*****	*****	1.6	*****	0.72	*****	1.92 (0.32, 11.58)	0.475
SV	5,986	*****	*****	*****	*****	0.88	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	7,919	*****	*****	*****	*****	1.79	*****	1.79	*****	-	-
SV	7,229	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	5,986	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	5,986	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	5,986	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	5,986	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	5,644	*****	*****	*****	*****	2.59	*****	2.59	*****	-	-
SV	6,518	*****	*****	*****	*****	0	*****				

Table 16. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	3,901	*****	*****	*****	*****	4.45	*****	4.45	*****	-	-
SV	3,901	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	4,250	*****	*****	*****	*****	3.45	*****	3.45	*****	-	-
SV	5,457	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	3,863	*****	*****	*****	*****	3.53	*****	0.48	*****	1.09 (0.07, 17.44)	0.951
SV	4,389	*****	*****	*****	*****	3.04	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	1,763	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	1,763	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	2,894	*****	*****	*****	*****	4.74	*****	1.14	*****	1.29 (0.08, 20.62)	0.858
SV	3,703	*****	*****	*****	*****	3.6	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	3,024	*****	*****	*****	*****	0	*****	-1.55	*****	-	-
SV	3,550	*****	*****	*****	*****	1.55	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	1,104	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	1,104	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	2,235	*****	*****	*****	*****	0	*****	-1.8	*****	-	-
SV	3,011	*****	*****	*****	*****	1.8	*****				

Table 16. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	1,953	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	2,030	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	400	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	400	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	1,427	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	1,773	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	1,379	*****	*****	*****	*****	3.25	*****	3.25	*****	-	-
SV	1,283	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	180	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	180	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	996	*****	*****	*****	*****	4.54	*****	4.54	*****	-	-
SV	1,140	*****	*****	*****	*****	0	*****				
Race: American Indian											
Overall											
Site-Adjusted Analysis											
ACEI-SV 14-day	160	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	143	*****	*****	*****	*****	0	*****				

Table 16. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	98	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	98	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	98	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	98	*****	*****	*****	*****	0	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	160	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	143	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	98	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	98	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	98	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	98	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	120	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	125	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	60	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	60	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	71	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	84	*****	*****	*****	*****	0	*****				

Sentinel

Table 16. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	77	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	85	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	25	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	25	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	43	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	56	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	61	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	64	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	18	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	18	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	37	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	46	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	37	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	33	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	23	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	26	*****	*****	*****	*****	0	*****				

Table 16. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	28	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	19	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	17	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	15	*****	*****	*****	*****	0	*****				
Race: Asian											
Overall											
Site-Adjusted Analysis											
ACEI-SV 14-day	525	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	537	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	414	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	414	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	414	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	414	*****	*****	*****	*****	0	*****				

Table 16. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	525	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	537	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	414	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	414	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	414	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	414	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	381	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	496	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	281	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	281	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	304	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	384	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	260	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	337	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	126	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	126	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	201	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	260	*****	*****	*****	*****	0	*****				

Table 16. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	195	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	258	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	71	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	71	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	152	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	204	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	134	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	139	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	22	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	22	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	104	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	105	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	101	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	89	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	15	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	15	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	76	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	71	*****	*****	*****	*****	0	*****				
Race: Black											

Table 16. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Overall											
Site-Adjusted Analysis											
ACEI-SV 14-day	5,969	*****	*****	*****	*****	6.92	*****	2.95	*****	1.79 (0.70, 4.55)	0.223
SV	5,968	*****	*****	*****	*****	3.96	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	4,916	*****	*****	*****	*****	10.79	*****	6.74	*****	2.67 (0.71, 10.05)	0.147
SV	4,916	*****	*****	*****	*****	4.05	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	4,916	*****	*****	*****	*****	7.05	*****	3.01	*****	1.80 (0.65, 4.96)	0.256
SV	4,916	*****	*****	*****	*****	4.04	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	5,969	*****	*****	*****	*****	13.97	*****	11.85	*****	6.43 (0.77, 53.41)	0.085
SV	5,968	*****	*****	*****	*****	2.12	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	4,916	*****	*****	*****	*****	17.46	*****	14.55	*****	6.00 (0.72, 49.84)	0.097
SV	4,916	*****	*****	*****	*****	2.91	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	4,916	*****	*****	*****	*****	16.92	*****	14.36	*****	6.51 (0.78, 54.09)	0.083
SV	4,916	*****	*****	*****	*****	2.56	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	4,445	*****	*****	*****	*****	13.8	*****	10.9	*****	4.85 (0.54, 43.40)	0.158
SV	5,422	*****	*****	*****	*****	2.9	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	3,379	*****	*****	*****	*****	11.15	*****	11.15	*****	-	-
SV	3,379	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	3,684	*****	*****	*****	*****	12.49	*****	9	*****	3.69 (0.38, 35.49)	0.259
SV	4,519	*****	*****	*****	*****	3.49	*****				

Table 16. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	2,740	*****	*****	*****	*****	0	*****	-4.38	*****	-	-
SV	3,115	*****	*****	*****	*****	4.38	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	1,211	*****	*****	*****	*****	0	*****	-12.61	*****	-	-
SV	1,211	*****	*****	*****	*****	12.61	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	2,271	*****	*****	*****	*****	0	*****	-5.28	*****	-	-
SV	2,577	*****	*****	*****	*****	5.28	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	2,051	*****	*****	*****	*****	2.61	*****	-2.67	*****	0.47 (0.04, 5.21)	0.54
SV	2,364	*****	*****	*****	*****	5.28	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	691	*****	*****	*****	*****	0	*****	-11.22	*****	-	-
SV	691	*****	*****	*****	*****	11.22	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	1,690	*****	*****	*****	*****	3.21	*****	0.07	*****	0.97 (0.06, 15.56)	0.985
SV	1,968	*****	*****	*****	*****	3.13	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	1,228	*****	*****	*****	*****	3.99	*****	-5.87	*****	0.40 (0.04, 4.42)	0.456
SV	1,074	*****	*****	*****	*****	9.86	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	198	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	198	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	995	*****	*****	*****	*****	0	*****	-11.28	*****	-	-
SV	927	*****	*****	*****	*****	11.28	*****				

Table 16. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	838	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	661	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	98	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	98	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	677	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	587	*****	*****	*****	*****	0	*****				

Table 16. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Race: Pacific Islander											
Overall											
Site-Adjusted Analysis											
ACEI-SV 14-day	46	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	47	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	38	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	38	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	38	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	38	*****	*****	*****	*****	0	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	46	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	47	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	38	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	38	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	38	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	38	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	33	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	43	*****	*****	*****	*****	0	*****				

Table 16. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	25	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	25	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	27	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	35	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	22	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	28	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	18	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	23	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	19	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	26	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	15	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	21	*****	*****	*****	*****	0	*****				

Table 16. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	13	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	15	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	11	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	12	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Race: White											
Overall											
Site-Adjusted Analysis											
ACEI-SV 14-day	34,273	*****	*****	*****	*****	2.02	*****	0.92	*****	1.89 (0.94, 3.77)	0.073
SV	30,126	*****	*****	*****	*****	1.09	*****				

Table 16. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	26,475	*****	*****	*****	*****	2.07	*****	1.45	*****	3.33 (0.92, 12.11)	0.067
SV	26,475	*****	*****	*****	*****	0.62	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	26,475	*****	*****	*****	*****	2.12	*****	1.21	*****	2.30 (1.04, 5.09)	0.04
SV	26,475	*****	*****	*****	*****	0.92	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	34,273	*****	*****	*****	*****	2.79	*****	1.53	*****	2.25 (0.58, 8.72)	0.239
SV	30,126	*****	*****	*****	*****	1.25	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	26,475	*****	*****	*****	*****	3.72	*****	2.66	*****	3.50 (0.73, 16.85)	0.118
SV	26,475	*****	*****	*****	*****	1.06	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	26,475	*****	*****	*****	*****	3.61	*****	2.19	*****	2.56 (0.66, 9.90)	0.173
SV	26,475	*****	*****	*****	*****	1.42	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	26,652	*****	*****	*****	*****	2.76	*****	1.14	*****	1.69 (0.40, 7.06)	0.474
SV	27,490	*****	*****	*****	*****	1.61	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	18,856	*****	*****	*****	*****	2.76	*****	2.76	*****	-	-
SV	18,856	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	20,494	*****	*****	*****	*****	2.87	*****	2.27	*****	4.65 (0.52, 41.63)	0.169
SV	24,319	*****	*****	*****	*****	0.61	*****				

Table 16. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	18,105	*****	*****	*****	*****	2.98	*****	1.53	*****	2.05 (0.38, 11.19)	0.407
SV	18,275	*****	*****	*****	*****	1.45	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	8,519	*****	*****	*****	*****	0	*****	-1.72	*****	-	-
SV	8,519	*****	*****	*****	*****	1.72	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	13,847	*****	*****	*****	*****	0.98	*****	0.16	*****	1.20 (0.07, 19.14)	0.899
SV	16,209	*****	*****	*****	*****	0.82	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	14,508	*****	*****	*****	*****	0.71	*****	-0.42	*****	0.63 (0.11, 3.79)	0.617
SV	15,017	*****	*****	*****	*****	1.13	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	5,593	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	5,593	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	11,032	*****	*****	*****	*****	0.94	*****	-0.32	*****	0.74 (0.12, 4.46)	0.747
SV	13,380	*****	*****	*****	*****	1.26	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	9,357	*****	*****	*****	*****	2.07	*****	2.07	*****	-	-
SV	8,235	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	2,006	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	2,006	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	6,969	*****	*****	*****	*****	2.12	*****	2.12	*****	-	-
SV	7,446	*****	*****	*****	*****	0	*****				

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Table 16. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
271 - 365 Days											
Site-Adjusted Analysis											
ACEI-SV 14-day	6,657	*****	*****	*****	*****	1.35	*****	0.43	*****	1.44 (0.13, 15.87)	0.767
SV	5,147	*****	*****	*****	*****	0.92	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ACEI-SV 14-day	901	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	901	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ACEI-SV 14-day	4,821	*****	*****	*****	*****	1.9	*****	0.9	*****	1.86 (0.17, 20.53)	0.612
SV	4,709	*****	*****	*****	*****	0.99	*****				

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

[2]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 17. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Risk Window

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)[1]	Wald P-Value[1]
Overall											
Site-Adjusted Analysis											
ARB-SV 14-day	35,088	*****	*****	*****	*****	3.28	*****	1.94	*****	2.49 (1.46, 4.25)	<0.001
SV	44,361	*****	*****	*****	*****	1.33	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	32,174	*****	*****	*****	*****	4.53	*****	2.96	*****	2.89 (1.35, 6.16)	0.006
SV	32,174	*****	*****	*****	*****	1.57	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	32,174	*****	*****	*****	*****	3.28	*****	1.92	*****	2.45 (1.36, 4.43)	0.003
SV	32,174	*****	*****	*****	*****	1.36	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	35,088	*****	*****	*****	*****	5.11	*****	3.97	*****	4.47 (1.46, 13.71)	0.009
SV	44,361	*****	*****	*****	*****	1.14	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	32,174	*****	*****	*****	*****	5.29	*****	3.97	*****	4.00 (1.13, 14.17)	0.032
SV	32,174	*****	*****	*****	*****	1.32	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	32,174	*****	*****	*****	*****	5.13	*****	3.96	*****	4.31 (1.22, 15.29)	0.024
SV	32,174	*****	*****	*****	*****	1.17	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	26,678	*****	*****	*****	*****	3.87	*****	2.39	*****	2.59 (0.76, 8.83)	0.13
SV	40,380	*****	*****	*****	*****	1.47	*****				

Table 17. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	22,573	*****	*****	*****	*****	4.62	*****	3.08	*****	3.00 (0.61, 14.86)	0.178
SV	22,573	*****	*****	*****	*****	1.54	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	24,555	*****	*****	*****	*****	4.2	*****	2.69	*****	2.78 (0.72, 10.76)	0.138
SV	29,561	*****	*****	*****	*****	1.51	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	17,947	*****	*****	*****	*****	3.77	*****	1.76	*****	1.80 (0.48, 6.70)	0.382
SV	26,440	*****	*****	*****	*****	2.02	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	10,134	*****	*****	*****	*****	5.78	*****	4.34	*****	4.00 (0.45, 35.79)	0.215
SV	10,134	*****	*****	*****	*****	1.45	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	16,557	*****	*****	*****	*****	4.09	*****	2.05	*****	1.98 (0.47, 8.27)	0.351
SV	19,509	*****	*****	*****	*****	2.04	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	14,275	*****	*****	*****	*****	2.57	*****	0.97	*****	1.68 (0.56, 5.02)	0.357
SV	21,443	*****	*****	*****	*****	1.6	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	6,661	*****	*****	*****	*****	4.29	*****	2.14	*****	2.00 (0.37, 10.92)	0.423
SV	6,661	*****	*****	*****	*****	2.14	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	13,165	*****	*****	*****	*****	2.79	*****	1.37	*****	2.01 (0.59, 6.90)	0.264
SV	16,012	*****	*****	*****	*****	1.42	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	8,980	*****	*****	*****	*****	2.18	*****	1.29	*****	2.33 (0.43, 12.71)	0.329
SV	11,557	*****	*****	*****	*****	0.89	*****				

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Table 17. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	2,297	*****	*****	*****	*****	0	*****	-2.71	*****	-	-
SV	2,297	*****	*****	*****	*****	2.71	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	8,256	*****	*****	*****	*****	1.78	*****	0.61	*****	1.52 (0.25, 9.08)	0.648
SV	8,794	*****	*****	*****	*****	1.17	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	6,253	*****	*****	*****	*****	1.47	*****	0.82	*****	2.13 (0.19, 23.50)	0.537
SV	7,227	*****	*****	*****	*****	0.65	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	999	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	999	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	5,732	*****	*****	*****	*****	0.81	*****	-0.03	*****	0.95 (0.06, 15.12)	0.969
SV	5,571	*****	*****	*****	*****	0.84	*****				

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

[2]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.

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Table 18. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
No Angioedema (-183, -1)											
Overall											
Site-Adjusted Analysis											
ARB-SV 14-day	35,055	*****	*****	*****	*****	2.93	*****	1.85	*****	2.77 (1.55, 4.97)	<0.001
SV	44,301	*****	*****	*****	*****	1.08	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	32,130	*****	*****	*****	*****	3.84	*****	2.62	*****	3.14 (1.34, 7.36)	0.008
SV	32,130	*****	*****	*****	*****	1.22	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	32,130	*****	*****	*****	*****	2.91	*****	1.8	*****	2.69 (1.41, 5.15)	0.003
SV	32,130	*****	*****	*****	*****	1.11	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	35,055	*****	*****	*****	*****	3.54	*****	2.97	*****	6.32 (1.36, 29.26)	0.018
SV	44,301	*****	*****	*****	*****	0.57	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	32,130	*****	*****	*****	*****	3.53	*****	2.65	*****	4.00 (0.85, 18.84)	0.08
SV	32,130	*****	*****	*****	*****	0.88	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	32,130	*****	*****	*****	*****	3.43	*****	2.64	*****	4.39 (0.93, 20.68)	0.061
SV	32,130	*****	*****	*****	*****	0.78	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	26,657	*****	*****	*****	*****	3.87	*****	2.39	*****	2.58 (0.76, 8.83)	0.13
SV	40,327	*****	*****	*****	*****	1.48	*****				

Table 18. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	22,545	*****	*****	*****	*****	4.63	*****	3.09	*****	3.00 (0.61, 14.86)	0.178
SV	22,545	*****	*****	*****	*****	1.54	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	24,524	*****	*****	*****	*****	4.2	*****	2.69	*****	2.78 (0.72, 10.75)	0.138
SV	29,521	*****	*****	*****	*****	1.51	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	17,933	*****	*****	*****	*****	3.78	*****	2.26	*****	2.40 (0.57, 10.05)	0.23
SV	26,402	*****	*****	*****	*****	1.52	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	10,118	*****	*****	*****	*****	5.79	*****	4.34	*****	4.00 (0.45, 35.79)	0.215
SV	10,118	*****	*****	*****	*****	1.45	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	16,536	*****	*****	*****	*****	4.1	*****	2.73	*****	2.96 (0.58, 15.28)	0.194
SV	19,481	*****	*****	*****	*****	1.36	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	14,263	*****	*****	*****	*****	2.57	*****	1.24	*****	2.04 (0.64, 6.47)	0.228
SV	21,412	*****	*****	*****	*****	1.33	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	6,649	*****	*****	*****	*****	4.3	*****	3.22	*****	4.00 (0.45, 35.79)	0.215
SV	6,649	*****	*****	*****	*****	1.07	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	13,147	*****	*****	*****	*****	2.79	*****	1.73	*****	2.70 (0.70, 10.48)	0.15
SV	15,990	*****	*****	*****	*****	1.06	*****				

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Table 18. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
181 - 270 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	8,973	*****	*****	*****	*****	2.19	*****	1.29	*****	2.33 (0.43, 12.70)	0.329
SV	11,540	*****	*****	*****	*****	0.9	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	2,294	*****	*****	*****	*****	0	*****	-2.71	*****	-	-
SV	2,294	*****	*****	*****	*****	2.71	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	8,246	*****	*****	*****	*****	1.78	*****	0.61	*****	1.52 (0.25, 9.08)	0.648
SV	8,778	*****	*****	*****	*****	1.17	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	6,246	*****	*****	*****	*****	1.47	*****	0.82	*****	2.13 (0.19, 23.49)	0.537
SV	7,216	*****	*****	*****	*****	0.65	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	998	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	998	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	5,723	*****	*****	*****	*****	0.81	*****	-0.03	*****	0.95 (0.06, 15.11)	0.968
SV	5,562	*****	*****	*****	*****	0.84	*****				
Angioedema (-183, -1)											
Overall											
Site-Adjusted Analysis											
ARB-SV 14-day	33	*****	*****	*****	*****	390.63	*****	215.65	*****	1.96 (0.48, 8.02)	0.347
SV	60	*****	*****	*****	*****	174.98	*****				

Table 18. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	22	*****	*****	*****	*****	835.65	*****	557.1	*****	3.00 (0.31, 28.84)	0.341
SV	22	*****	*****	*****	*****	278.55	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	22	*****	*****	*****	*****	571.43	*****	302.61	*****	1.86 (0.31, 11.19)	0.498
SV	22	*****	*****	*****	*****	268.82	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	33	*****	*****	*****	*****	1,860.47	*****	1,440.30	*****	4.17 (0.74, 23.58)	0.107
SV	60	*****	*****	*****	*****	420.17	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	22	*****	*****	*****	*****	2,272.73	*****	1,515.15	*****	3.00 (0.31, 28.84)	0.341
SV	22	*****	*****	*****	*****	757.58	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	22	*****	*****	*****	*****	2,205.88	*****	1,631.17	*****	3.45 (0.36, 33.15)	0.284
SV	22	*****	*****	*****	*****	574.71	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	23	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	55	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	13	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	13	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	14	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	20	*****	*****	*****	*****	0	*****				

Table 18. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	14	*****	*****	*****	*****	0	*****	-320.51	*****	-	-
SV	42	*****	*****	*****	*****	320.51	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	-1041.67	*****	-	-
SV	13	*****	*****	*****	*****	1,041.67	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	12	*****	*****	*****	*****	0	*****	-153.85	*****	-	-
SV	35	*****	*****	*****	*****	153.85	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	21	*****	*****	*****	*****	0	*****				

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Table 18. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Prior Angioedema (-183, -1) and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	16	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				

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

[2]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 New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Race: Unknown											
Overall											
Site-Adjusted Analysis											
ARB-SV 14-day	5,599	*****	*****	*****	*****	1.71	*****	0.96	*****	2.37 (0.38, 14.70)	0.354
SV	7,272	*****	*****	*****	*****	0.75	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	4,778	*****	*****	*****	*****	2.43	*****	2.43	*****	-	-
SV	4,778	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	4,778	*****	*****	*****	*****	1.33	*****	0.77	*****	2.59 (0.23, 28.82)	0.439
SV	4,778	*****	*****	*****	*****	0.56	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	5,599	*****	*****	*****	*****	5.08	*****	5.08	*****	-	-
SV	7,272	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	4,778	*****	*****	*****	*****	3.08	*****	3.08	*****	-	-
SV	4,778	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	4,778	*****	*****	*****	*****	2.98	*****	2.98	*****	-	-
SV	4,778	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	3,983	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	6,558	*****	*****	*****	*****	0	*****				

Table 19. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	3,097	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	3,097	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	3,394	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	4,349	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	2,676	*****	*****	*****	*****	0	*****	-3.02	*****	-	-
SV	4,423	*****	*****	*****	*****	3.02	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	1,408	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	1,408	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	2,292	*****	*****	*****	*****	0	*****	-4.55	*****	-	-
SV	2,930	*****	*****	*****	*****	4.55	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	2,116	*****	*****	*****	*****	2.42	*****	0.88	*****	2.44 (0.15, 39.11)	0.527
SV	3,574	*****	*****	*****	*****	1.54	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	916	*****	*****	*****	*****	7.1	*****	7.1	*****	-	-
SV	916	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	1,814	*****	*****	*****	*****	2.8	*****	2.8	*****	-	-
SV	2,382	*****	*****	*****	*****	0	*****				

Table 19. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
181 - 270 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	1,359	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	2,036	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	364	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	364	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	1,179	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	1,384	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	933	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	1,291	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	152	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	152	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	803	172.13	78.29	0.21	0	0	*****	0	*****	-	-
SV	891	193.31	79.24	0.22	0	0	*****				
Race: American Indian											
Overall											
Site-Adjusted Analysis											
ARB-SV 14-day	81	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	145	*****	*****	*****	*****	0	*****				

Table 19. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	66	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	66	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	66	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	66	*****	*****	*****	*****	0	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	81	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	145	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	66	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	66	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	66	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	66	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	57	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	129	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	43	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	43	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	49	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	60	*****	*****	*****	*****	0	*****				

Table 19. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	33	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	87	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	16	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	16	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	26	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	36	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	29	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	66	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	13	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	13	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	24	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	29	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	16	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	33	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	12	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	13	*****	*****	*****	*****	0	*****				

Table 19. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
271 - 365 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	12	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	19	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Race: Asian											
Overall											
Site-Adjusted Analysis											
ARB-SV 14-day	847	*****	*****	*****	*****	3.86	*****	3.86	*****	-	-
SV	532	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	452	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	452	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	452	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	452	*****	*****	*****	*****	0	*****				

Table 19. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
0 - 30 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	847	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	532	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	452	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	452	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	452	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	452	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	587	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	490	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	295	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	295	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	318	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	418	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	393	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	334	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	146	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	146	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	219	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	293	*****	*****	*****	*****	0	*****				

Table 19. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
91 - 180 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	309	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	256	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	85	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	85	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	165	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	221	*****	*****	*****	*****	0	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	207	*****	*****	*****	*****	24.17	*****	24.17	*****	-	-
SV	138	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	33	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	33	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	116	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	116	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	134	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	88	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	14	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	14	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	70	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	74	*****	*****	*****	*****	0	*****				
Race: Black											

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Table 19. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Overall											
Site-Adjusted Analysis											
ARB-SV 14-day	4,731	*****	*****	*****	*****	5.14	*****	1.2	*****	1.30 (0.45, 3.71)	0.628
SV	5,990	*****	*****	*****	*****	3.94	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	4,182	*****	*****	*****	*****	8	*****	4.8	*****	2.50 (0.49, 12.89)	0.273
SV	4,182	*****	*****	*****	*****	3.2	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	4,182	*****	*****	*****	*****	5.06	*****	0.4	*****	1.11 (0.36, 3.43)	0.862
SV	4,182	*****	*****	*****	*****	4.65	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	4,731	*****	*****	*****	*****	8.81	*****	6.7	*****	4.07 (0.42, 39.15)	0.224
SV	5,990	*****	*****	*****	*****	2.11	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	4,182	*****	*****	*****	*****	10.26	*****	6.84	*****	3.00 (0.31, 28.84)	0.341
SV	4,182	*****	*****	*****	*****	3.42	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	4,182	*****	*****	*****	*****	9.96	*****	6.95	*****	3.19 (0.33, 30.63)	0.316
SV	4,182	*****	*****	*****	*****	3.01	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	3,528	*****	*****	*****	*****	4.32	*****	1.44	*****	1.59 (0.10, 25.44)	0.743
SV	5,447	*****	*****	*****	*****	2.88	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	2,863	*****	*****	*****	*****	6.55	*****	6.55	*****	-	-
SV	2,863	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	3,123	*****	*****	*****	*****	4.9	*****	0.83	*****	1.28 (0.08, 20.43)	0.862
SV	3,840	*****	*****	*****	*****	4.07	*****				

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Table 19. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	2,191	*****	*****	*****	*****	6.31	*****	1.96	*****	1.47 (0.09, 23.51)	0.785
SV	3,141	*****	*****	*****	*****	4.35	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	1,029	*****	*****	*****	*****	14.68	*****	14.68	*****	-	-
SV	1,029	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	1,925	*****	*****	*****	*****	7.2	*****	1.15	*****	1.21 (0.08, 19.39)	0.892
SV	2,243	*****	*****	*****	*****	6.05	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	1,653	*****	*****	*****	*****	0	*****	-5.26	*****	-	-
SV	2,381	*****	*****	*****	*****	5.26	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	613	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	613	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	1,447	*****	*****	*****	*****	0	*****	-3.54	*****	-	-
SV	1,727	*****	*****	*****	*****	3.54	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	939	*****	*****	*****	*****	5.19	*****	-4.59	*****	0.55 (0.05, 6.01)	0.621
SV	1,080	*****	*****	*****	*****	9.78	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	161	*****	*****	*****	*****	0	*****	-36.95	*****	-	-
SV	161	*****	*****	*****	*****	36.95	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	804	*****	*****	*****	*****	6.04	*****	-6.77	*****	0.50 (0.05, 5.50)	0.57
SV	824	*****	*****	*****	*****	12.82	*****				
271 - 365 Days											

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Table 19. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Site-Adjusted Analysis											
ARB-SV 14-day	658	*****	*****	*****	*****	7.1	*****	7.1	*****	-	-
SV	663	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	77	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	77	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	567	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	507	*****	*****	*****	*****	0	*****				

Table 19. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Race: Pacific Islander											
Overall											
Site-Adjusted Analysis											
ARB-SV 14-day	45	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	46	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	29	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	29	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	29	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	29	*****	*****	*****	*****	0	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	45	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	46	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	29	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	29	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	29	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	29	*****	*****	*****	*****	0	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	37	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	43	*****	*****	*****	*****	0	*****				

Table 19. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	24	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	24	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	25	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	28	*****	*****	*****	*****	0	*****				
61 - 90 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	23	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	27	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	14	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	17	*****	*****	*****	*****	0	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	13	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	25	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	16	*****	*****	*****	*****	0	*****				

Table 19. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
181 - 270 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	14	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	11	*****	*****	*****	*****	0	*****				
271 - 365 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	*****	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	*****	*****	*****	*****	*****	0	*****				
Race: White											
Overall											
Site-Adjusted Analysis											
ARB-SV 14-day	23,785	*****	*****	*****	*****	3.3	*****	2.21	*****	3.14 (1.59, 6.19)	<0.001
SV	30,376	*****	*****	*****	*****	1.09	*****				

Table 19. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	22,086	*****	*****	*****	*****	4.62	*****	3.16	*****	3.17 (1.26, 7.93)	0.014
SV	22,086	*****	*****	*****	*****	1.46	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	22,086	*****	*****	*****	*****	3.54	*****	2.58	*****	3.75 (1.70, 8.25)	0.001
SV	22,086	*****	*****	*****	*****	0.97	*****				
0 - 30 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	23,785	*****	*****	*****	*****	4.59	*****	3.35	*****	3.70 (0.98, 13.96)	0.053
SV	30,376	*****	*****	*****	*****	1.24	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	22,086	*****	*****	*****	*****	5.09	*****	3.82	*****	4.00 (0.85, 18.84)	0.08
SV	22,086	*****	*****	*****	*****	1.27	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	22,086	*****	*****	*****	*****	4.94	*****	3.8	*****	4.34 (0.92, 20.43)	0.064
SV	22,086	*****	*****	*****	*****	1.14	*****				
31 - 60 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	18,488	*****	*****	*****	*****	4.75	*****	3.15	*****	2.98 (0.75, 11.93)	0.122
SV	27,717	*****	*****	*****	*****	1.6	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	15,838	*****	*****	*****	*****	5.43	*****	4.34	*****	5.00 (0.58, 42.80)	0.142
SV	15,838	*****	*****	*****	*****	1.09	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	17,208	*****	*****	*****	*****	5.1	*****	4.37	*****	7.05 (0.85, 58.55)	0.071
SV	20,332	*****	*****	*****	*****	0.72	*****				

Table 19. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
61 - 90 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	12,635	*****	*****	*****	*****	4.27	*****	2.83	*****	2.99 (0.55, 16.35)	0.206
SV	18,438	*****	*****	*****	*****	1.44	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	7,333	*****	*****	*****	*****	5.97	*****	5.97	*****	-	-
SV	7,333	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	11,797	*****	*****	*****	*****	4.57	*****	3.61	*****	4.75 (0.53, 42.46)	0.164
SV	13,673	*****	*****	*****	*****	0.96	*****				
91 - 180 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	10,156	*****	*****	*****	*****	3.08	*****	1.96	*****	2.70 (0.67, 10.79)	0.16
SV	15,150	*****	*****	*****	*****	1.12	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	4,880	*****	*****	*****	*****	4.34	*****	1.45	*****	1.50 (0.25, 8.98)	0.657
SV	4,880	*****	*****	*****	*****	2.9	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	9,486	*****	*****	*****	*****	3.31	*****	1.82	*****	2.22 (0.55, 8.88)	0.26
SV	11,393	*****	*****	*****	*****	1.49	*****				
181 - 270 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	6,454	*****	*****	*****	*****	1.52	*****	1.52	*****	-	-
SV	8,260	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	1,738	*****	*****	*****	*****	0	*****	0	*****	-	-
SV	1,738	*****	*****	*****	*****	0	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	6,006	*****	*****	*****	*****	1.63	*****	1.63	*****	-	-
SV	6,300	*****	*****	*****	*****	0	*****				

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Table 19. Effect Estimates for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Risk Window

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)[1]	Wald P-Value[1]
271 - 365 Days											
Site-Adjusted Analysis											
ARB-SV 14-day	4,514	*****	*****	*****	*****	1.02	*****	0.1	*****	1.11 (0.07, 17.75)	0.941
SV	5,163	*****	*****	*****	*****	0.92	*****				
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05[2]											
ARB-SV 14-day	781	*****	*****	*****	*****	0	*****	-7	*****	-	-
SV	781	*****	*****	*****	*****	7	*****				
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
ARB-SV 14-day	4,186	*****	*****	*****	*****	1.1	*****	-0.08	*****	0.94 (0.06, 15.00)	0.964
SV	3,984	*****	*****	*****	*****	1.18	*****				

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

[2]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.

Figure 1a. Histogram of Propensity Score (PS) Distribution, Before Adjustment, Comparing New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020

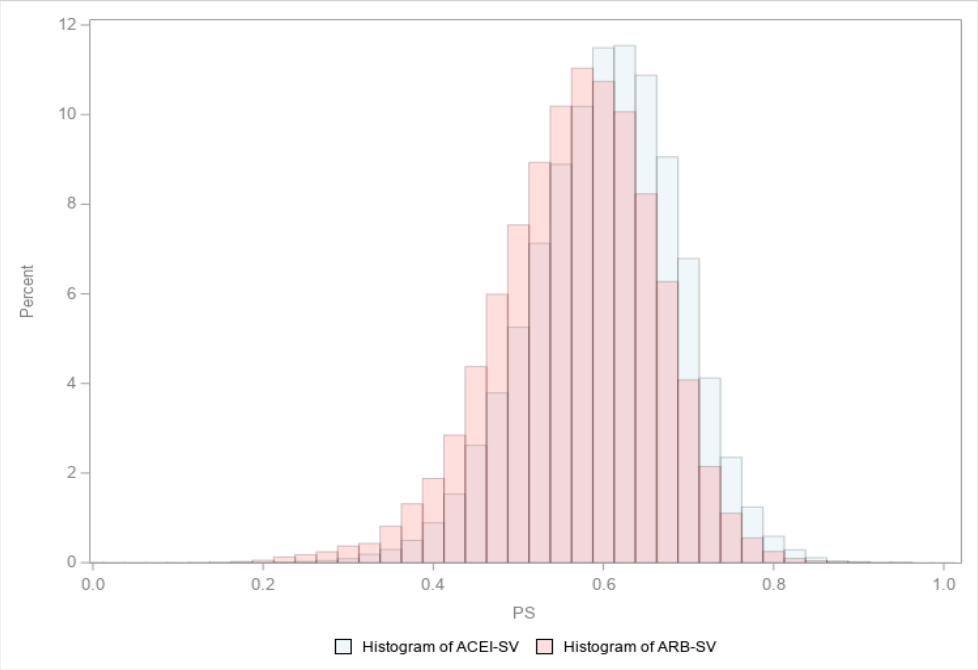


Figure 1b. Histogram of Propensity Score (PS) Fixed Ratio 1:1 Aggregated Adjusted Cohort, Matched Caliper = 0.05 Comparing New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020

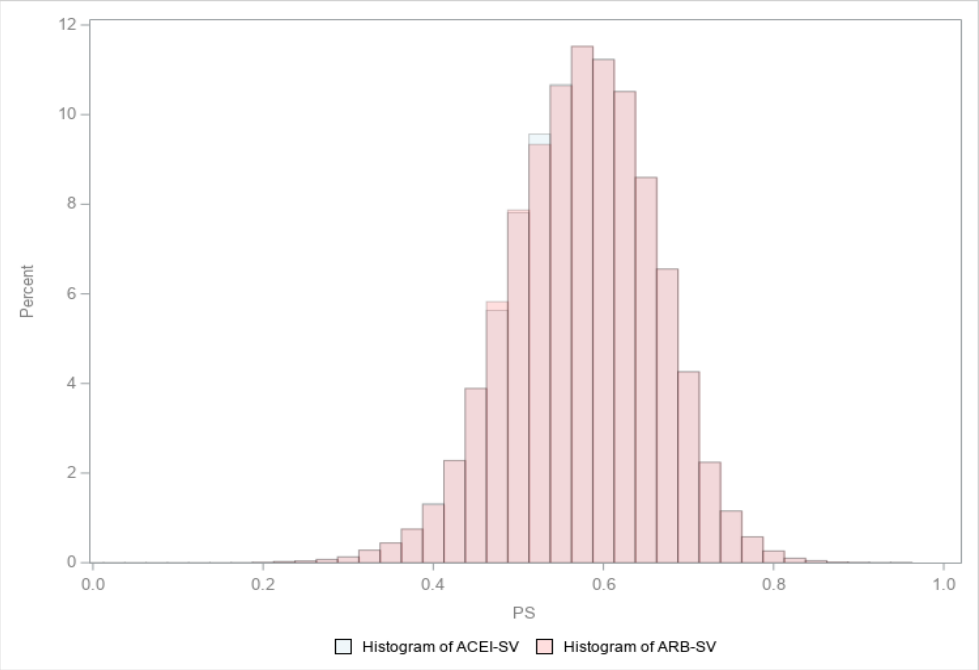


Figure 2a. Histogram of Propensity Score (PS) Distribution, Before Adjustment, Comparing New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020

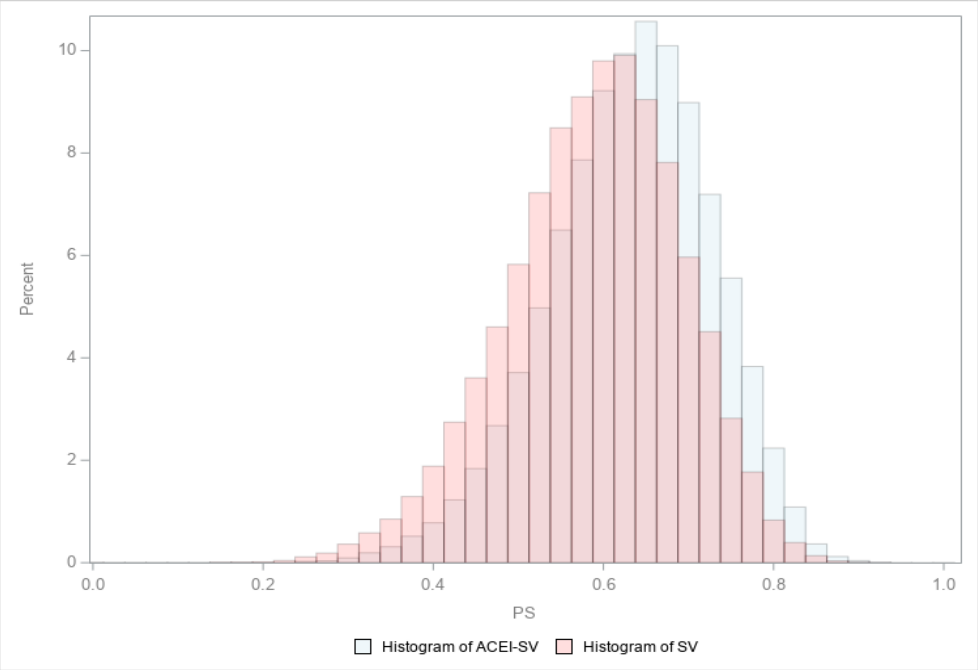


Figure 2b. Histogram of Propensity Score (PS) Fixed Ratio 1:1 Aggregated Adjusted Cohort, Matched Caliper = 0.05, Comparing New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020

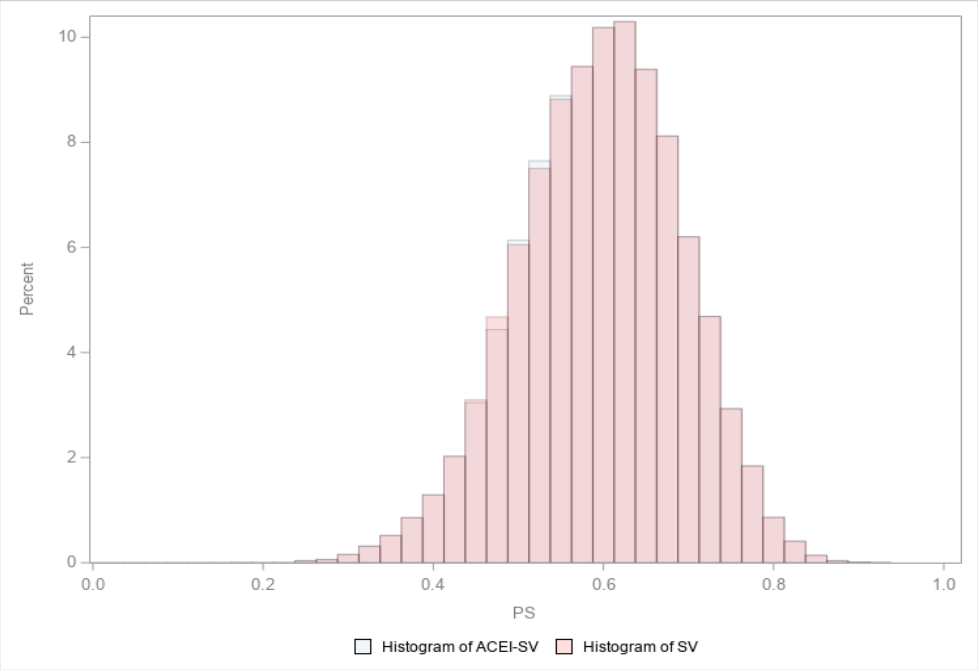


Figure 3a. Histogram of Propensity Score (PS) Distribution, Before Adjustment, Comparing for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020

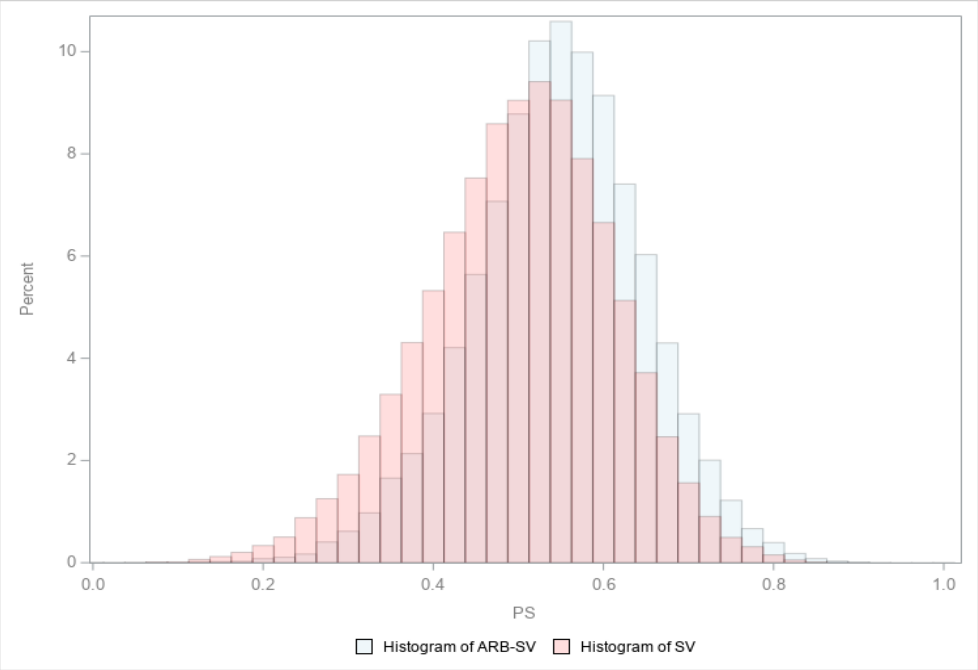


Figure 3b. Histogram for Propensity Score (PS) Fixed Ratio 1:1 Aggregated Adjusted Cohort, Matched Caliper = 0.05, Comparing for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020

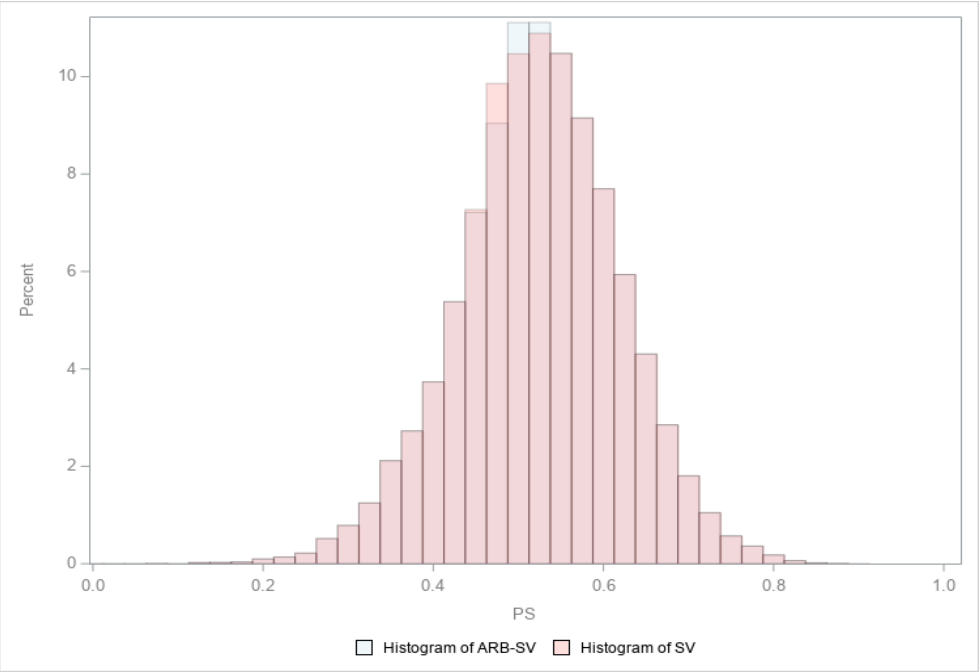


Figure 4a. Histogram of Propensity Score (PS) Distribution, Before Adjustment, Comparing New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020

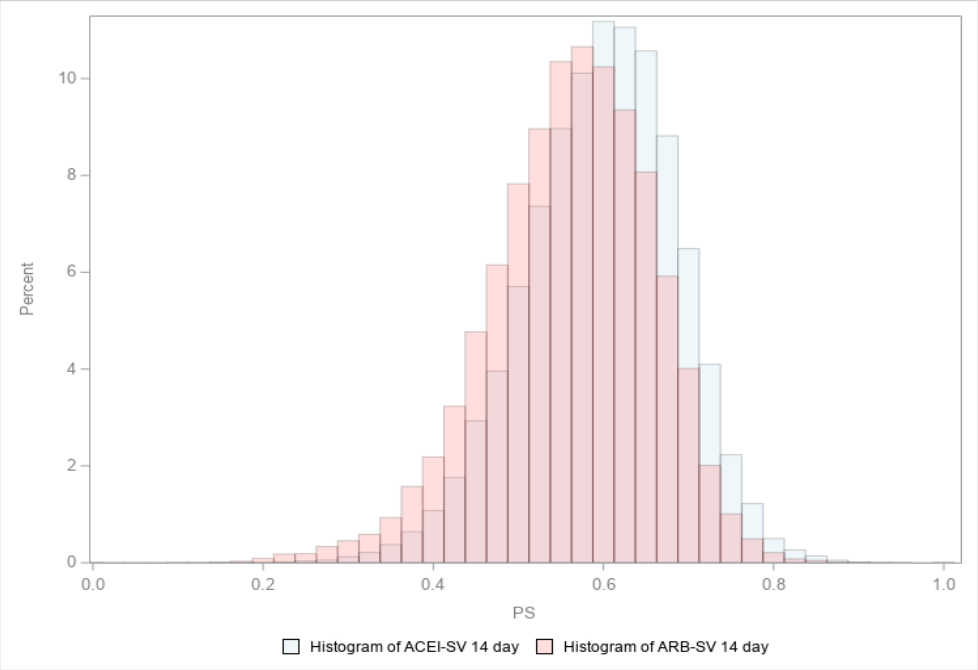


Figure 4b. Histogram for Propensity Score (PS) Fixed Ratio 1:1 Aggregated Adjusted Cohort, Matched Caliper = 0.05, Comparing New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020

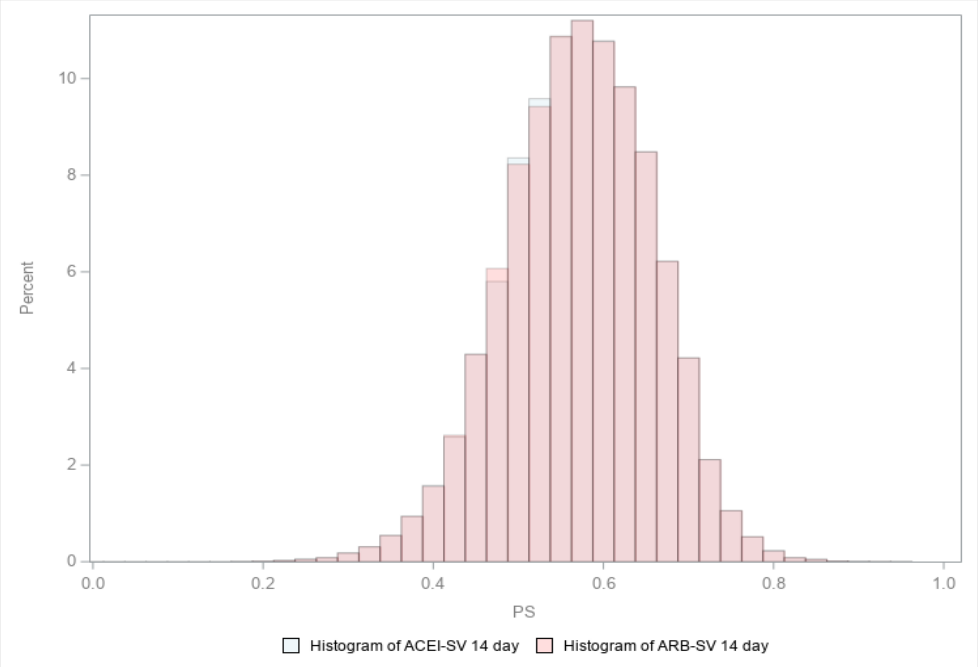


Figure 5a. Histogram of Propensity Score (PS) Distribution, Before Adjustment, Comparing New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020

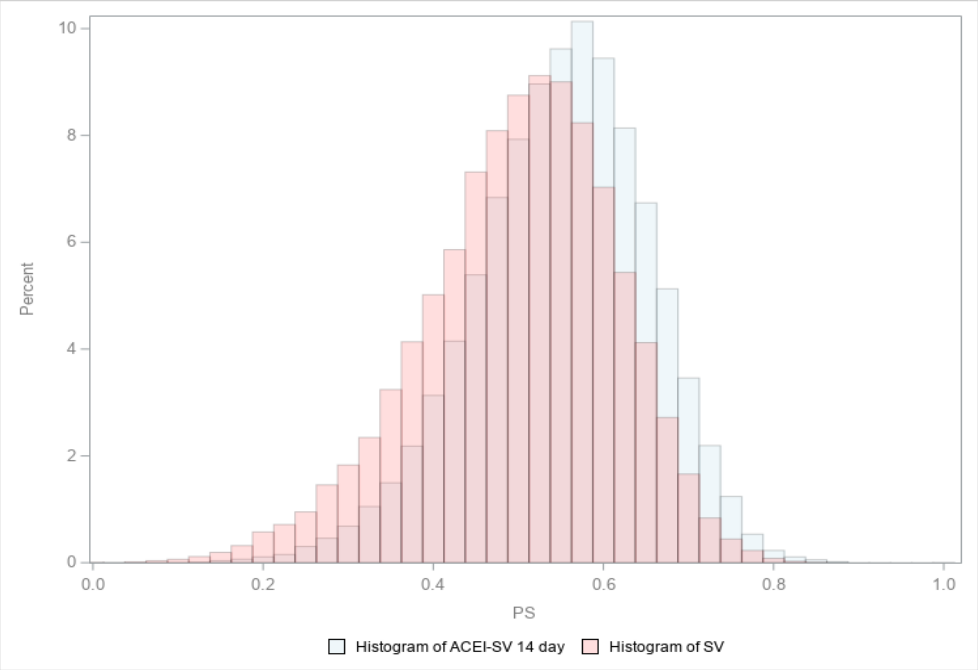


Figure 5b. Histogram for Propensity Score (PS) Fixed Ratio 1:1 Aggregated Adjusted Cohort, Matched Caliper = 0.05, Comparing New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020

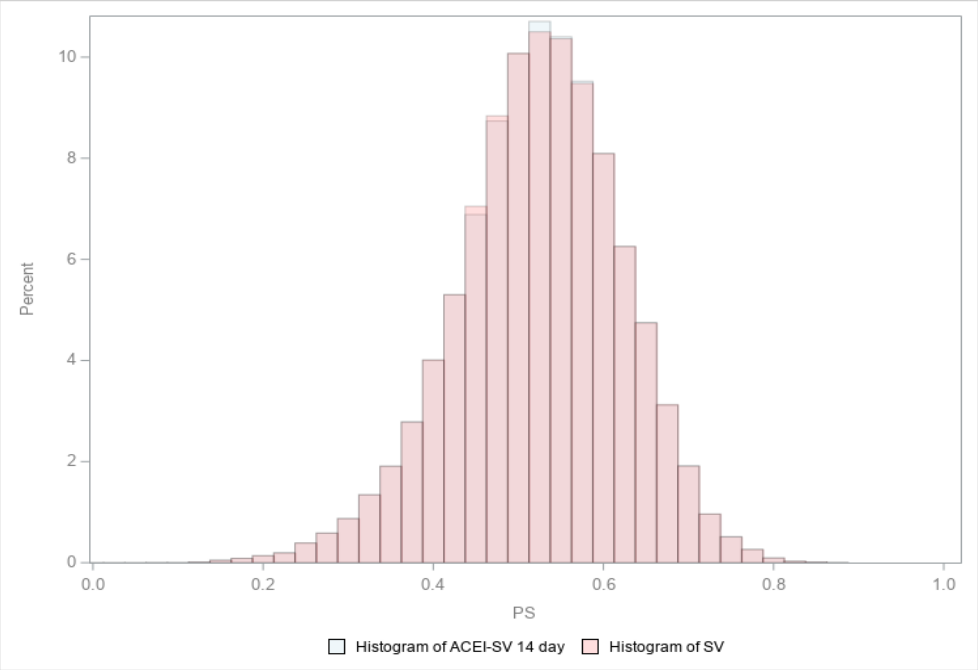


Figure 6a. Histogram of Propensity Score (PS) Distribution, Before Adjustment Comparing for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020

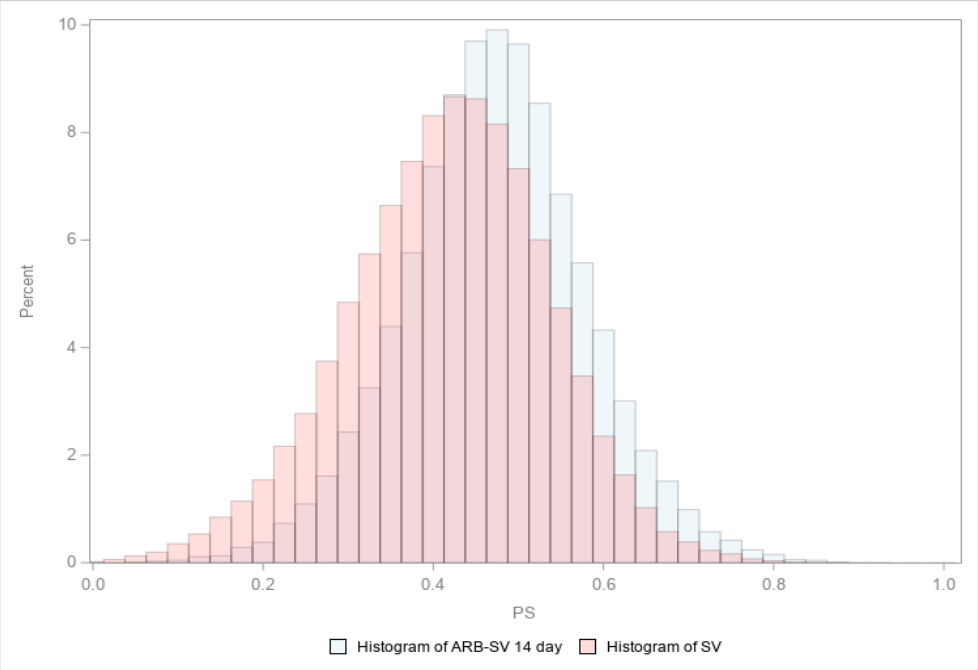


Figure 6b. Histogram of Propensity Score (PS) Fixed Ratio 1:1 Aggregated Adjusted Cohort, Matched Caliper = 0.05, Comparing for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020

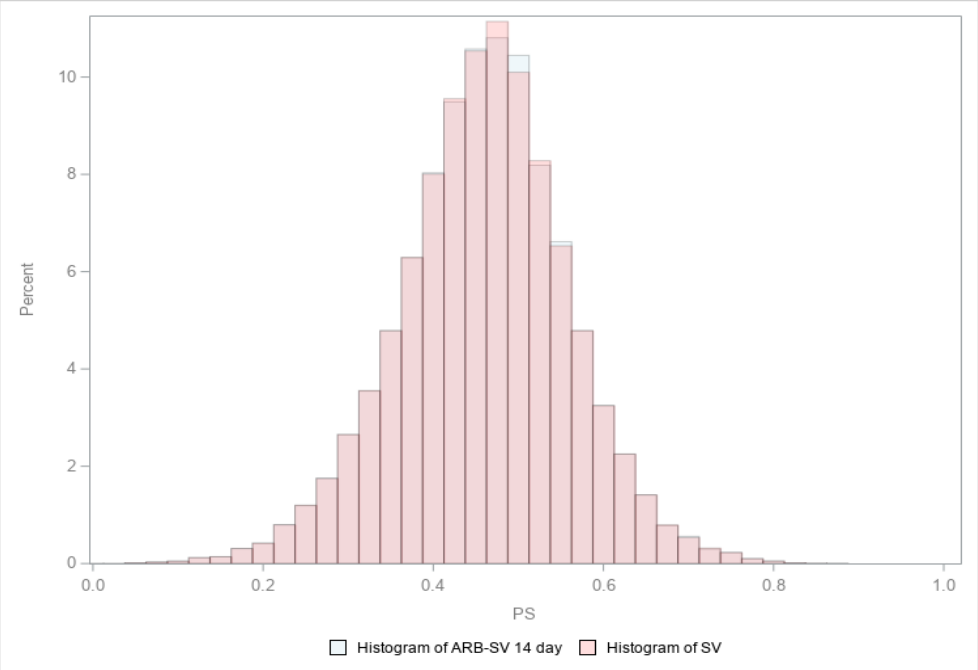


Figure 7a. Kaplan Meier Survival Curves for Risk of Angioedema Comparing New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, Unconditional Propensity Score Matched Cohort in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020, Overall

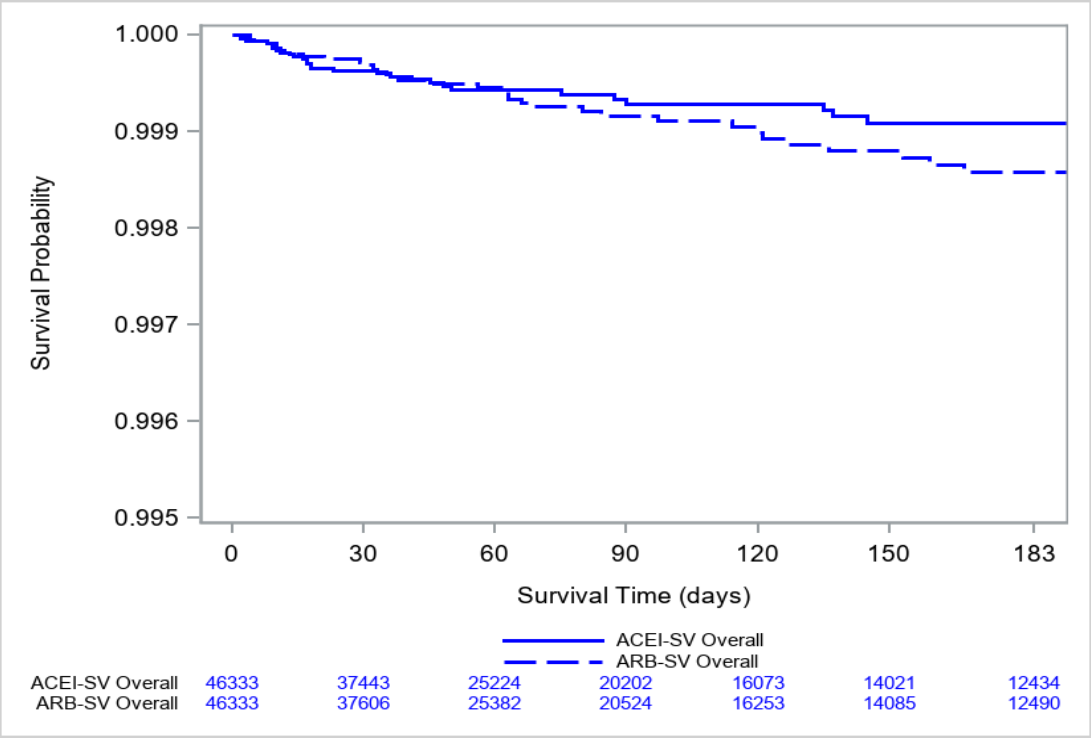


Figure 7b. Kaplan Meier Survival Curves for Risk of Angioedema Comparing New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, Unconditional Propensity Score Matched Cohort, No Prior Angioedema (-183, -1) in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020

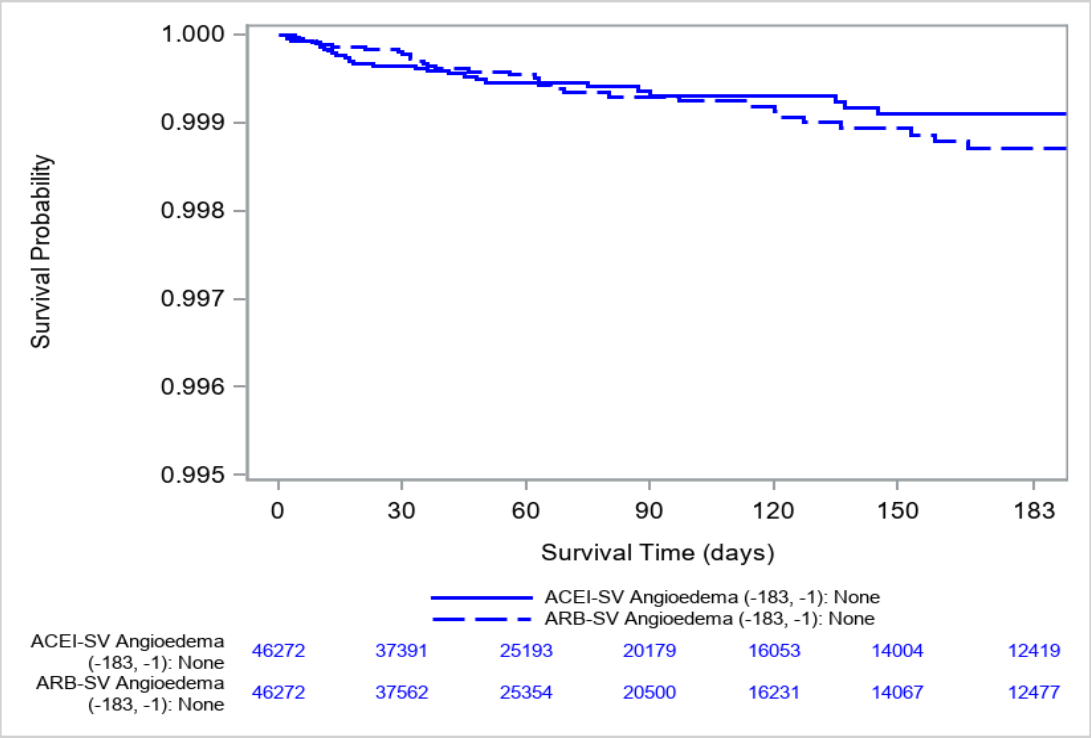


Figure 8a. Kaplan Meier Survival Curves for Risk of Angioedema Comparing New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, Unconditional Propensity Score Matched Cohort in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020, Overall

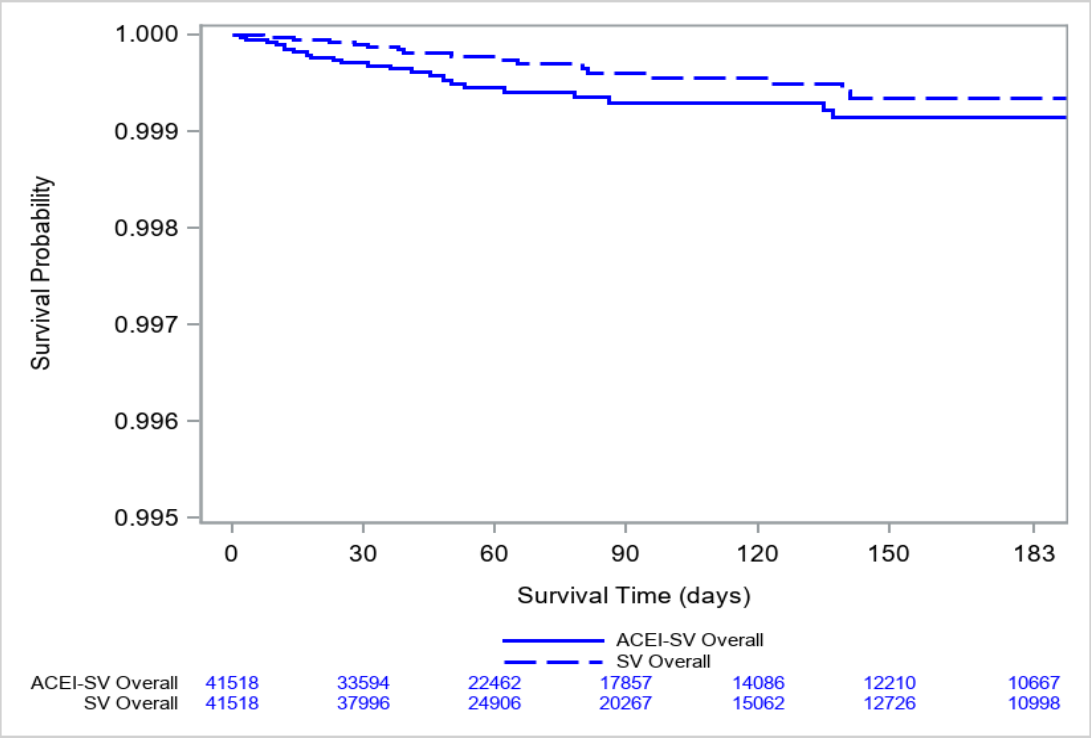


Figure 8b. Kaplan Meier Survival Curves for Risk of Angioedema Comparing New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 183 Days Prior, and New Initiators of SV, Unconditional Propensity Score Matched Cohort, No Prior Angioedema (-183, -1) in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020

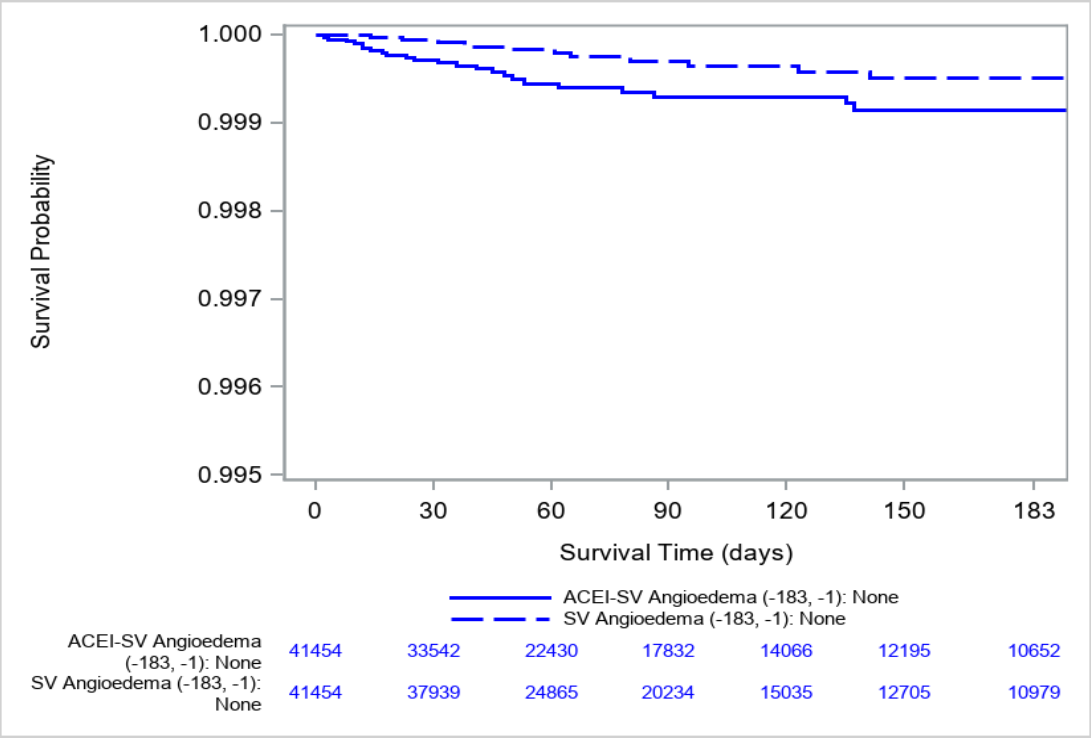


Figure 9a. Kaplan Meier Survival Curves for Risk of Angioedema Comparing for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, Unconditional Propensity Score Matched Cohort in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020, Overall

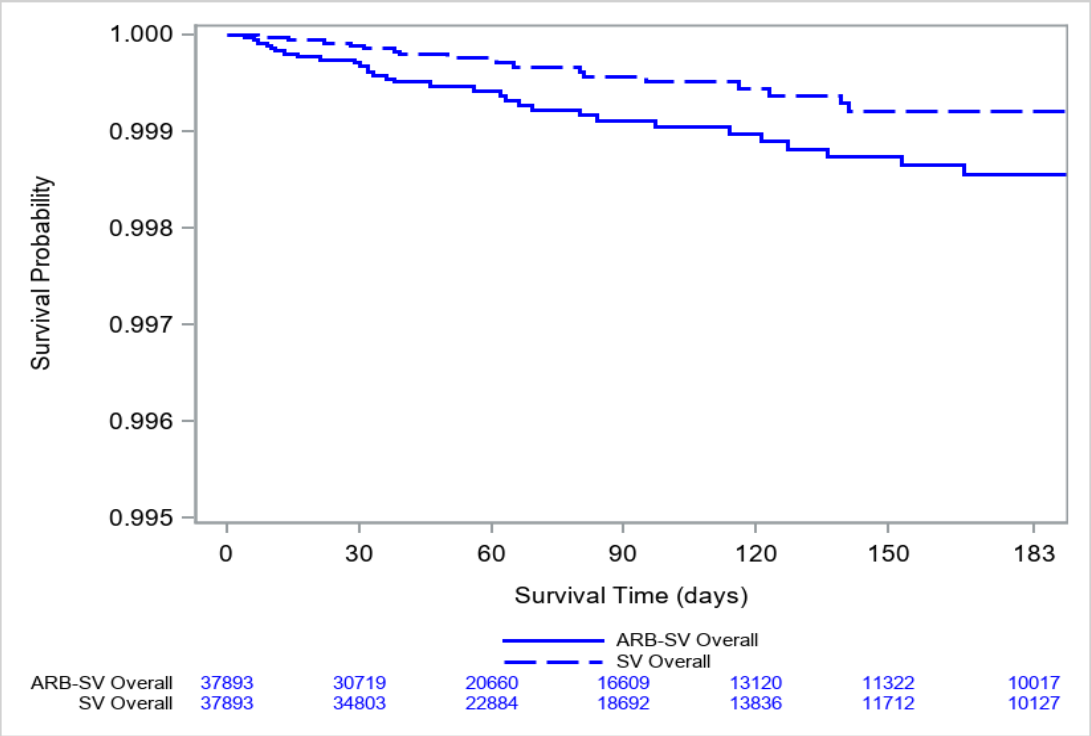


Figure 9b. Kaplan Meier Survival Curves for Risk of Angioedema Comparing for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 183 Days Prior, and New Initiators of SV, No Prior Angioedema (-183, -1) in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020

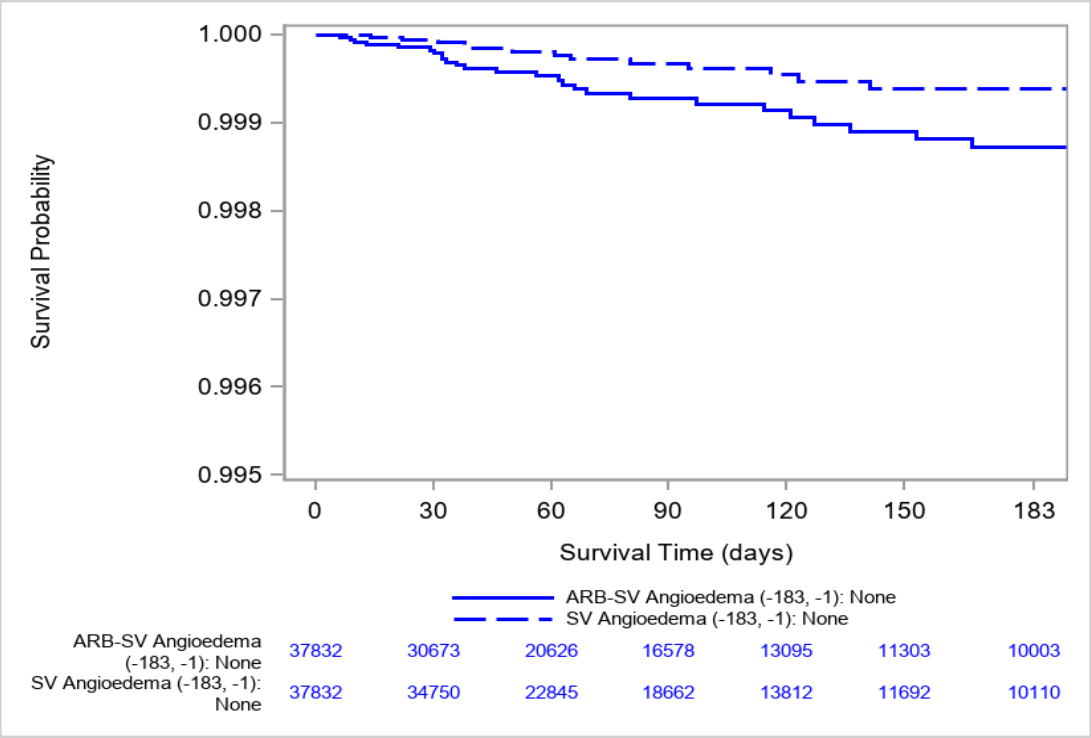


Figure 10a. Kaplan Meier Survival Curves for Risk of Angioedema Comparing New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, Unconditional Propensity Score Matched Cohort in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020, Overall

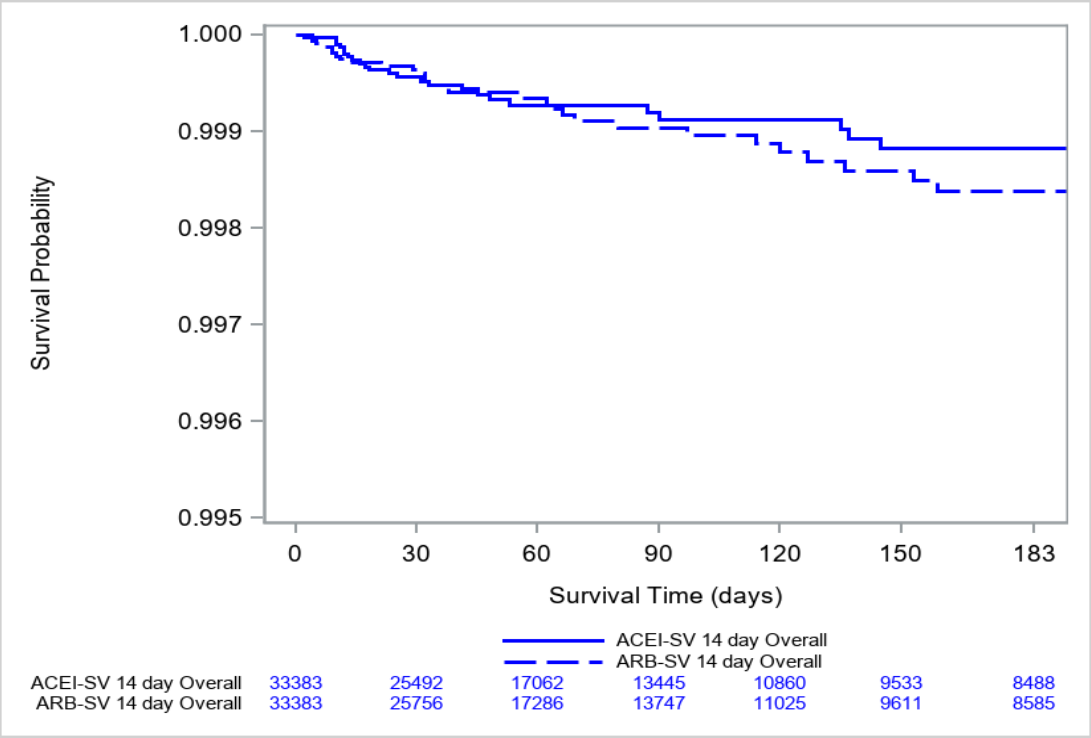


Figure 10b. Kaplan Meier Survival Curves for Risk of Angioedema Comparing New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, Unconditional Propensity Score Matched Cohort, No Prior Angioedema (-183, -1) in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020

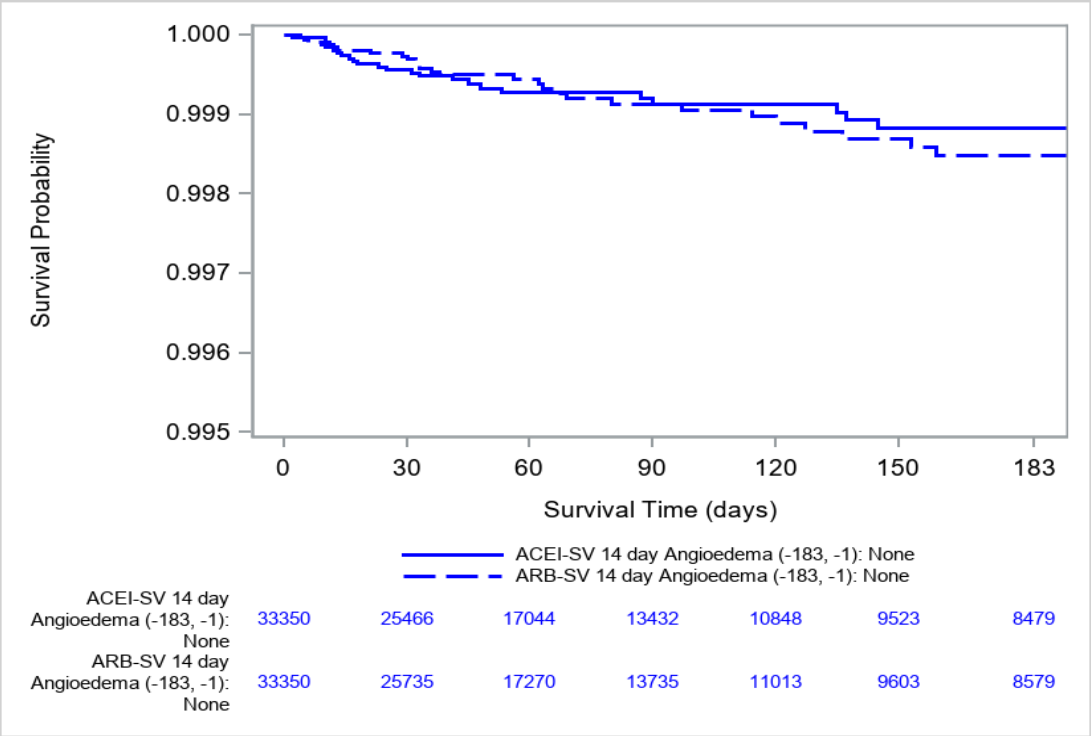


Figure 11a. Kaplan Meier Survival Curves for Risk of Angioedema Comparing New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, Unconditional Propensity Score Matched Cohort in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020, Overall

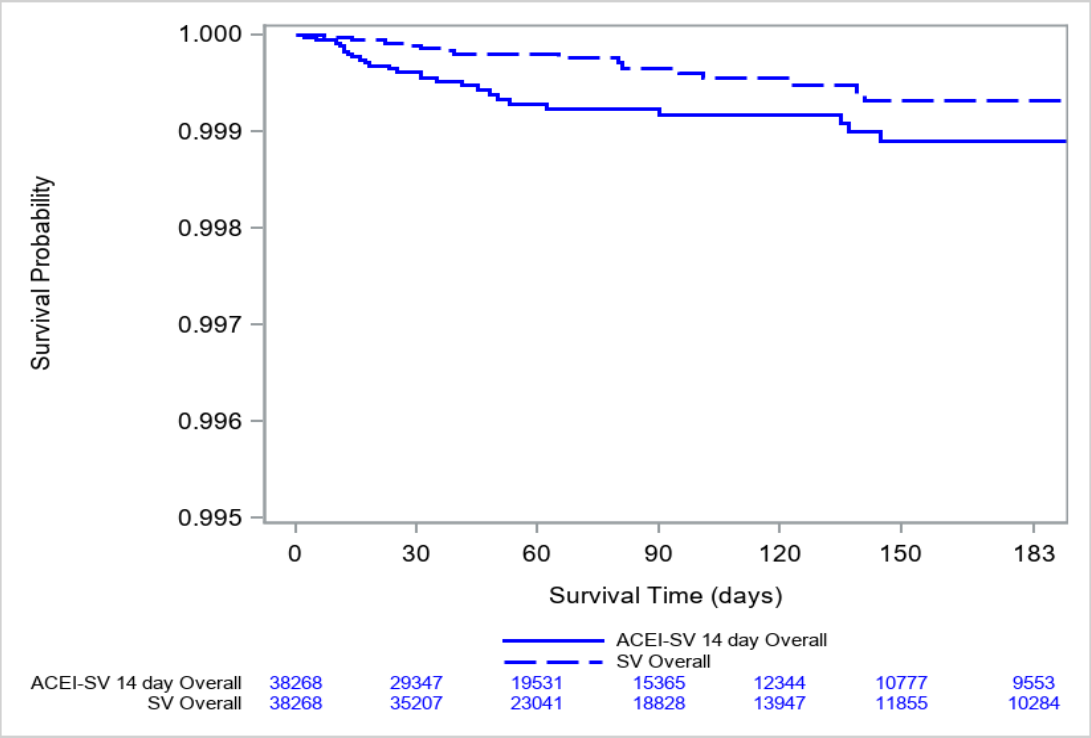


Figure 11b. Kaplan Meier Survival Curves for Risk of Angioedema Comparing New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin-Converting Enzyme Inhibitors (ACEI) in the 14 Days Prior, and New Initiators of SV, Unconditional Propensity Score Matched Cohort, No Prior Angioedema (-183, -1) in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020

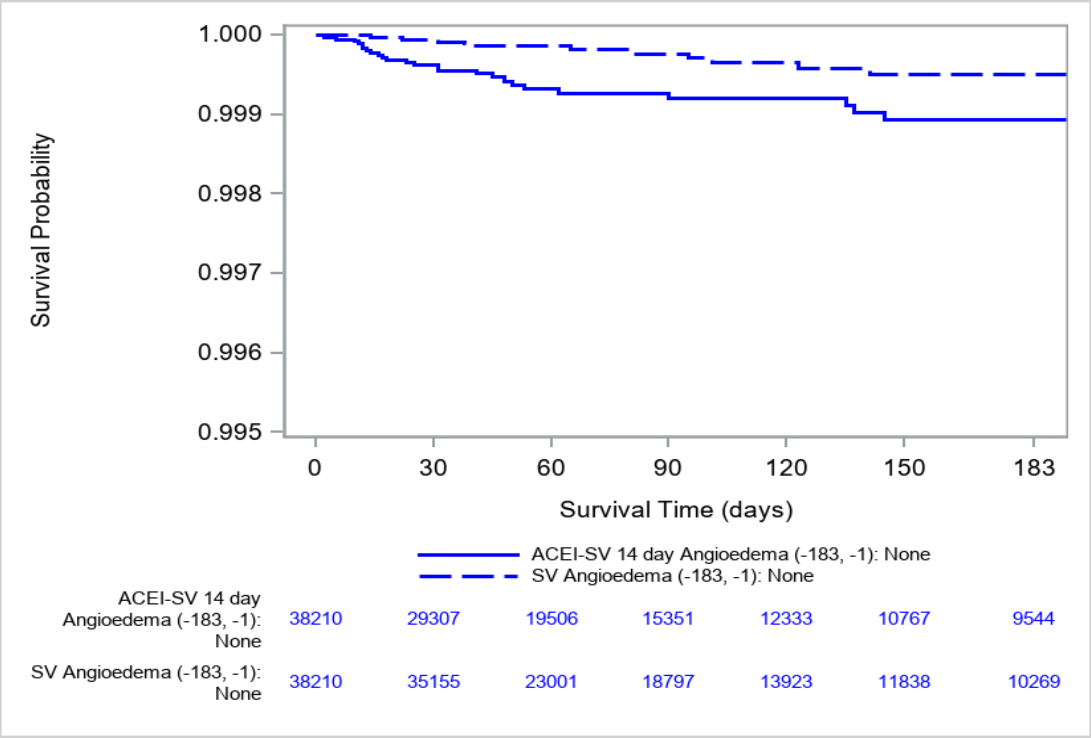


Figure 12a. Kaplan Meier Survival Curves for Risk of Angioedema Comparing for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, Unconditional Propensity Score Matched Cohort in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020, Overall

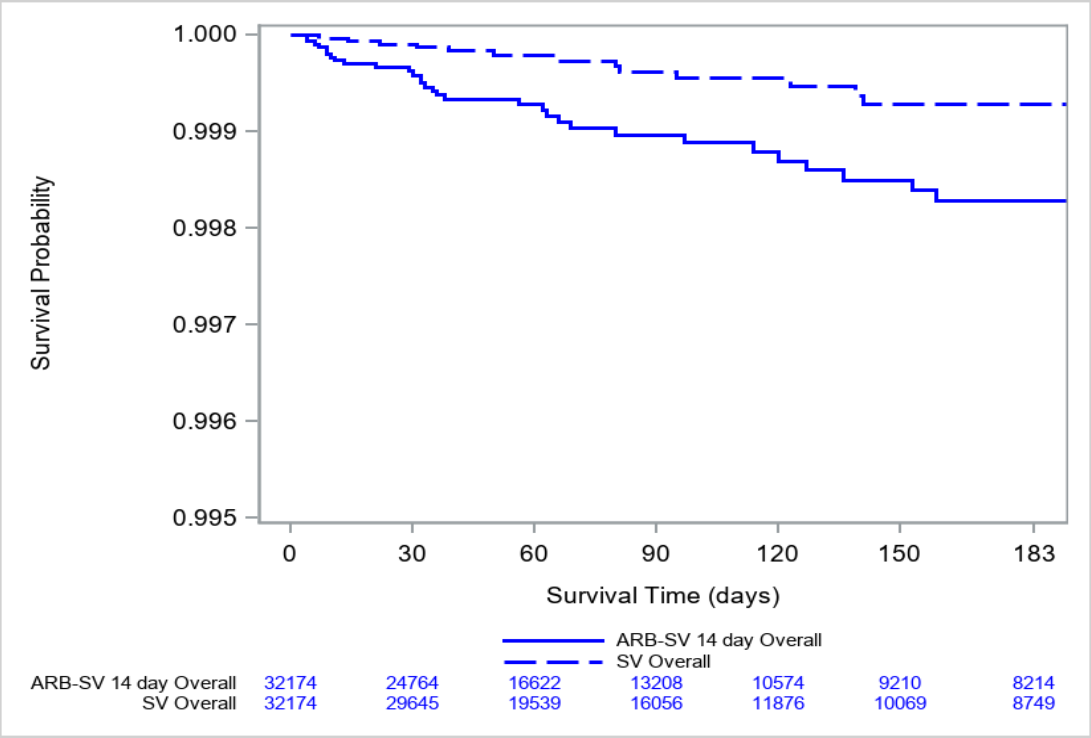
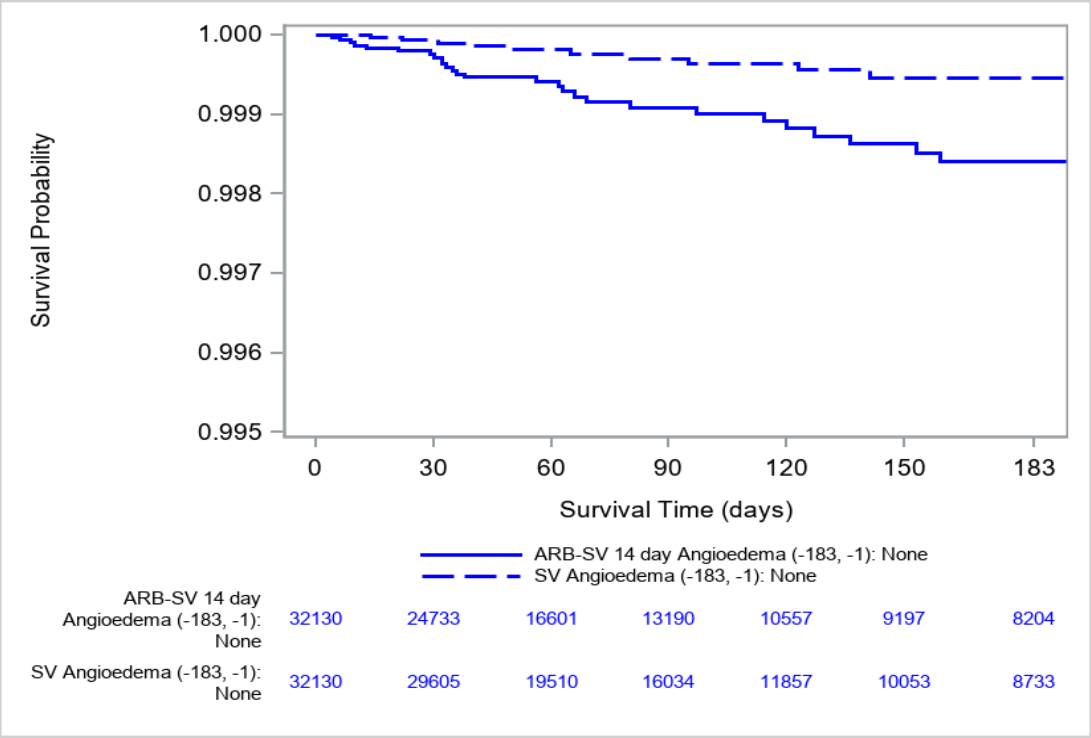


Figure 12b. Kaplan Meier Survival Curves for Risk of Angioedema Comparing for New Initiators of Sacubitril/Valsartan (SV) with Use of Angiotensin II Receptor Blockers (ARB) in the 14 Days Prior, and New Initiators of SV, No Prior Angioedema (-183, -1) in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020



Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (January 18, 2022)

DP ID	Start Date[1]	End Date[1]
DP01	1/1/2010	12/31/2019
DP02	1/1/2008	12/31/2019
DP03	1/1/2008	2/29/2020
DP04	1/1/2007	10/31/2019
DP05	1/1/2006	1/31/2020

[1]The start and end dates are based on available data at the time of cder_mpl2p_wp021_nsdp_v01 query execution

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

Generic Name	Brand Name
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) Codes Used to Define Outcomes in this Request

Code	Description	Code Category	Code Type
	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 Inclusion 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
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

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

Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
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
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

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
I50.31	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
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

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
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
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

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
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
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

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
T78.04XA	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
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

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
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
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	Diagnosis	ICD-10-CM
Z88.2	Allergy status to sulfonamides	Diagnosis	ICD-10-CM
Z88.3	Allergy status to other anti-infective agents	Diagnosis	ICD-10-CM
Z88.4	Allergy status to anesthetic agent	Diagnosis	ICD-10-CM
Z88.5	Allergy status to narcotic agent	Diagnosis	ICD-10-CM
Z88.6	Allergy status to analgesic agent	Diagnosis	ICD-10-CM
Z88.7	Allergy status to serum and vaccine	Diagnosis	ICD-10-CM
Z88.8	Allergy status to other drugs, medicaments and biological substances	Diagnosis	ICD-10-CM
Z88.9	Allergy status to unspecified drugs, medicaments and biological substances	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	Angioneurotic edema not elsewhere classified	Diagnosis	ICD-9-CM
T783XXA	Angioneurotic edema, initial encounter	Diagnosis	ICD-10-CM
T783XXD	Angioneurotic edema, subsequent encounter	Diagnosis	ICD-10-CM
T783XXS	Angioneurotic edema, sequela	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
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

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
250.7	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
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

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
E10.21	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
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

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
E10.3493	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
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
E10.36	Type 1 diabetes mellitus with diabetic cataract	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
E10.37X1	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
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

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
E11.3292	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
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

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
E11.3523	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
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

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
E11.59	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
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
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

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
E13.3319	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
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

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Code	Description	Code Category	Code Type
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
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

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Code	Description	Code Category	Code Type
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 (two or more), per 30 minutes	Procedure	HCPCS
G0245	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
G0246	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

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Code	Description	Code Category	Code Type
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
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

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Code	Description	Code Category	Code Type
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
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
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

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Code	Description	Code Category	Code Type
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
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

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Code	Description	Code Category	Code Type
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
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

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Code	Description	Code Category	Code Type
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
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
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)

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

Generic Name	Brand Name
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
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

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	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)
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

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

Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
dexchlorpheniramine maleate	Ryclora
dexchlorpheniramine maleate	dexchlorpheniramine maleate
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/chlorpheniramine maleate	Diabetic Tussin Night Time
dextromethorphan HBr/acetaminophen/diphenhydramine HCl	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
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
HBr/acetaminophen/doxylamine	

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

Generic Name	Brand Name
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
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

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	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
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

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	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
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

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

Generic Name	Brand Name
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
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

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	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
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

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 Fast-MaxDay-Nt(doxyl)
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
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

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

Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
guaifenesin/pseudoephedrine HCl	ExeFen-IR
guaifenesin/pseudoephedrine HCl	Maxifed
guaifenesin/pseudoephedrine HCl	Mucinex D
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
hydrocortisone/aloe vera	Cortisone with Aloe
hydrocortisone/aloe vera	Cortizone-10 with aloe
hydrocortisone/aloe vera	Hydrocortisone Plus
hydrocortisone/aloe vera	Hydroskin with Aloe

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

Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
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)
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

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

Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
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
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

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	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
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

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

Generic Name	Brand Name
prednisolone acetate	Flo-Pred
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
pseudoephedrine HCl/codeine phosphate/guaifenesin	Coditussin DAC
pseudoephedrine HCl/codeine phosphate/guaifenesin	Guaifenesin DAC
pseudoephedrine HCl/codeine phosphate/guaifenesin	Lortuss EX

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	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
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

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

Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
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)
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 (NSAID)	
CHLORPHENIRAMINE MALEATE/PHENYLEPHRINE HCL/IBUPROFEN	Advil Allergy-Congestion Rlf
CHLORPHENIRAMINE MALEATE/PSEUDOEPHEDRINE HCL/IBUPROFEN	Advil Allergy Sinus

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

Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
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
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)	

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

Generic Name	Brand Name
amiloride HCl	amiloride
amiloride HCl/hydrochlorothiazide	amiloride-hydrochlorothiazide
bumetanide	bumetanide
chlorothiazide	Diuril
chlorothiazide	chlorothiazide
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 v11.2.3 with additional programming to assess the risk for angioedema associated with various sacubitril/valsartan (SV) new user subgroups among heart failure patients in the Sentinel Distributed Database (SDD).

Query Period: 7/7/2015 - DP-specific data completeness end date at time of execution of cder_mpl2r_wp016 and cder_mpl2p_wp021
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, KM curves (zoomed in, at-risk table shown)
Data Partners: AEOS, CMS, HCOS, HUOS, OPOS
Freeze Data: On
Additional Programming Needed: Local reporting for KM curves by subgroup and stratified analyses by user-specified risk window

	Comparison 1		**Comparison 2**		**Comparison 3**	
	ACEI-SV	**ARB-SV**	**ACEI-SV**	**SV**	**ARB-SV**	**SV**
Drug/Exposure						
Request Package Group	SV_ARB	SV_ACEI	SV_ARB	SV_ACEI_ARB	SV_ACEI	SV_ACEI_ARB
Exposure/Comparator	SV	SV	SV	SV	SV	SV
Incident with Respect to:	**SV, ARB**	**SV, ACEI**	**SV, ARB**	**SV, ACEI, ARB**	**SV, ACEI**	**SV, ACEI, ARB**
Incidence Assessment	Dispensing date or days supply		Dispensing date or days supply		Dispensing date or days supply	
Washout (days)	183		183		183	
Cohort Definition	First valid incident exposure episode		First valid incident exposure episode		First valid incident exposure episode	
Stockpiling overlapping claims	Default		Default		Default	
Episode Gap (days)	14		14		14	
Episode Extension Period (days)	14		14		14	
Maximum Episode Duration (days)	365		365		365	
Censor Criteria	ACEI, ARB, end of treatment, outcome occurrence, disenrollment, recorded death, data end date		ACEI, ARB, end of treatment, outcome occurrence, disenrollment, recorded death, data end date		ACEI, ARB, end of treatment, outcome occurrence, disenrollment, recorded death, data end date	

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Appendix H: Specifications Defining Parameters for this Request

	Comparison 1		Comparison 2		Comparison 3	
	ACEI-SV	**ARB-SV**	**ACEI-SV**	**SV**	**ARB-SV**	**SV**
Inclusion/Exclusion*						
Pre-Existing Condition	Heart failure		Heart failure		Heart failure	
Include/Exclude	Include		Include		Include	
Lookback Period (days)	-183, 0		-183, 0		-183, 0	
Pre-Existing Condition	**ACEI**	**ARB**	**ACEI**	-----	**ARB**	-----
Include/Exclude	**Include**	**Include**	**Include**	-----	**Include**	-----
Care Setting/PDX	**Any**	**Any**	**Any**	-----	**Any**	-----
Lookback Period (days)	**-183, 0**	**-183, 0**	**-183, 0**	-----	**-183, 0**	-----
Inclusion Assessment	**Dispensing date or days supply**	**Dispensing date or days supply**	**Dispensing date or days supply**	-----	**Dispensing date or days supply**	-----
Pre-Existing Condition	ACEI, ARB		ACEI, ARB		ACEI, ARB	
Include/Exclude	Exclude		Exclude		Exclude	
Care Setting/PDX	Any		Any		Any	
Lookback Period (days)	0		0		0	
Inclusion Assessment	Dispensing date		Dispensing date		Dispensing date	
Event/Outcome						
Event/Outcome	Angioedema		Angioedema		Angioedema	
Care Setting/PDX	Inpatient, emergency department or outpatient		Inpatient, emergency department or outpatient		Inpatient, emergency department or outpatient	
Washout (days)	0		0		0	
Blackout Period (days)	0		0		0	
Propensity Score Matching						
Covariates	See Appendix I		See Appendix I		See Appendix I	
Matching Ratio	1:1		1:1		1:1	
Matching Caliper Settings	0.05		0.05		0.05	
Analysis Type	Conditional and unconditional		Conditional and unconditional		Conditional and unconditional	
Risk Window Analysis	0-30, 31-60, 61-90, 91-180, 181-270, 271-365		0-30, 31-60, 61-90, 91-180, 181-270, 271-365		0-30, 31-60, 61-90, 91-180, 181-270, 271-365	
Subgroup Analyses						
Stratifying variable	Angioedema		Angioedema		Angioedema	
Evaluation Window (days)	-183, -1		-183, -1		-183, -1	
Re-matching	Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort	
Priority output	Yes		Yes		Yes	
Risk Window Analysis (days)	0-30, 31-60, 61-90, 91-180, 181-270, 271-365		0-30, 31-60, 61-90, 91-180, 181-270, 271-365		0-30, 31-60, 61-90, 91-180, 181-270, 271-365	
Stratifying variable	Angioedema		Angioedema		Angioedema	
Evaluation Window (days)	Pre-index enrollment history, -1		Pre-index enrollment history, -1		Pre-index enrollment history, -1	

Appendix H: Specifications Defining Parameters for this Request

	Comparison 1		Comparison 2		Comparison 3	
	ACEI-SV	**ARB-SV**	**ACEI-SV**	**SV**	**ARB-SV**	**SV**
Re-matching	Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort	
Priority output	No		No		No	
Stratifying variable	Serious allergies		Serious allergies		Serious allergies	
Evaluation Window (days)	-183, -1		-183, -1		-183, -1	
Re-matching	Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort	
Priority output	No		No		No	
Stratifying variable	Age group		Age group		Age group	
Re-matching	Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort	
Priority output	No		No		No	
Stratifying variable	Sex		Sex		Sex	
Re-matching	Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort	
Priority output	No		No		No	
Stratifying variable	Race		Race		Race	
Re-matching	Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort	
Priority output	Yes		Yes		Yes	
Risk Window Analysis (days)	0-30, 31-60, 61-90, 91-180, 181-270, 271-365		0-30, 31-60, 61-90, 91-180, 181-270, 271-365		0-30, 31-60, 61-90, 91-180, 181-270, 271-365	

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 (NDC) are checked against First Data Bank's “National Drug Data File (NDDF®) Plus.”

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Appendix H: Specifications Defining Parameters for this Request

	Comparison 4		Comparison 5		Comparison 6	
	ACEI-SV	**ARB-SV**	**ACEI-SV**	**SV**	**ARB-SV**	**SV**
Drug/Exposure						
Request Package Group	SV_ARB_14	SV_ACEI_14	SV_ARB_14	SV_ACEI_ARB	SV_ACEI_14	SV_ACEI_ARB
Exposure/Comparator	SV	SV	SV	SV	SV	SV
Incident with Respect to:	**SV, ARB**	**SV, ACEI**	**SV, ARB**	**SV, ACEI, ARB**	**SV, ACEI**	**SV, ACEI, ARB**
Incidence Assessment	Dispensing date or days supply		Dispensing date or days supply		Dispensing date or days supply	
Washout (days)	183		183		183	
Cohort Definition	First valid incident exposure episode		First valid incident exposure episode		First valid incident exposure episode	
Stockpiling overlapping claims	Default		Default		Default	
Episode Gap (days)	14		14		14	
Episode Extension Period (days)	14		14		14	
Maximum Episode Duration (days)	365		365		365	
Censor Criteria	ACEI, ARB, end of treatment, outcome occurrence, disenrollment, recorded death, data end date		ACEI, ARB, end of treatment, outcome occurrence, disenrollment, recorded death, data end date		ACEI, ARB, end of treatment, outcome occurrence, disenrollment, recorded death, data end date	
Inclusion/Exclusion*						
Pre-Existing Condition	Heart failure		Heart failure		Heart failure	
Include/Exclude	Include		Include		Include	
Lookback Period (days)	-183, 0		-183, 0		-183, 0	
Pre-Existing Condition	**ACEI**	**ARB**	**ACEI**	-----	**ARB**	-----
Include/Exclude	**Include**	**Include**	**Include**	-----	**Include**	-----
Care Setting/PDX	**Any**	**Any**	**Any**	-----	**Any**	-----
Lookback Period (days)	**-14, 0**	**-14, 0**	**-14, 0**	-----	**-14, 0**	-----
Inclusion Assessment	**Dispensing date or days supply**	**Dispensing date or days supply**	**Dispensing date or days supply**	-----	**Dispensing date or days supply**	-----
Pre-Existing Condition	ACEI, ARB		ACEI, ARB		ACEI, ARB	
Include/Exclude	Exclude		Exclude		Exclude	
Care Setting/PDX	Any		Any		Any	
Lookback Period (days)	0		0		0	
Inclusion Assessment	Dispensing date		Dispensing date		Dispensing date	
Event/Outcome						
Event/Outcome	Angioedema		Angioedema		Angioedema	

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Appendix H: Specifications Defining Parameters for this Request

	Comparison 4		Comparison 5		Comparison 6	
	ACEI-SV	ARB-SV	ACEI-SV	SV	ARB-SV	SV
Care Setting/PDX	Inpatient, emergency department or outpatient		Inpatient, emergency department or outpatient		Inpatient, emergency department or outpatient	
Washout (days)	0		0		0	
Blackout Period (days)	0		0		0	
Propensity Score Matching						
Covariates	See Appendix I		See Appendix I		See Appendix I	
Matching Ratio	1:1		1:1		1:1	
Matching Caliper Settings	0.05		0.05		0.05	
Analysis Type	Conditional and unconditional		Conditional and unconditional		Conditional and unconditional	
Risk Window Analysis	0-30, 31-60, 61-90, 91-180, 181-270, 271-365		0-30, 31-60, 61-90, 91-180, 181-270, 271-365		0-30, 31-60, 61-90, 91-180, 181-270, 271-365	
Subgroup Analyses						
Stratifying variable	Angioedema		Angioedema		Angioedema	
Evaluation Window (days)	-183, -1		-183, -1		-183, -1	
Re-matching	Re-matching should be done with the pre-		Re-matching should be done with the pre-		Re-matching should be done with the pre-	
Priority output	Yes		Yes		Yes	
Risk Window Analysis (days)	0-30, 31-60, 61-90, 91-180, 181-270, 271-365		0-30, 31-60, 61-90, 91-180, 181-270, 271-365		0-30, 31-60, 61-90, 91-180, 181-270, 271-365	
Stratifying variable	Angioedema		Angioedema		Angioedema	
Evaluation Window (days)	Pre-index enrollment history, -1		Pre-index enrollment history, -1		Pre-index enrollment history, -1	
Re-matching	Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort	
Priority output	No		No		No	
Stratifying variable	Serious allergies		Serious allergies		Serious allergies	
Evaluation Window (days)	-183, -1		-183, -1		-183, -1	
Re-matching	Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort	
Priority output	No		No		No	
Stratifying variable	Age group		Age group		Age group	
Re-matching	Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort	
Priority output	No		No		No	

Appendix H: Specifications Defining Parameters for this Request

	Comparison 4		Comparison 5		Comparison 6	
	ACEI-SV	ARB-SV	ACEI-SV	SV	ARB-SV	SV
Stratifying variable	Sex		Sex		Sex	
Re-matching	Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort	
Priority output	No		No		No	
Stratifying variable	Race		Race		Race	
Re-matching	Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort		Re-matching should be done with the pre-matched cohort	
Priority output	Yes		Yes		Yes	
Risk Window Analysis (days)	0-30, 31-60, 61-90, 91-180, 181-270, 271-365		0-30, 31-60, 61-90, 91-180, 181-270, 271-365		0-30, 31-60, 61-90, 91-180, 181-270, 271-365	

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 (NDC) are checked against First Data Bank's “National Drug Data File (NDDF®) Plus.”

Appendix I: Specifications Defining Baseline Characterstics and Propensity Score Analysis Covariates Evaluated in this Request

Baseline Covariate Groups Evaluated in this Request	KEY: Highlighted = Characteristic not included in Propensity-Score Model
Covariate	**Covariate Evaluation Window**
Age (continuous)	Index date
Age-group	
18-44	Index date
45-54	Index date
55-64	Index date
65+	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
Hispanic Ethnicity	Index date
Year	
2015	Index date
2016	Index date
2017	Index date
2018	Index date
2019	Index date
2020	Index date
Combined comorbidity score	-183 to 0
Angioedema	-183 to -1
Angioedema	Ever to -1
Ambulatory allergies (AV/OA) or allergy treatment	-183 to -1
Serious allergies (ED/IP)	-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
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
Number of institutional stay visits	-183 to 0
Number of ambulatory visits	-183 to 0
Number of other ambulatory visits	-183 to 0
Drug utilization	
Mean number of filled prescriptions	-183 to 0
Mean number of generics	-183 to 0
Mean number of unique drug classes	-183 to 0