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Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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#### Overview for Request cder\_mpl2r\_wp016

Request ID: cder\_mpl2r\_wp016

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

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

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

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

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

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

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

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

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

cder\_mpl2r\_wp016 Page 1 of 247



#### Overview for Request cder\_mpl2r\_wp016

Propensity Score Estimation: For each comparison, we fit a logistic regression model to estimate the propensity score (PS) based on potential confounders outlined in Appendix J. The matching ratio for the PS was 1:1 and the matching caliper was 0.05. Patients in the exposed and comparator cohorts were nearest neighbor matched without replacement, meaning that each comparator patient was matched one time, at most, to an exposed patient. We also used PS stratification (deciles) for our main analyses comparing SV to ACEI and ARBs and risk of angioedema. For each comparison, we used risk set-based approach to estimate the adjusted hazard ratio and 95% confidence intervals for the unadjusted analyses, unconditional and conditional matched analyses, and PS stratified analyses. Subgroup analyses for effect estimation included angioedema diagnosis in 183 days prior to index date and separately, in entire enrollment history prior to index date; serious allergies diagnosis in the 183 days prior to index date; sex; age group; race; and follow-up time.

### See Appendices H and I for the specifications of parameters used in the analyses for this request.

**Limitations:** As with all observational studies, this evaluation was limited in its ability to control for all sources of potential bias. Algorithms used to define exposures, outcomes, inclusion and exclusion criteria, and covariates are imperfect and may be misclassified. Therefore, data should be interpreted with this limitation in mind.

<u>Notes:</u> 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).

cder\_mpl2r\_wp016 Page 2 of 247



- <u>CIDA Glossary</u> List of terms and their definitions found in this report pertaining to Sentinel's Cohort Identification and Descriptive Analysis (CIDA) Tool
- <u>PSA Glossary</u> List of terms and their definitions found in this report pertaining to Sentinel's Propensity Score Analysis (PSA)
  Tool
  - <u>Table 1a</u> Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Unadjusted, Aggregated)
  - Table 1b Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Adjusted, Aggregated), Fixed Ratio 1:1, Caliper: 0.05
  - Table 1c Weighted Baseline Characteristics of Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Propensity Score (PS) Stratified, Aggregated), Percentiles: 10
  - Table 1d Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Unadjusted, Aggregated)
  - Table 1e Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Adjusted, Aggregated), Fixed Ratio 1:1, Caliper: 0.05
  - Table 1f Weighted Baseline Characteristics of Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Propensity Score (PS) Stratified, Aggregated), Percentiles: 10
  - Table 1g Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 7-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Unadjusted, Aggregated), Fixed Ratio 1:1, Caliper: 0.05
  - Table 1h Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 7-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Adjusted, Aggregated), Fixed Ratio 1:1, Caliper: 0.05
  - <u>Table 1i</u> Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 7-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Unadjusted, Aggregated), Fixed Ratio 1:1, Caliper: 0.05
  - <u>Table 1j</u> Cohort of New Initiators of Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 7-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 (Adjusted, Aggregated), Fixed Ratio 1:1, Caliper: 0.05
  - <u>Table 2</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type
  - Table 3 Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Follow-up Time
  - <u>Table 4</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1)
  - <u>Table 5</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1) and Follow-up Time

cder\_mpl2r\_wp016 Page 3 of 247



- <u>Table 6</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (ever, -1)
- <u>Table 7</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Serious Allergies
- <u>Table 8</u> Effect Estimates for Risk of Angioedema Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI) 14-Day Gap in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Sex and Follow-up Time
- <u>Table 9</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Age Group
- <u>Table 10</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time
- Table 11 Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Race
- Table 12 Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time
- Table 13 Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type
- <u>Table 14</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Follow-up Time
- <u>Table 15</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1)
- <u>Table 16</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1) and Follow-up Time
- Table 17 Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (ever, -1)
- Table 18 Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Serious Allergies
- Table 19 Effect Estimates for Risk of Angioedema Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARB) 14-Day Gap in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Sex and Follow-up Time
- <u>Table 20</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Age Group

cder\_mpl2r\_wp016 Page 4 of 247



- Table 21 Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Age Group and Follow-up Time
- Table 22 Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Race
- <u>Table 23</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type, Race and Follow-up Time
- Table 24 Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 7-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type
- <u>Table 25</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 7-Day Gap, and Risk of Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type
- Table 26 Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type
- Table 27 Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1)
- <u>Table 28</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (ever, -1)
- <u>Table 29</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Serious Allergies
- <u>Table 30</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Sex
- <u>Table 31</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Age Group
- Table 32 Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Race
- <u>Table 33</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type
- <u>Table 34</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (-183, -1)
- <u>Table 35</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Angioedema (ever, -1)

cder\_mpl2r\_wp016 Page 5 of 247



- Table 36 Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Serious Allergies
- Table 37 Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Sex
- <u>Table 38</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Age Group
- <u>Table 39</u> Effect Estimates for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Serious Angioedema in the Sentinel Distributed Database (SDD) between July 7, 2015 and February 29, 2020 by Analysis Type and Race
- **Figures 1a** Histograms of Propensity Score (PS) Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, Aggregated
- Figures 1b Histograms of Propensity Score (PS) Fixed Ratio 1:1 Matched Cohort, Matched Caliper = 0.05 Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap
- Figures 2a Histograms of Propensity Score (PS) Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin II Receptor Blockers (ARBs), 14-day gap, Aggregated
- Figures 2b Histograms of Propensity Score (PS) Fixed Ratio 1:1 Matched Cohort, Matched Caliper = 0.05 Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin II Receptor Blockers (ARBs), 14-Day Gap
- **Figures 3a** Histograms of Propensity Score (PS) Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin-Converting Enzyme Inhibitors (ACEI), 7-Day Gap, Aggregated
- Figures 3b Histograms of Propensity Score (PS) Fixed Ratio 1:1 Matched Cohort, Matched Caliper = 0.05 Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin-Converting Enzyme Inhibitors (ACEI), 7-Day Gap
- **Figures 4a** Histograms of Propensity Score (PS) Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin II Receptor Blockers (ARBs), 7-day gap, Aggregated
- Figures 4b Histograms of Propensity Score (PS) Fixed Ratio 1:1 Matched Cohort, Matched Caliper = 0.05 Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin II Receptor Blockers (ARBs), 7-Day Gap
  - Figure 5 Kaplan Meier Survival Curves for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema
  - Figure 6 Kaplan Meier Survival Curves for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema
  - Figure 7 Kaplan Meier Survival Curves for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 7-Day Gap, and Risk of Angioedema
  - Figure 8 Kaplan Meier Survival Curves for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 7-Day Gap, and Risk of Angioedema
  - Figure 9 Kaplan Meier Survival Curves for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Serious Angioedema
- Figure 10 Kaplan Meier Survival Curves for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Serious Angioedema
- Figure 11 Kaplan Meier Survival Curves for Risk of Angioedema, Sacubitril/Valsartan (SV) (14-day gap) and Angiotensin-Converting Enzyme Inhibitors (ACEI) (14-day gap)

cder\_mpl2r\_wp016 Page 6 of 247



	Table of Contents
Figure 12	Kaplan Meier Survival Curves for Risk of Angioedema, Sacubitril/Valsartan (SV) (14-day gap) and
	Angiotensin II Receptor Blockers (ARBs) (14-day gap)
Appendix A	Start and End Dates for Each Data Partner up to Request End Date (09/30/2020)
· · · · · · · · · · · · · · · · · · ·	Generic and Brand Names of Medical Products Used to Define Exposures in this Request
Appendix C	International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International
	Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), International Classification of
	Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), Current Procedural Terminology, Fourth
	Edition (CPT-4), and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define
	Outcome in this Request
Appendix D	Generic and Brand Names of Medical Products Used to Define Exposure Incidence and Exclusion Criteria in this
	Request
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
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
Appendix G	Generic and Brand Names of Medical Products Used to Define Covariates in this Request
Appendix H	Specifications Defining Parameters for this Request
Appendix I	Specifications Defining Parameters for Baseline Covariate Groups in this Request

cder\_mpl2r\_wp016 Page 7 of 247



# 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.

cder\_mpl2p\_wp021 Page 11 of 311



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

**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

cder mpl2p wp021 Page 12 of 311



# 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 metrics to the propensity score estimation model:

- 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 included in the "Continuous enrollment before exposure" field.

**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 (proportional hazards) regression.

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 ratio.

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 1:1 matched cohort only.

**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 patients identified in exposure and comparator cohorts are used in the analysis.

**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 returned to the SOC, aggregated, and used to calculate effect estimates.

**Risk-set Level Data Return** - alternative to the patient-level data return approach. In this approach, the PSM tool will produce deidentified, 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 unmatched and the matched population.

**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

cder\_mpl2p\_wp032 Page 11 of 286



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

(Constant of the Constant of t	Medical Product		Covariate Balance			
	SV (14-	day gap)	ACEI (14	-day gap)		
					Absolute	Standardized
Characteristic <sup>1,2</sup>	Number	Percent	Number	Percent	Difference	Difference
Patients (Number)	41,998	100.0%	695,012	100.0%	-	-
		Standard		Standard		
Demographics	Mean	Deviation	Mean	Deviation		
Mean age, years	71.6	11.8	72.7	12.5	-1.108	-0.091
Age	Number 1.520	Percent	Number 24 504	Percent	0.555	0.021
18-44 years	1,538	3.7%	21,594	3.1%	0.555	0.031
45-54 years	2,863	6.8%	45,064 97,267	6.5%	0.333	0.013
55-64 years	5,807 31,790	13.8% 75.7%	97,267 531,087	14.0% 76.4%	-0.168 -0.720	-0.005 -0.017
<i>≥65 years</i> Sex	31,790	73.7%	331,007	70.4%	-0.720	-0.017
Female	14,867	35.4%	341,886	49.2%	-13.792	-0.282
Male	27,131	64.6%	353,126	50.8%	13.792	0.282
Race	27,131	04.070	333,120	30.070	13.732	0.202
American Indian or Alaska Native	132	0.3%	4,529	0.7%	-0.337	-0.049
Asian	519	1.2%	7,874	1.1%	0.103	0.010
Black or African American	5,566	13.3%	92,129	13.3%	-0.003	-0.000
Native Hawaiian or Other Pacific Islander	46	0.1%	741	0.1%	0.003	0.001
Unknown	7,029	16.7%	99,645	14.3%	2.399	0.066
White	28,706	68.4%	490,094	70.5%	-2.165	-0.047
Hispanic Origin	708	1.7%	15,586	2.2%	-0.557	-0.040
Year						
2015	430	1.0%	87,092	12.5%	-11.507	-0.470
2016	4,087	9.7%	172,883	24.9%	-15.143	-0.409
2017	8,846	21.1%	156,612	22.5%	-1.471	-0.036
2018	11,912	28.4%	143,025	20.6%	7.784	0.182
2019	16,392	39.0%	133,649	19.2%	19.801	0.447
2020	331	0.80%	1,751	0.30%	0.536	0.075
		Standard		Standard		
Recorded History of:	Mean	Deviation	Mean	Deviation		
Charlson/Elixhauser Combined Comorbidity	5.6	2.8	5.8	3.0	-0.259	-0.089
Score <sup>3</sup>						
	Number	Percent	Number	Percent		
Ambulatory allergies or allergy treatment	20,540	48.9%	320,744	46.1%	2.758	0.055
Ambulatory allergies or treatment and not	16,919	40.3%	253,012	36.4%	3.881	0.080
serious allergies		0.40/	064	0.40/	0.011	0.002
Angioedema (-183, -1)	57	0.1%	864	0.1%	0.011	0.003
Angioedema (ever, -1)	<i>571</i>	1.4%	7,320	1.1%	0.306	0.028
Diabetes	19,570	46.6%	326,116	46.9%	-0.325	-0.007
Ischemic heart disease	31,758	75.6%	433,085	62.3%	13.305	0.291
Renal disorders Serious allergies	18,574	44.2% 12.5%	289,803	41.7% 16.0%	2.528	0.051
History of Use:	5,684	13.5%	110,980	16.0%	-2.434	-0.069
Diuretics (thiazides, potassium sparing, loop	33,728	80.3%	458,232	65.9%	14.377	0.329
diuretics)	33,720	30.370	730,232	03.370	17.377	0.323
Everolimus	12	0.0%	183	0.0%	0.002	0.001
Evel Ollings	14	3.070	103	5.070	5.002	0.001

cder\_mpl2r\_wp016 Page 11 of 247



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

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

<sup>&</sup>lt;sup>1</sup>Covariates in italics were not included in the propensity score logistic regression model

cder\_mpl2r\_wp016 Page 12 of 247

<sup>&</sup>lt;sup>2</sup>Covariates in blue show a standardized difference greater than 0.1

<sup>&</sup>lt;sup>3</sup>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)

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



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

(Adjusted, Aggregated), Fixed Natio 1.1, early	1 0.03	Medical	Product		Covaria	te Balance
	SV (14-	day gap)		-day gap)	00.00	
			(2)	Г	Absolute	Standardized
Characteristic <sup>1,2</sup>	Number	Percent	Number	Percent	Difference	Difference
Patients (Number)	41,998	100.0%	41,998	6.0%	-	-
		Standard		Standard		
Demographics	Mean	Deviation	Mean	Deviation		
Mean age, years	71.6	11.8	71.6	12.1	0.033	0.003
Age	Number	Percent	Number	Percent	0.101	0.010
18-44 years	1,538	3.7%	1,462	3.5%	0.181	0.010
45-54 years	2,863	6.8%	2,925	7.0%	-0.148	-0.006
55-64 years	5,807	13.8%	6,460	15.4%	-1.555 1.533	-0.045
≥65 years	31,790	75.7%	31,151	74.2%	1.522	0.038
Sex	14.067	25 40/	15 072	25 00/	0.400	0.010
Female Male	14,867	35.4% 64.6%	15,072 26,926	35.9% 64.1%	-0.488 0.488	-0.010 0.010
Race	27,131	04.0%	20,920	04.1%	0.466	0.010
American Indian or Alaska Native	132	0.3%	132	0.3%	0.000	0.000
Asian	519	1.2%	536	1.3%	-0.040	-0.004
Black or African American	5,566	13.3%	5,557	13.2%	0.021	0.001
Native Hawaiian or Other Pacific Islander	46	0.1%	41	0.1%	0.012	0.004
		51275				
Unknown	7,029	16.7%	7,058	16.8%	-0.069	-0.003
White	28,706	68.4%	28,674	68.3%	0.076	0.002
Hispanic Origin	708	1.7%	843	2.0%	-0.321	-0.024
Year						
2015	430	1.0%	378	0.9%	0.124	0.013
2016	4,087	9.7%	4,104	9.8%	-0.040	-0.001
2017	8,846	21.1%	8,931	21.3%	-0.202	-0.005
2018	11,912	28.4%	11,867	28.3%	0.107	0.002
2019	16,392	39.0%	16,366	39.0%	0.062	0.001
2020	331	0.80%	352	0.80%	-0.050	-0.006
		Standard		Standard		
Recorded History of:	Mean	Deviation	Mean	Deviation		
Charlson/Elixhauser Combined Comorbidity	5.6	2.8	5.6	2.8	0.006	0.002
Score <sup>3</sup>						
	Number	Percent	Number	Percent		
Ambulatory allergies or allergy treatment	20,540	48.9%	20,437	48.7%	0.245	0.005
Ambulatory allergies or treatment and not	16,919	40.3%	16,914	40.3%	0.012	0.000
serious allergies						
Angioedema (-183, -1)	57	0.1%	53	0.1%	0.010	0.003
Angioedema (ever, -1)	<i>571</i>	1.4%	448	1.1%	0.293	0.027
Diabetes	19,570	46.6%	19,715	46.9%	-0.345	-0.007
Ischemic heart disease	31,758	75.6%	31,645	75.3%	0.269	0.006
Renal disorders	18,574	44.2%	18,577	44.2%	-0.007	-0.000
Serious allergies	5,684	13.5%	5,702	13.6%	-0.043	-0.001
History of Use:					_	
Diuretics (thiazides, potassium sparing, loop	33,728	80.3%	33,786	80.4%	-0.138	-0.003
diuretics)			4-			
Everolimus	12	0.0%	13	0.0%	-0.002	-0.001

cder\_mpl2r\_wp016 Page 13 of 247



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

		Medical	Covaria	Covariate Balance		
	SV (14-	SV (14-day gap) ACEI (14-day		-day gap)		
					Absolute	Standardized
Characteristic <sup>1,2</sup>	Number	Percent	Number	Percent	Difference	Difference
Nonsteroidal anti-inflammatory drugs	4,213	10.0%	4,192	10.0%	0.050	0.002
(NSAIDs)						
Sirolimus	****	****	****	****	0.000	0.000
		Standard		Standard		
Health Service Utilization Intensity:	Mean	Deviation	Mean	Deviation		
Mean number of ambulatory encounters	18.2	17.0	18.2	21.5	-0.011	-0.001
Mean number of emergency room	0.6	1.3	0.6	1.1	0.002	0.002
encounters						
Mean number of inpatient hospital	0.8	1.1	0.8	0.9	0.002	0.002
encounters						
Mean number of non-acute institutional	0.3	0.9	0.3	0.8	-0.001	-0.002
encounters						
Mean number of other ambulatory	9.2	14.1	9.2	12.8	-0.024	-0.002
encounters						
Mean number of filled prescriptions	26.5	20.5	26.7	22.3	-0.208	-0.010
Mean number of generics	11.6	5.4	11.7	5.5	-0.035	-0.006
Mean number of unique drug classes	11.0	4.9	11.0	4.9	0.014	0.003

<sup>&</sup>lt;sup>1</sup>Covariates in italics were not included in the propensity score logistic regression model

cder\_mpl2r\_wp016 Page 14 of 247

<sup>&</sup>lt;sup>2</sup>Covariates in blue show a standardized difference greater than 0.1

<sup>&</sup>lt;sup>3</sup>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)

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



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

between July 7, 2013 and February 23, 2020	(Fropensity 3		Product	ateu, reitei		te Balance
	SV (14-	day gap)		-day gap)	Covaria	Bulance
	37 (14-	uay gap <i>j</i>	ACEI (14	-uay gap <i>)</i> 	Absolute	Standardized
Characteristic <sup>1,2,3</sup>	Number	Percent	Number	Percent	Difference	Difference
Patients (Number)	41,998	100.0%	695,012	100.0%	-	-
	·	Standard	·	Standard		
Demographics	Mean	Deviation	Mean	Deviation		
Mean age, years	72.3	12.2	72.7	12.5	-0.418	-0.034
Age	Number	Percent	Number	Percent		
18-44 years	1,456	3.5%	21,633	3.1%	0.355	0.020
45-54 years	2,752	6.6%	45,109	6.5%	0.062	0.003
55-64 years	5,690	13.5%	97,451	14.0%	-0.473	-0.014
≥65 years	32,100	76.4%	530,819	76.4%	0.057	0.001
Sex						
Female	19,800	47.1%	336,959	48.5%	-1.338	-0.027
Male	22,198	52.9%	358,053	51.5%	1.338	0.027
Race						
American Indian or Alaska Native	235	0.6%	4,407	0.6%	-0.075	-0.010
Asian	489	1.2%	7,914	1.1%	0.025	0.002
Black or African American	5,426	12.9%	92,228	13.3%	-0.351	-0.010
Native Hawaiian or Other Pacific Islander	34	0.1%	744	0.1%	-0.026	-0.009
Unknown	7,013	16.7%	99,598	14.3%	2.369	0.110
White	28,802	68.6%	490,120	70.5%	-1.941	-0.050
Hispanic Origin	703	1.7%	15,517	2.2%	-0.558	-0.040
Year						
2015	4,956	11.8%	82,533	11.9%	-0.074	-0.002
2016	9,386	22.3%	166,944	24.0%	-1.672	-0.040
2017	9,299	22.1%	156,252	22.5%	-0.339	-0.008
2017	9,003	21.4%	146,432	21.1%	0.368	0.009
			-			
2019	9,192	21.9%	140,943	20.3%	1.607	0.039
2020	162	0.40% Standard	1,909	0.30% Standard	0.111	0.019
December 118-town of	20					
Recorded History of:	Mean	Deviation	Mean	Deviation	0.100	0.004
Charlson/Elixhauser Combined Comorbidity	5.9	3.1	5.8	3.0	0.103	0.034
Score <sup>4</sup>		_		_		
	Number	Percent	Number	Percent		
Ambulatory allergies or allergy treatment	20,161	48.0%	321,762	46.3%	1.709	0.034
Ambulatory allergies or treatment and not	15,900	37.9%	254,456	36.6%	1.246	0.026
serious allergies						
Angioedema (-183, -1)	56	0.1%	866	0.1%	0.008	0.002
Angioedema (ever, -1)	532	1.3%	7,325	1.1%	0.214	0.020
Diabetes	19,849	47.3%	326,148	46.9%	0.334	0.007
Ischemic heart disease	27,212	64.8%	438,289	63.1%	1.731	0.036
Renal disorders	18,387	43.8%	290,929	41.9%	1.921	0.039
Serious allergies	6,765	16.1%	110,244	15.9%	0.245	0.007
History of Use:						
Diuretics (thiazides, potassium sparing, loop	29,007	69.1%	463,884	66.7%	2.322	0.050
diuretics)						
Everolimus	****	****	184	0.0%	-0.008	-0.005

cder\_mpl2r\_wp016 Page 15 of 247



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

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

<sup>&</sup>lt;sup>1</sup>Covariates in italics were not included in the propensity score logistic regression model

cder\_mpl2r\_wp016 Page 16 of 247

<sup>&</sup>lt;sup>2</sup>Covariates in blue show a standardized difference greater than 0.1

<sup>&</sup>lt;sup>3</sup>Weighted patient characteristics tables facilitate the assessment of covariate balance after PS stratification. Treated/control patients are weig hted by the proportion of the total patient population included in their PS stratum divided by the proportion of the total treated/control patient population included in their PS stratum.

<sup>&</sup>lt;sup>4</sup>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)

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

Aggregated	Medical Product		Covaria	Covariate Balance		
	SV (14-	day gap)		I-day gap)		
					Absolute	Standardized
Characteristic <sup>1,2</sup>	Number	Percent	Number	Percent	Difference	Difference
Patients (Number)	43,777	100.0%	337,157	100.0%	-	-
		Standard		Standard		
Demographics	Mean	Deviation	Mean	Deviation		
Mean age, years	71.5	11.9	73.8	12.0	-2.285	-0.191
Age	Number	Percent	Number	Percent	1 211	0.070
18-44 years	1,634	3.7%	8,500	2.5%	1.211	0.070
45-54 years	3,068	7.0%	18,297	5.4%	1.581	0.066
55-64 years	6,120	14.0%	40,556	12.0%	1.951	0.058
≥65 years	32,955	75.3%	269,804	80.0%	-4.744	-0.114
Sex	45.466	25.20/	407.005	EE 70/	20.402	0.440
Female	15,466	35.3%	187,905	55.7%	-20.403	-0.419
Male	28,311	64.7%	149,252	44.3%	20.403	0.419
Race American Indian or Alaska Native	143	0.3%	1,947	0.6%	-0.251	-0.037
Asian	511	1.2%	7,817	2.3%	-1.151	-0.037
Black or African American	5,853	13.4%	55,815	16.6%	-3.185	-0.089
Native Hawaiian or Other Pacific Islander	3,833 46	0.1%	478	0.1%	-0.037	-0.010
Native Hawaiian of Other Facilic Islander	40	0.170	478	0.170	-0.037	-0.010
Unknown	7,289	16.7%	47,812	14.2%	2.469	0.068
White	29,935	68.4%	223,288	66.2%	2.154	0.046
Hispanic Origin	751	1.7%	9,038	2.7%	-0.965	-0.066
Year			5,555			
2015	430	1.0%	32,231	9.6%	-8.577	-0.391
2016	4,168	9.5%	70,705	21.0%	-11.450	-0.323
2017	9,173	21.0%	73,808	21.9%	-0.937	-0.023
2018	12,488	28.5%	81,684	24.2%	4.299	0.098
2019	17,167	39.2%	77,624	23.0%	16.192	0.355
2020	351	0.80%	1,105	0.30%	0.474	0.063
2020	331	Standard	1,103	Standard	0.171	0.000
Recorded History of:	Mean	Deviation	Mean	Deviation		
Charlson/Elixhauser Combined Comorbidity	5.6	2.8	5.8	3.0	-0.171	-0.059
Score <sup>3</sup>						
	Number	Percent	Number	Percent		
Ambulatory allergies or allergy treatment	21,349	48.8%	169,542	50.3%	-1.518	-0.030
Ambulatory allergies or treatment and not	17,590	40.2%	134,478	39.9%	0.295	0.006
serious allergies						
Angioedema (-183, -1)	60	0.1%	825	0.2%	-0.108	-0.025
Angioedema (ever, -1)	599	1.4%	7,359	2.2%	-0.814	-0.062
Diabetes	20,372	46.5%	173,558	51.5%	-4.941	-0.099
Ischemic heart disease	33,124	75.7%	203,999	60.5%	15.160	0.330
Renal disorders	19,390	44.3%	154,663	45.9%	-1.580	-0.032
Serious allergies	5,930	13.5%	54,432	16.1%	-2.598	-0.073
History of Use:						
Diuretics (thiazides, potassium sparing, loop	35,208	80.4%	222,934	66.1%	14.304	0.328
diuretics)	13	0.00/	00	0.00/	0.003	0.004
Everolimus	12	0.0%	98	0.0%	-0.002	-0.001

cder\_mpl2r\_wp016 Page 17 of 247



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

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

<sup>&</sup>lt;sup>1</sup>Covariates in italics were not included in the propensity score logistic regression model

cder\_mpl2r\_wp016 Page 18 of 247

<sup>&</sup>lt;sup>2</sup>Covariates in blue show a standardized difference greater than 0.1

<sup>&</sup>lt;sup>3</sup>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)

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

Aggregated), Fixed Ratio 1.1, Camper. 0.05	Medical Product		Covaria	Covariate Balance		
	SV (14-	day gap)		l-day gap)		
	(- :	 			Absolute	Standardized
Characteristic 1,2	Number	Percent	Number	Percent	Difference	Difference
Patients (Number)	43,755	99.9%	43,755	13.0%	-	-
		Standard		Standard		
Demographics	Mean	Deviation	Mean	Deviation		
Mean age, years	71.5	11.9	71.6	11.9	-0.033	-0.003
Age	Number	Percent	Number	Percent	0.040	0.010
18-44 years	1,623	3.7%	1,517	3.5%	0.242	0.013
45-54 years	3,059	7.0%	3,067	7.0%	-0.018	-0.001
55-64 years	6,118	14.0%	6,380	14.6%	-0.599	-0.018
≥65 years	32,955	75.3%	32,791	74.9%	0.375	0.009
Sex	45.466	25.20/	45 554	25 50/	0.004	0.004
Female	15,466	35.3%	15,554	35.5%	-0.201	-0.004
Male	28,289	64.7%	28,201	64.5%	0.201	0.004
Race American Indian or Alaska Native	143	0.3%	155	0.4%	-0.027	-0.005
Asian	511	1.2%	506	1.2%	0.027	0.001
Black or African American	5,852	13.4%	5,880	13.4%	-0.064	-0.002
Native Hawaiian or Other Pacific Islander	3,832 46	0.1%	3,880	0.1%	0.025	0.002
Native Hawaiian of Other Facilic Islander	40	0.176	33	0.176	0.023	0.008
Unknown	7,271	16.6%	7,265	16.6%	0.014	0.001
White	29,932	68.4%	29,914	68.4%	0.041	0.001
Hispanic Origin	, 751	1.7%	833	1.9%	-0.187	-0.014
Year						
2015	430	1.0%	400	0.9%	0.069	0.007
2016	4,168	9.5%	4,044	9.2%	0.283	0.010
2017	9,173	21.0%	9,222	21.1%	-0.112	-0.003
2018	12,486	28.5%	12,664	28.9%	-0.407	-0.009
2019	17,148	39.2%	17,038	38.9%	0.251	0.005
2020	350	0.80%	387	0.90%	-0.085	-0.009
1010	330	Standard	307	Standard	0.003	0.003
Recorded History of:	Mean	Deviation	Mean	Deviation		
Charlson/Elixhauser Combined Comorbidity	5.6	2.8	5.6	2.9	-0.030	-0.011
Score <sup>3</sup>						
	Number	Percent	Number	Percent		
Ambulatory allergies or allergy treatment	21,340	48.8%	21,523	49.2%	-0.418	-0.008
Ambulatory allergies or treatment and not	17,582	40.2%	17,679	40.4%	-0.222	-0.005
serious allergies						
Angioedema (-183, -1)	60	0.1%	58	0.1%	0.005	0.001
Angioedema (ever, -1)	598	1.4%	916	2.1%	-0.727	-0.056
Diabetes	20,371	46.6%	20,282	46.4%	0.203	0.004
Ischemic heart disease	33,103	75.7%	33,062	75.6%	0.094	0.002
Renal disorders	19,388	44.3%	19,531	44.6%	-0.327	-0.007
Serious allergies	5,928	13.5%	5,967	13.6%	-0.089	-0.003
History of Use:	25.400	00.40/	25 470	00.40/	0.046	0.000
Diuretics (thiazides, potassium sparing, loop	35,186	80.4%	35,179	80.4%	0.016	0.000
diuretics) Everolimus	12	0.0%	16	0.0%	-0.000	-0.005
Everoillius	12	0.0%	16	0.0%	-0.009	-0.005

cder\_mpl2r\_wp016 Page 19 of 247



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

		Medical	Covaria	Covariate Balance		
	SV (14-day gap) AR		ARBs (14	ARBs (14-day gap)		
					Absolute	Standardized
Characteristic <sup>1,2</sup>	Number	Percent	Number	Percent	Difference	Difference
Nonsteroidal anti-inflammatory drugs	4,405	10.1%	4,394	10.0%	0.025	0.001
(NSAIDs)						
Sirolimus	****	****	****	****	0.000	0.000
		Standard		Standard		
Health Service Utilization Intensity:	Mean	Deviation	Mean	Deviation		
Mean number of ambulatory encounters	18.2	17.1	18.3	19.0	-0.087	-0.005
Mean number of emergency room	0.7	1.4	0.7	1.3	0.007	0.005
encounters						
Mean number of inpatient hospital	0.8	1.1	0.8	1.1	-0.015	-0.014
encounters						
Mean number of non-acute institutional	0.3	0.9	0.3	0.9	-0.008	-0.010
encounters						
Mean number of other ambulatory	9.2	14.0	9.4	13.8	-0.153	-0.011
encounters						
Mean number of filled prescriptions	26.6	20.7	26.2	20.5	0.441	0.021
Mean number of generics	11.6	5.5	11.7	5.5	-0.085	-0.016
Mean number of unique drug classes	11.0	4.9	11.0	4.8	-0.025	-0.005

<sup>&</sup>lt;sup>1</sup>Covariates in italics were not included in the propensity score logistic regression model

cder\_mpl2r\_wp016 Page 20 of 247

<sup>&</sup>lt;sup>2</sup>Covariates in blue show a standardized difference greater than 0.1

<sup>&</sup>lt;sup>3</sup>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)

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

residury 23, 2020 (Fropensity Score (FS) Struction	150,7188.580		Product		Covaria	te Balance
	SV /14			l day gan)	Covaria	Le Balance
	3V (14-	day gap)	AKDS (14	I-day gap)	Absolute	Standardized
Characteristic <sup>1,2,3</sup>	Number	Percent	Number	Percent	Difference	Difference
Patients (Number)	43,777	100.0%	337,157	100.0%	-	-
	·	Standard		Standard		
Demographics	Mean	Deviation	Mean	Deviation		
Mean age, years	73.2	12.0	73.6	12.0	-0.382	-0.032
Age	Number	Percent	Number	Percent		
18-44 years	1,249	2.9%	<i>8,753</i>	2.6%	0.258	0.016
45-54 years	2,559	5.8%	18,681	5.5%	0.306	0.013
55-64 years	5,585	12.8%	41,057	12.2%	0.579	0.018
≥65 years	34,384	78.5%	268,666	79.7%	-1.143	-0.030
Sex						
Female	22,862	52.2%	180,403	53.5%	-1.282	-0.026
Male	20,915	47.8%	156,754	46.5%	1.282	0.026
Race						
American Indian or Alaska Native	201	0.5%	1,862	0.6%	-0.092	-0.013
Asian	887	2.0%	7,405	2.2%	-0.170	-0.012
Black or African American	6,822	15.6%	54,823	16.3%	-0.677	-0.019
Native Hawaiian or Other Pacific Islander	46	0.1%	466	0.1%	-0.032	-0.009
Unknown	7,504	17.1%	47,484	14.1%	3.058	0.134
White	28,316	64.7%	225,116	66.8%	-2.086	-0.050
Hispanic Origin	944	2.2%	8,771	2.6%	-0.446	-0.029
Year			•			
2015	3,661	8.4%	28,920	8.6%	-0.214	-0.008
2016	8,426	19.2%	66,279	19.7%	-0.410	-0.010
2017	9,453	21.6%	73,686	21.9%	-0.262	-0.006
2018	10,758	24.6%	83,656	24.8%	-0.237	-0.005
2019	11,261	25.7%	83,387	24.7%	0.991	0.023
2020	217	0.50%	1,230	0.40%	0.131	0.02
2020	21,	Standard	1,230	Standard	0.131	0.02
Recorded History of:	Mean	Deviation	Mean	Deviation		
Charlson/Elixhauser Combined Comorbidity	5.7	2.9	5.8	3.0	-0.010	-0.003
Score⁴						
	Number	Percent	Number	Percent		
Ambulatory allergies or allergy treatment	22,289	50.9%	169,231	50.2%	0.722	0.014
Ambulatory allergies or treatment and not	17,968	41.0%	134,696	40.0%	1.093	0.022
serious allergies						
Angioedema (-183, -1)	134	0.3%	784	0.2%	0.074	0.014
Angioedema (ever, -1)	675	1.5%	7,308	2.2%	-0.626	-0.046
Diabetes	21,885	50.0%	172,051	51.0%	-1.037	-0.021
Ischemic heart disease	27,492	62.8%	209,958	62.3%	0.526	0.011
Renal disorders	20,094	45.9%	154,462	45.8%	0.088	0.002
Serious allergies	6,724	15.4%	53,664	15.9%	-0.556	-0.015
History of Use:						
Diuretics (thiazides, potassium sparing, loop	30,349	69.3%	228,471	67.8%	1.563	0.034
diuretics)						
Everolimus	****	****	97	0.0%	-0.009	-0.006
Nonsteroidal anti-inflammatory drugs (NSAIDs)	5,657	12.9%	43,061	12.8%	0.151	0.005
, , ,						

cder\_mpl2r\_wp016 Page 21 of 247



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

		Medical	Product		Covaria	te Balance
	SV (14-0	day gap)	ARBs (14	-day gap)		
					Absolute	Standardized
Characteristic <sup>1,2,3</sup>	Number	Percent	Number	Percent	Difference	Difference
Sirolimus	12	0.0%	133	0.0%	-0.012	-0.006
		Standard		Standard		
Health Service Utilization Intensity:	Mean	Deviation	Mean	Deviation		
Mean number of ambulatory encounters	20.2	20.3	20.2	22.2	0.017	0.001
Mean number of emergency room encounters	8.0	1.9	0.8	1.6	0.029	0.016
Mean number of inpatient hospital encounters	0.8	1.2	0.8	1.1	-0.007	-0.006
Mean number of non-acute institutional	0.4	1.1	0.4	1.0	-0.005	-0.004
encounters						
Mean number of other ambulatory encounters	11.2	17.6	11.5	17.1	-0.317	-0.018
Mean number of filled prescriptions	28.6	22.8	27.6	22.2	0.984	0.044
Mean number of generics	12.0	5.8	12.0	5.8	0.043	0.007
Mean number of unique drug classes	11.3	5.2	11.2	5.1	0.106	0.020

<sup>&</sup>lt;sup>1</sup>Covariates in italics were not included in the propensity score logistic regression model

cder\_mpl2r\_wp016 Page 22 of 247

<sup>&</sup>lt;sup>2</sup>Covariates in blue show a standardized difference greater than 0.1

<sup>&</sup>lt;sup>3</sup>Weighted patient characteristics tables facilitate the assessment of covariate balance after PS stratification. Treated/control patients are weighted by the proportion of the total patient population included in their PS stratum divided by the proportion of the total treated/control patient population included in their PS stratum.

<sup>&</sup>lt;sup>4</sup>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)

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

,,	•	Medical	Covariate Balance			
	SV (7-d	lay gap)	ACEI (7-	day gap)		
					Absolute	Standardized
Characteristic <sup>1,2</sup>	Number	Percent	Number	Percent	Difference	Difference
Patients (Number)	41,998	100.0%	695,012	100.0%	-	-
		Standard		Standard		
Demographics	Mean	Deviation	Mean	Deviation	1 100	2.001
Mean age, years	71.6	11.8	72.7	12.5	-1.108	-0.091
Age	Number 1.520	Percent	Number 24 504	Percent	0.555	0.021
18-44 years	1,538	3.7%	21,594	3.1%	0.555	0.031
45-54 years	2,863	6.8%	45,064	6.5%	0.333	0.013
55-64 years	5,807 31,790	13.8% 75.7%	97,267 531,087	14.0% 76.4%	-0.168 -0.720	-0.005 -0.017
≥65 years Sex	31,790	73.7%	331,007	70.4%	-0.720	-0.017
Female)	14,867	35.4%	341,886	49.2%	-13.792	-0.282
Male	27,131	64.6%	353,126	50.8%	13.792	0.282
Race	27,131	04.070	333,120	30.070	13.732	0.202
American Indian or Alaska Native	132	0.3%	4,529	0.7%	-0.337	-0.049
Asian	519	1.2%	7,874	1.1%	0.103	0.010
Black or African American	5,566	13.3%	92,129	13.3%	-0.003	-0.000
Native Hawaiian or Other Pacific Islander	46	0.1%	741	0.1%	0.003	0.001
Unknown	7,029	16.7%	99,645	14.3%	2.399	0.066
White	28,706	68.4%	490,094	70.5%	-2.165	-0.047
Hispanic Origin	708	1.7%	15,586	2.2%	-0.557	-0.040
Year						
2015	430	1.0%	87,092	12.5%	-11.507	-0.470
2016	4,087	9.7%	172,883	24.9%	-15.143	-0.409
2017	8,846 11,912	21.1%	156,612	22.5%	-1.471	-0.036
2018		28.4%	143,025	20.6%	7.784	0.182
2019	16,392	39.0%	133,649	19.2%	19.801	0.447
2020	331	0.80%	1,751	0.30%	0.536	0.075
		Standard		Standard		
Recorded History of:	Mean	Deviation	Mean	Deviation		
Charlson/Elixhauser Combined Comorbidity	5.6	2.8	5.8	3.0	-0.259	-0.089
Score <sup>3</sup>						
	Number	Percent	Number	Percent		
Ambulatory allergies or allergy treatment	20,540	48.9%	320,744	46.1%	2.758	0.055
Ambulatory allergies or treatment and not	16,919	40.3%	253,012	36.4%	3.881	0.080
serious allergies	<b>-</b> 7	0.10/	064	0.10/	0.011	0.003
Angioedema (-183, -1)	57	0.1%	864	0.1%	0.011	0.003
Angioedema (ever, -1) Diabetes	<i>571</i>	1.4%	7,320	1.1%	0.306	0.028
	19,570	46.6%	326,116	46.9%	-0.325	-0.007
Ischemic heart disease Renal disorders	31,758 18,574	75.6% 44.2%	433,085 289,803	62.3% 41.7%	13.305 2.528	0.291 0.051
Serious allergies	18,574 5,684		289,803 110,980	41.7% 16.0%		-0.069
History of Use:	3,004	13.5%	110,500	10.0%	-2.434	-0.009
Diuretics (thiazides, potassium sparing, loop	33,728	80.3%	458,232	65.9%	14.377	0.329
diuretics)	33,720	33.370	155,252	03.370	2	0.023
Everolimus	12	0.0%	183	0.0%	0.002	0.001
					<b></b>	

cder\_mpl2r\_wp016 Page 23 of 247



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

		Medical	Covariate Balance			
	SV (7-d	lay gap)	ACEI (7-	day gap)		
					Absolute	Standardized
Characteristic <sup>1,2</sup>	Number	Percent	Number	Percent	Difference	Difference
Nonsteroidal anti-inflammatory drugs	4,213	10.0%	88,980	12.8%	-2.771	-0.087
(NSAIDs)						
Sirolimus	****	****	208	0.0%	-0.006	-0.004
		Standard		Standard		
Health Service Utilization Intensity:	Mean	Deviation	Mean	Deviation		
Mean number of ambulatory encounters	18.2	17.0	17.3	19.7	0.886	0.048
Mean number of emergency room	0.6	1.3	0.9	1.8	-0.205	-0.129
encounters						
Mean number of inpatient hospital	0.8	1.1	1.0	1.2	-0.212	-0.190
encounters						
Mean number of non-acute institutional	0.3	0.9	0.4	1.1	-0.163	-0.168
encounters						
Mean number of other ambulatory	9.2	14.1	12.8	18.0	-3.641	-0.226
encounters						
Mean number of filled prescriptions	26.5	20.5	26.9	23.0	-0.349	-0.016
Mean number of generics	11.6	5.4	11.5	5.7	0.106	0.019
Mean number of unique drug classes	11.0	4.9	10.8	5.0	0.195	0.039

<sup>&</sup>lt;sup>1</sup>Covariates in italics were not included in the propensity score logistic regression model

cder\_mpl2r\_wp016 Page 24 of 247

<sup>&</sup>lt;sup>2</sup>Covariates in blue show a standardized difference greater than 0.1

<sup>&</sup>lt;sup>3</sup>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)

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

(10)		Medical	Covaria	Covariate Balance		
	SV (7-c	day gap)	ACEI (7-	day gap)		
					Absolute	Standardized
Characteristic <sup>1,2</sup>	Number	Percent	Number	Percent	Difference	Difference
Patients (Number)	41,998	100.0%	41,998	6.0%	-	-
		Standard		Standard		
Demographics	Mean	Deviation	Mean	Deviation		
Mean age, years	71.6	11.8	71.6	12.1	0.033	0.003
Age	Number	Percent	Number	Percent	0.101	0.010
18-44 years	1,538	3.7%	1,462	3.5%	0.181	0.010
45-54 years	2,863 5,863	6.8%	2,925	7.0%	-0.148	-0.006
55-64 years	5,807 31,790	13.8% 75.7%	<i>6,460</i> 31,151	15.4% 74.2%	-1.555 1.522	-0.045 0.038
≥65 years	31,790	73.7%	31,131	74.2%	1.522	0.036
Sex Female	14,867	35.4%	15,072	35.9%	-0.488	-0.010
Male	27,131	64.6%	26,926	64.1%	0.488	0.010
Race	27,131	04.070	20,320	04.170	0.400	0.010
American Indian or Alaska Native	132	0.3%	132	0.3%	0.000	0.000
Asian	519	1.2%	536	1.3%	-0.040	-0.004
Black or African American	5,566	13.3%	5,557	13.2%	0.021	0.001
Native Hawaiian or Other Pacific Islander	46	0.1%	41	0.1%	0.012	0.004
Unknown	7,029	16.7% 68.4%	7,058	16.8%	-0.069	-0.003
White	28,706	68.4%	28,674	68.3%	0.076	0.002
Hispanic Origin	708	1.7%	843	2.0%	-0.321	-0.024
Year						
2015	430	1.0%	378	0.9%	0.124	0.013
2016	4,087	9.7%	4,104	9.8%		-0.001
2017	8,846	21.1%	8,931	21.3%	-0.202	-0.005
2018	11,912	28.4%	11,867	28.3%	0.107	0.002
2019	16,392	39.0%	16,366	39.0%	0.062	0.001
2020	331	0.80%	352	0.80%	-0.050	-0.006
		Standard		Standard		
Recorded History of:	Mean	Deviation	Mean	Deviation		
Charlson/Elixhauser Combined Comorbidity	5.6	2.8	5.6	2.8	0.006	0.002
Score <sup>3</sup>						
	Number	Percent	Number	Percent		
Ambulatory allergies or allergy treatment	20,540	48.9%	20,437	48.7%	0.245	0.005
Ambulatory allergies or treatment and not	16,919	40.3%	16,914	40.3%	0.012	0.000
serious allergies	F.7	0.10/	F.3	0.10/	0.010	0.003
Angioedema (-183, -1)	57	0.1%	53	0.1%	0.010	0.003
Angioedema (ever, -1)	<i>571</i>	1.4%	448	1.1%	0.293	0.027
Diabetes Ischemic heart disease	19,570 31,758	46.6% 75.6%	19,715 31,645	46.9% 75.3%	-0.345 0.269	-0.007 0.006
Renal disorders	31,738 18,574	75.6% 44.2%	31,645 18,577	75.3% 44.2%	-0.007	-0.000
Serious allergies	5,684	44.2% 13.5%	5,702	44.2% 13.6%	-0.007 -0.043	-0.000 -0.001
History of Use:	J,U0 <del>4</del>	13.3/0	3,702	13.0/0	-0.043	-0.001
Diuretics (thiazides, potassium sparing, loop	33,728	80.3%	33,786	80.4%	-0.138	-0.003
diuretics)	,	22.0,0	,. ••			
Everolimus	12	0.0%	13	0.0%	-0.002	-0.001

cder\_mpl2r\_wp016 Page 25 of 247



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

		Medical	Product		Covaria	te Balance
	SV (7-d	lay gap)	ACEI (7-	day gap)		
					Absolute	Standardized
Characteristic 1,2	Number	Percent	Number	Percent	Difference	Difference
Nonsteroidal anti-inflammatory drugs	4,213	10.0%	4,192	10.0%	0.050	0.002
(NSAIDs)						
Sirolimus	****	****	****	****	0.000	0.000
		Standard		Standard		
Health Service Utilization Intensity:	Mean	Deviation	Mean	Deviation		
Mean number of ambulatory encounters	18.2	17.0	18.2	21.5	-0.011	-0.001
Mean number of emergency room	0.6	1.3	0.6	1.1	0.002	0.002
encounters						
Mean number of inpatient hospital	0.8	1.1	0.8	0.9	0.002	0.002
encounters						
Mean number of non-acute institutional	0.3	0.9	0.3	0.8	-0.001	-0.002
encounters						
Mean number of other ambulatory	9.2	14.1	9.2	12.8	-0.024	-0.002
encounters						
Mean number of filled prescriptions	26.5	20.5	26.7	22.3	-0.208	-0.010
Mean number of generics	11.6	5.4	11.7	5.5	-0.035	-0.006
Mean number of unique drug classes	11.0	4.9	11.0	4.9	0.014	0.003

<sup>&</sup>lt;sup>1</sup>Covariates in italics were not included in the propensity score logistic regression model

cder\_mpl2r\_wp016 Page 26 of 247

<sup>&</sup>lt;sup>2</sup>Covariates in blue show a standardized difference greater than 0.1

<sup>&</sup>lt;sup>3</sup>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)

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

Aggregatedy, Fixed Ratio 1.1, Camper. 0.03		Medical	Product		Covaria	te Balance
	SV (7-c	lay gap)	ARBs (7	-day gap)		
	,		,	/ 0   /	Absolute	Standardized
Characteristic <sup>1,2</sup>	Number	Percent	Number	Percent	Difference	Difference
Patients (Number)	43,777	100.0%	337,157	100.0%	-	-
		Standard		Standard		
Demographics	Mean	Deviation	Mean	Deviation	2.205	0.404
Mean age, years	71.5 Number	11.9	73.8 Number	12.0	-2.285	-0.191
Age 18-44 years	1,634	Percent 3.7%	8,500	Percent 2.5%	1.211	0.070
45-54 years	3,068	7.0%	18,297	5.4%	1.581	0.066
	-		-			
55-64 years	6,120	14.0% 75.3%	40,556 269,804	12.0%	1.951 -4.744	0.058 -0.114
≥65 years	32,955	75.5%	209,804	80.0%	-4.744	-0.114
Sex Female	15,466	35.3%	187,905	55.7%	20.402	-0.419
Male	28,311	64.7%	149,252	44.3%	-20.403 20.403	0.419
Race	20,311	04.776	145,232	44.570	20.403	0.419
American Indian or Alaska Native	143	0.3%	1,947	0.6%	-0.251	-0.037
Asian	511	1.2%	7,817	2.3%	-1.151	-0.088
Black or African American	5,853	13.4%	55,815	16.6%	-3.185	-0.089
Native Hawaiian or Other Pacific Islander	46	0.1%	478	0.1%	-0.037	-0.010
		0.2,0		0.270	0.007	0.020
Unknown	7,289	16.7%	47,812	14.2%	2.469	0.068
White	29,935	68.4%	223,288	66.2%	2.154	0.046
Hispanic Origin	751	1.7%	9,038	2.7%	-0.965	-0.066
Year						
2015	430	1.0%	32,231	9.6%	-8.577	-0.391
2016	4,168	9.5%	70,705	21.0%	2.154 -0.965 -8.577 -11.450 -0.937 4.299	-0.323
2017	9,173	21.0%	73,808	21.9%	-0.937	-0.023
2018	12,488	28.5%	81,684	24.2%		0.098
2019	17,167	39.2%	77,624	23.0%	16.192	0.355
2020	351	0.80%	1,105	0.30%	0.474	0.063
		Standard		Standard		
Recorded History of:	Mean	Deviation	Mean	Deviation		
Charlson/Elixhauser Combined Comorbidity	5.6	2.8	5.8	3.0	-0.171	-0.059
Score <sup>3</sup>						
	Number	Percent	Number	Percent		
Ambulatory allergies or allergy treatment	21,349	48.8%	169,542	50.3%	-1.518	-0.030
Ambulatory allergies or treatment and not	17,590	40.2%	134,478	39.9%	0.295	0.006
serious allergies						
Angioedema (-183, -1)	60	0.1%	825	0.2%	-0.108	-0.025
Angioedema (ever, -1)	599	1.4%	7,359	2.2%	-0.814	-0.062
Diabetes	20,372	46.5%	173,558	51.5%	-4.941	-0.099
Ischemic heart disease	33,124	75.7%	203,999	60.5%	15.160	0.330
Renal disorders	19,390	44.3%	154,663	45.9%	-1.580	-0.032
Serious allergies	5,930	13.5%	54,432	16.1%	-2.598	-0.073
History of Use:	25.222	00.404	222.224	66.101	44.224	0.000
Diuretics (thiazides, potassium sparing, loop	35,208	80.4%	222,934	66.1%	14.304	0.328
diuretics)	12	0.00/	00	0.00/	0.003	0.001
Everolimus	12	0.0%	98	0.0%	-0.002	-0.001

cder\_mpl2r\_wp016 Page 27 of 247



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

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

<sup>&</sup>lt;sup>1</sup>Covariates in italics were not included in the propensity score logistic regression model

cder\_mpl2r\_wp016 Page 28 of 247

<sup>&</sup>lt;sup>2</sup>Covariates in blue show a standardized difference greater than 0.1

<sup>&</sup>lt;sup>3</sup>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)

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

Aggregated), Fixed Ratio 1:1, eariper: 0:05		Medical	Covariate Balance				
	SV (7-day gap) ARBs (7-			-dav gap)			
					Absolute	Standardized	
Characteristic 1,2	Number	Percent	Number	Percent	Difference	Difference	
Patients (Number)	43,755	99.9%	43,755	13.0%	-	-	
		Standard		Standard			
Demographics	Mean	Deviation	Mean	Deviation			
Mean age, years	71.5	11.9	71.6	11.9	-0.033	-0.003	
Age	Number	Percent	Number	Percent	0.040	0.010	
18-44 years	1,623	3.7%	1,517	3.5%	0.242	0.013	
45-54 years	3,059	7.0%	3,067	7.0%	-0.018	-0.001	
55-64 years	6,118	14.0%	6,380	14.6%	-0.599	-0.018	
≥65 years	32,955	75.3%	32,791	74.9%	0.375	0.009	
Sex							
Female	15,466	35.3%	15,554	35.5%	-0.201	-0.004	
Male	28,289	64.7%	28,201	64.5%	0.201	0.004	
Race	4.40	0.00/	455	2 40/	0.007	0.005	
American Indian or Alaska Native	143	0.3%	155	0.4%	-0.027	-0.005	
Asian	511	1.2%	506	1.2%	0.011	0.001	
Black or African American	5,852	13.4%	5,880	13.4%	-0.064	-0.002	
Native Hawaiian or Other Pacific Islander	46	0.1%	35	0.1%	0.025	0.008	
Unknown	7,271	16.6%	7,265	16.6%	0.014	0.001	
White	29,932	68.4%	29,914	68.4%	0.041	0.001	
Hispanic Origin	<i>751</i>	1.7%	833	1.9%	-0.187	-0.014	
Year							
2015	430	1.0%	400	0.9%	0.069	0.007	
2016	4,168	9.5%	4,044	9.2%	0.283	0.010	
2017	9,173	21.0%	9,222	21.1%	-0.112	-0.003	
2018	12,486	28.5%	12,664	28.9%	-0.407	-0.009	
2019	17,148	39.2%	17,038	38.9%	0.251	0.005	
2020	350	0.80%	387	0.90%	-0.085	-0.009	
		Standard		Standard			
Recorded History of:	Mean	Deviation	Mean	Deviation			
Charlson/Elixhauser Combined Comorbidity	5.6	2.8	5.6	2.9	-0.030	-0.011	
Score <sup>3</sup>							
Ambulatory alloraics or alloray treatment	Number	Percent	Number	Percent 40, 20/	0.410	0.000	
Ambulatory allergies or allergy treatment	21,340	48.8%	21,523	49.2%	-0.418	-0.008	
Ambulatory allergies or treatment and not	17,582	40.2%	17,679	40.4%	-0.222	-0.005	
serious allergies	60	0.10/	58	0.19/	0.005	0.001	
Angioedema (-183, -1)		0.1%		0.1%	0.005		
Angioedema (ever, -1)	598	1.4%	916	2.1%	-0.727	-0.056	
Diabetes	20,371	46.6% 75.7%	20,282	46.4% 75.6%	0.203	0.004	
Ischemic heart disease	33,103	75.7%	33,062	75.6%	0.094	0.002	
Renal disorders	19,388	44.3%	19,531	44.6%	-0.327	-0.007	
Serious allergies	5,928	13.5%	5,967	13.6%	-0.089	-0.003	
History of Use: Diuretics (thiazides, potassium sparing, loop	35,186	80.4%	35,179	80.4%	0.016	0.000	
diuretics)	,		<b>, -</b>				
Everolimus	12	0.0%	16	0.0%	-0.009	-0.005	

cder\_mpl2r\_wp016 Page 29 of 247



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

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

<sup>&</sup>lt;sup>1</sup>Covariates in italics were not included in the propensity score logistic regression model

cder\_mpl2r\_wp016 Page 30 of 247

<sup>&</sup>lt;sup>2</sup>Covariates in blue show a standardized difference greater than 0.1

<sup>&</sup>lt;sup>3</sup>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)

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



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

			Average	Average		Incidence Rate per		Incidence Rate	Difference			
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	<b>Hazard Ratio</b>		
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald	
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval)	P-Value	
<b>Site-Adjusted Analys</b>	sis											
SV	41,998	****	****	****	****	1.33	****	-5.4	****	0.19 (0.12, 0.29)	<0.001	
ACEI	695,012	****	****	****	****	6.73	****	-5.4		0.19 (0.12, 0.29)	<0.001	
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>							
SV	41,998	****	****	****	****	1.59	****	-9.07	****	0.15 (0.08, 0.26)	<0.001	
ACEI	41,998	****	****	****	****	10.66	****	-9.07		0.13 (0.08, 0.28)	<0.001	
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05							
SV	41,998	****	****	****	****	1.33	****	-5.84	****	0.18 (0.11, 0.29)	<0.001	
ACEI	41,998	****	****	****	****	7.17	****	-3.64		0.16 (0.11, 0.29)	<0.001	
<b>Propensity Score Ad</b>	justed Stratified	Analysis; I	Percentiles=	10 <sup>1</sup>								
SV	41,998	****	****	****	****	1.33	****	E /I	****	0.19 (0.12 0.20)	<0.001	
ACEI	695,012	****	****	****	****	6.73	****	-5.4		0.18 (0.12, 0.29)	<0.001	

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 31 of 247

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



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

			Average	Average		Incidence Rate per		Incidence Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
						Overall					
Site-Adjusted Analysis											
SV (14-day gap)	41,998	****	****	****	****	1.33	****	-5.4	****	0.19 ( 0.12, 0.29)	<0.001
ACEI (14-day gap)	695,012	****	****	****	****	6.73	****	-3.4		0.13 ( 0.12,  0.23)	<b>\0.001</b>
Fixed Ratio 1:1 Proper	sity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	41,998	****	****	****	****	1.59	****	-9.07	****	0.15 ( 0.08, 0.26)	<0.001
ACEI (14-day gap)	41,998	****	****	****	****	10.66	****	-9.07		0.15 (0.06, 0.20)	<0.001
Fixed Ratio 1:1 Proper	sity Score Ma				•						
SV (14-day gap)	41,998	****	****	****	****	1.33	****	-5.84	****	0.18 ( 0.11, 0.29)	<0.001
ACEI (14-day gap)	41,998	****	****	****	****	7.17	****	-3.64		0.18 ( 0.11, 0.29)	<b>\0.001</b>
					0	- 30 Days					
<b>Site-Adjusted Analysis</b>											
SV (14-day gap)	41,998	****	****	****	****	0.9	****	-14.43	****	0.06 ( 0.02, 0.18)	< 0.001
ACEI (14-day gap)	695,012	****	****	****	****	15.33	****	14.43		0.00 ( 0.02,  0.10)	\0.001
Fixed Ratio 1:1 Proper	sity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	41,998	****	****	****	****	0.94	****	-17.83	****	0.05 ( 0.02, 0.16)	<0.001
ACEI (14-day gap)	41,998	****	****	****	****	18.76	****	-17.05		0.03 (0.02, 0.16)	<0.001
Fixed Ratio 1:1 Proper		tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	41,998	****	****	****	****	0.9	****	-17.22	****	0.05 ( 0.02, 0.16)	<0.001
ACEI (14-day gap)	41,998	****	****	****	****	18.12	****	-17.22		0.03 ( 0.02,  0.10)	<b>\0.001</b>
					31	- 60 Days					
Site-Adjusted Analysis											
SV (14-day gap)	38,241	****	****	****	****	1.55	****	-4.49	****	0.26 ( 0.10, 0.69)	0.007
ACEI (14-day gap)	638,495	****	****	****	****	6.05	****			0.20 (0.10, 0.03)	0.007
Fixed Ratio 1:1 Proper	sity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	34,662	****	****	****	****	1.95	****	-3.89	****	0.22 / 0.11 1.02\	0.057
ACEI (14-day gap)	34,662	****	****	****	****	5.84	****	-3.89		0.33 ( 0.11, 1.03)	0.057

cder\_mpl2r\_wp016 Page 32 of 247



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

						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	38,241	****	****	****	****	1.55	****	-3.29	****	0.32 ( 0.10, 0.98)	0.047
ACEI (14-day gap)	38,053	****	****	****	****	4.84	****	-3.29		0.32 ( 0.10, 0.36)	0.047
					61	- 90 Days					
Site-Adjusted Analysis											
SV (14-day gap)	25,273	****	****	****	****	2.11	****	-3.67	****	0.37 ( 0.14, 0.99)	0.047
ACEI (14-day gap)	463,109	****	****	****	****	5.78	****	3.07		0.57 ( 0.14, 0.55)	0.047
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	16,757	****	****	****	****	3.4	****	-0.85	****	0.80 ( 0.21, 2.98)	0.739
ACEI (14-day gap)	16,757	****	****	****	****	4.25	****	-0.85		0.80 ( 0.21, 2.38)	0.739
Fixed Ratio 1:1 Proper	nsity Score Ma			nalysis; Cal	•						
SV (14-day gap)	25,273	****	****	****	****	2.11	****	-3.05	****	0.41 ( 0.13, 1.29)	0.128
ACEI (14-day gap)	27,895	****	****	****	****	5.16	****	-3.03		0.41 ( 0.13, 1.23)	0.120
					91	- 180 Days					
Site-Adjusted Analysis											
SV (14-day gap)	20,547	****	****	****	****	1.66	****	-2.73	****	0.38 ( 0.17, 0.85)	0.019
ACEI (14-day gap)	397,838	****	****	****	****	4.39	****	2.75		0.55 ( 0.17 ) 0.05 )	0.013
Fixed Ratio 1:1 Proper	nsity Score Ma										
SV (14-day gap)	11,738	****	****	****	****	1.94	****	-5.18	****	0.27 ( 0.08, 0.98)	0.046
ACEI (14-day gap)	11,738	****	****	****	****	7.12	****	-5.16		0.27 (0.00, 0.30)	0.040
Fixed Ratio 1:1 Proper	-				•						
SV (14-day gap)	20,547	****	****	****	****	1.66	****	-2.81	****	0.37 ( 0.15,  0.92)	0.033
ACEI (14-day gap)	23,945	****	****	****	****	4.47	****	2.01		0.57 (0.15, 0.52)	<u> </u>
					181	- 270 Days					
Site-Adjusted Analysis											
SV (14-day gap)	11,098	****	****	****	****	0.93	****	-3.19	****	0.23 ( 0.06, 0.91)	0.037
ACEI (14-day gap)	235,612	****	****	****	****	4.12	****	3.13		5.25 ( 5.55, 5.51)	0.007

cder\_mpl2r\_wp016 Page 33 of 247



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

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval) <sup>2</sup>	Wald P-Value <sup>2</sup>
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Con	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	3,606	****	****	****	****	0	****	-6.97	****	-	-
ACEI (14-day gap)	3,606	****	****	****	****	6.97	****				
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Unc	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	11,098	****	****	****	****	0.93	****	-4.34	****	0.18 ( 0.04, 0.80)	0.024
ACEI (14-day gap)	13,550	****	****	****	****	5.28	****	-4.54			
					271	- 365 Days					
Site-Adjusted Analysi	is										
SV (14-day gap)	6,937	****	****	****	****	0.68	****	-2.87	****	0.19 ( 0.03, 1.33)	0.094
ACEI (14-day gap)	164,817	****	****	****	****	3.54	****	-2.07			
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Con	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	1,512	****	****	****	****	0	****	-7.46	****	-	-
ACEI (14-day gap)	1,512	****	****	****	****	7.46	****				
<b>Fixed Ratio 1:1 Prope</b>	ensity Score Ma	tched Unc	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	6,937	****	****	****	****	0.68	****	-1.48	****	0.33 ( 0.04, 2.97)	0.323
ACEI (14-day gap)	8,796	****	****	****	****	2.16	****				
1											

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 34 of 247

<sup>&</sup>lt;sup>2</sup>Data presented by a dash are unable to be calculated. This table may not use all data representations.

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



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

			Average	Average		Incidence Rate per		Incidence Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	•	Person Years	Users	Interval)	P-Value
No Angioedema (-18							11011 00010		000.0		
Site-Adjusted Analys	sis										
SV	41,941	****	****	****	****	1.07	****	-5.41	****	0.15 (0.09, 0.25)	<0.001
ACEI	694,148	****	****	****	****	6.47	****				
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	41,930	****	****	****	****	1.14	****	0.43	****	0.11 (0.06, 0.21)	<0.001
ACEI	41,930	****	****	****	****	10.56	****	-9.43			
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	41,930	****	****	****	****	1.07	****	-5.99	****	0.15 (0.09, 0.24)	<0.001
ACEI	41,930	****	****	****	****	7.06	****				
Angioedema (-183, -											
Site-Adjusted Analys											
SV	57	****	****	****	****	193.8	****	-74.4	****	0.75 (0.27, 2.07)	0.584
ACEI	864	****	****	****	****	268.2	****	-/			
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	42	****	****	****	****	355.03	****	118.34	****	1.50 (0.25, 8.98)	0.657
ACEI	42	****	****	****	****	236.69	****				0.037
Fixed Ratio 1:1 Prop	ensity Score Ma										
SV	42	****	****	****	****	195.82	****	81.21	****	1.97 (0.33, 11.91)	0.46
ACEI	42	****	****	****	****	114.61	****				0.40

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 35 of 247

<sup>\*\*\*\*\*</sup>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.



			_	_		Incidence		Incidence	D:"		
		_	Average	Average		Rate per		Rate	Difference	Hazard Ratio	
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per		344-1-1
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
No Angioedema (-183	, -1)										
						Overall					
Site-Adjusted Analysis											
SV (14-day gap)	41,941	****	****	****	****	1.07	****	-5.41	****	0.15 ( 0.09, 0.25)	< 0.001
ACEI (14-day gap)	694,148	****	****	****	****	6.47	****	5.41		0.15 ( 0.05,  0.25)	10.001
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	41,930	****	****	****	****	1.14	****	0.42	****	0.11 ( 0.00 , 0.21)	40 001
ACEI (14-day gap)	41,930	****	****	****	****	10.56	****	-9.43		0.11 ( 0.06, 0.21)	<0.001
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	41,930	****	****	****	****	1.07	****	-5.99	****	0.15 ( 0.09, 0.24)	<0.001
ACEI (14-day gap)	41,930	****	****	****	****	7.06	****	-5.99		0.15 (0.09, 0.24)	<0.001
					0	- 30 Days					
Site-Adjusted Analysis	5										
SV (14-day gap)	41,941	****	****	****	****	0.3	****	-14.16	****	0.02 ( 0.00, 0.15)	<0.001
ACEI (14-day gap)	694,148	****	****	****	****	14.46	****	-14.10		0.02 (0.00, 0.13)	<0.001
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	41,930	****	****	****	****	0.31	****	40.47	****	0.03 ( 0.00 . 0.43)	.0.004
ACEI (14-day gap)	41,930	****	****	****	****	18.48	****	-18.17	****	0.02 ( 0.00, 0.12)	<0.001
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	41,930	****	****	****	****	0.3	****	47.55	****	0.00 / 0.00 .0.10	0.004
ACEI (14-day gap)	41,930	****	****	****	****	17.85	****	-17.55	***	0.02 ( 0.00, 0.12)	<0.001
, , , , , , , ,	·				31	- 60 Days					
Site-Adjusted Analysis	5					•					
SV (14-day gap)	38,191	****	****	****	****	1.55	****	4.10	****	0.27 / 0.40 . 0.72\	0.01
ACEI (14-day gap)	637,749	****	****	****	****	5.74	****	-4.19	<b>ጥጥጥጥ</b>	0.27 ( 0.10, 0.73)	0.01

cder\_mpl2r\_wp016 Page 36 of 247



			Average	Average		Incidence Rate per		Incidence Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	<b>Hazard Ratio</b>	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	<b>Events</b>	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Propen	sity Score Ma	tched Cond	litional Ana	ysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	34,610	****	****	****	****	1.95	****	2.0	****	0.22 / 0.11 1.02)	0.057
ACEI (14-day gap)	34,610	****	****	****	****	5.84	****	-3.9		0.33 ( 0.11, 1.03)	0.057
Fixed Ratio 1:1 Propen	sity Score Ma	tched Unco	nditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	38,182	****	****	****	****	1.55	****	-3.3	****	0.32 ( 0.10, 0.98)	0.047
ACEI (14-day gap)	37,993	****	****	****	****	4.85	****	-3.3		0.52 ( 0.10, 0.96)	0.047
					61	- 90 Days					
Site-Adjusted Analysis											
SV (14-day gap)	25,238	****	****	****	****	1.58	****	-4.06	****	0.28 ( 0.09, 0.88)	0.03
ACEI (14-day gap)	462,621	****	****	****	****	5.65	****	-4.00		0.28 ( 0.09, 0.88)	0.03
Fixed Ratio 1:1 Propen	sity Score Ma	tched Cond	litional Ana	ysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	16,735	****	****	****	****	2.55	****	1 7	****	0.60 / 0.14 (2.51)	0.494
ACEI (14-day gap)	16,735	****	****	****	****	4.25	****	-1.7		0.60 ( 0.14, 2.51)	0.484
Fixed Ratio 1:1 Propen	sity Score Ma				•						
SV (14-day gap)	25,233	****	****	****	****	1.58	****	-3.58	****	0.31 ( 0.09, 1.10)	0.07
ACEI (14-day gap)	27,852	****	****	****	****	5.16	****	-3.38		0.51 (0.05, 1.10)	0.07
					91 -	- 180 Days					
Site-Adjusted Analysis											
SV (14-day gap)	20,519	****	****	****	****	1.39	****	-2.94	****	0.32 ( 0.13, 0.78)	0.012
ACEI (14-day gap)	397,439	****	****	****	****	4.32	****	2.57		0.52 ( 0.15,  0.76)	0.012
Fixed Ratio 1:1 Propen	sity Score Ma	tched Cond	litional Ana	ysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	11,721	****	****	****	****	1.3	****	-5.84	****	0.18 ( 0.04, 0.82)	0.027
ACEI (14-day gap)	11,721	****	****	****	****	7.13	****	-3.04		0.10 ( 0.04, 0.82)	0.027
Fixed Ratio 1:1 Propen	sity Score Ma	tched Unco	nditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	20,515	****	****	****	****	1.39	****	-3.09	****	0.31 ( 0.11,  0.82)	0.018
ACEI (14-day gap)	23,905	****	****	****	****	4.48	****	-3.09		0.31 (0.11, 0.02)	0.010

cder\_mpl2r\_wp016 Page 37 of 247



			Average	Average		Incidence		Incidence Rate	Difference		
		Person	Average Person	Average Person	Number	Rate per 1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years		Years	of	Person	-		-	(95% Confidence	Wald
			Days		_		1,000	per 1,000	1,000 New	•	
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Cito Adiustad Analysis					181	- 270 Days					
Site-Adjusted Analysis		****	****	****	****	0.03	****				
SV (14-day gap)	11,083	****	****	****	****	0.93	****	-3.15	****	0.23 (0.06, 0.92)	0.038
ACEI (14-day gap)	235,412					4.08	46 46 46 46			<u> </u>	
Fixed Ratio 1:1 Proper											
SV (14-day gap)	3,599	****	****	****	****	0	****	-6.98	****	-	_
ACEI (14-day gap)	3,599	****	****	****	****	6.98	****	0.50			
Fixed Ratio 1:1 Proper	nsity Score Ma				•						
SV (14-day gap)	11,082	****	****	****	****	0.93	****	-3.97	****	0.20 ( 0.04, 0.87)	0.032
ACEI (14-day gap)	13,529	****	****	****	****	4.91	****	-3.57		0.20 ( 0.04, 0.87)	0.032
					271	- 365 Days					
Site-Adjusted Analysis	3										
SV (14-day gap)	6,928	****	****	****	****	0.68	****	-2.78	****	0.19 ( 0.03, 1.36)	0.099
ACEI (14-day gap)	164,674	****	****	****	****	3.46	****	-2.76		0.19 (0.05, 1.50)	0.099
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	1,509	****	****	****	****	0	****	7.45	****		
ACEI (14-day gap)	1,509	****	****	****	****	7.45	****	-7.45	***	-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	6,927	****	****	****	****	0.68	****	4.40	****	0.22 ( 0.04 . 2.07)	0.222
ACEI (14-day gap)	8,783	****	****	****	****	2.17	****	-1.49	***	0.33 ( 0.04, 2.97)	0.323
Angioedema (-183, -1)	<u> </u>										
						Overall					
Site-Adjusted Analysis	3										
SV (14-day gap)	57	****	****	****	****	193.8	****			0.75 / 0.07 .0.55)	
ACEI (14-day gap)	864	****	****	****	****	268.2	****	-74.4	****	0.75 ( 0.27, 2.07)	0.584

cder\_mpl2r\_wp016 Page 38 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	42	****	****	****	****	355.03	****	110.24	****	1 [0 / 0 2	0.657
ACEI (14-day gap)	42	****	****	****	****	236.69	****	118.34		1.50 ( 0.25, 8.98)	0.657
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	42	****	****	****	****	195.82	****	81.21	****	1.97 ( 0.33, 11.91)	0.46
ACEI (14-day gap)	42	****	****	****	****	114.61	****	81.21		1.97 (0.33, 11.91)	0.46
					0	- 30 Days					
Site-Adjusted Analysis	5										
SV (14-day gap)	453	****	****	****	****	301.66	****	-146.73	****	0.57 ( 0.14, 2.34)	0.432
ACEI (14-day gap)	8,744	****	****	****	****	448.39	****	-140.73		0.57 (0.14, 2.54)	0.432
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	630	****	****	****	****	40	****	0	****	1 00 / 0 06 15 00)	1
ACEI (14-day gap)	630	****	****	****	****	40	****	0		1.00 ( 0.06, 15.99)	1
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	4,023	****	****	****	****	6.84	****	1.71	****	1.04/0.07.16.67\	0.976
ACEI (14-day gap)	5,300	****	****	****	****	5.12	****	1./1		1.04 ( 0.07, 16.67)	0.976
					31	- 60 Days					
Site-Adjusted Analysis											
SV (14-day gap)	50	****	****	****	****	0	****	-276.46	****	_	_
ACEI (14-day gap)	749	****	****	****	****	276.46	****	-270.40		_	
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	95	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	95	****	****	****	****	0	****	0	THE THE THE THE	-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	371	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	536	****	****	****	****	0	****	U		-	-

cder\_mpl2r\_wp016 Page 39 of 247



			_	_		Incidence		Incidence			
		_	Average	Average		Rate per	<b>5</b> ' 1	Rate	Difference	Hazard Ratio	
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per		Wald
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
					61	- 90 Days					
Site-Adjusted Analysis		de de de de de		de de de de de	de de de de de		district di				
SV (14-day gap)	35	****	****	****	****	387.6	****	253.22	****	3.57 (0.42, 30.57)	0.245
ACEI (14-day gap)	497	****	****	****	****	134.37	****				
Fixed Ratio 1:1 Proper	nsity Score Ma										
SV (14-day gap)	91	****	****	****	****	162.07	****	162.07	****	_	_
ACEI (14-day gap)	91	****	****	****	****	0	****	102.07		_	_
Fixed Ratio 1:1 Proper	nsity Score Ma				•						
SV (14-day gap)	360	****	****	****	****	34.19	****	34.19	****	_	_
ACEI (14-day gap)	524	****	****	****	****	0	****	34.19		_	
					91	- 180 Days					
<b>Site-Adjusted Analysis</b>	1										
SV (14-day gap)	28	****	****	****	****	190.84	****	117.12	****	2.92 ( 0.33, 25.76)	0.335
ACEI (14-day gap)	408	****	****	****	****	73.72	****	117.12		2.92 ( 0.33, 23.70)	0.333
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	70	****	****	****	****	242.13	****	242.42	****		
ACEI (14-day gap)	70	****	****	****	****	0	****	242.13		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	352	****	****	****	****	63.49	****	63.49	****		
ACEI (14-day gap)	521	****	****	****	****	0	****	63.49		-	-
					181	- 270 Days					
Site-Adjusted Analysis	}										
SV (14-day gap)	18	****	****	****	****	0	****	40.22	****		
ACEI (14-day gap)	202	****	****	****	****	48.23	****	-48.23	*** *** *** ***	-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	****	****	****	****	****	0	****	660.05	****		
ACEI (14-day gap)	****	****	****	****	****	662.25	****	-662.25	<b>ተ</b> ተ ተ ተ ተ	-	-

cder\_mpl2r\_wp016 Page 40 of 247



		Person	Average Person	Average Person	Number	Incidence Rate per 1,000	Risk per	Incidence Rate Difference	Difference in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	per= 0.05						
SV (14-day gap)	14	****	****	****	****	0	****	206.75	****		
ACEI (14-day gap)	15	****	****	****	****	306.75	****	-306.75		-	-
					271	- 365 Days					
Site-Adjusted Analysis	5										
SV (14-day gap)	12	****	****	****	****	0	****	04.4	****		
ACEI (14-day gap)	145	****	****	****	****	94.4	****	-94.4		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	****	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	****	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	per= 0.05						
SV (14-day gap)	****	****	****	****	****	0	****	0	****		_
ACEI (14-day gap)	11	****	****	****	****	0	****	0		<u>-</u>	<u>-</u>

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 41 of 247

<sup>&</sup>lt;sup>2</sup>Data presented by a dash are unable to be calculated. This table may not use all data representations.

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



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

			Average	Average		Incidence Rate per		Incidence Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	` Interval)	P-Value
No Angioedema (eve	er, -1)										
Site-Adjusted Analys	sis										
SV	41,427	****	****	****	****	1.01	****	-4.86	****	0.16 (0.10, 0.27)	<0.001
ACEI	687,692	****	****	****	****	5.87	****	-4.80		0.16 (0.10, 0.27)	<0.001
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	41,416	****	****	****	****	1.04	****	-8.4	****	0.11 (0.06 0.33)	<0.001
ACEI	41,416	****	****	****	****	9.43	****	-8.4		0.11 (0.06, 0.22)	<0.001
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	41,416	****	****	****	****	1.01	****	-5.41	****	0.15 (0.09, 0.26)	<0.001
ACEI	41,416	****	****	****	****	6.43	****	-5.41		0.13 (0.03, 0.20)	<0.001
Angioedema (ever, -	•										
Site-Adjusted Analys	sis										
SV	571	****	****	****	****	24.05	****	-73.01	****	0.24 (0.10, 0.59)	0.002
ACEI	7,320	****	****	****	****	97.06	****	-75.01		0.24 (0.10, 0.33)	0.002
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	437	****	****	****	****	47.03	****	-58.79	****	0.44 (0.14, 1.44)	0.177
ACEI	437	****	****	****	****	105.82	****	-30./3		0.44 (0.14, 1.44)	0.177
Fixed Ratio 1:1 Prop	ensity Score Ma			nalysis; Cali							
SV	437	****	****	****	****	31.92	****	-50.6	****	0.38 (0.14, 1.07)	0.067
ACEI	437	****	****	****	****	82.51	****	-50.0		0.56 (0.14, 1.07)	0.007

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 42 of 247

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



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

				_		Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	<b>Person Years</b>	Users	Interval)	P-Value
No Serious Allergies											
Site-Adjusted Analysis	S										
SV	36,314	****	****	****	****	1.14	****	-5.33	****	0.17 (0.10, 0.27)	<0.001
ACEI	584,032	****	****	****	****	6.47	****	-5.55		0.17 (0.10, 0.27)	<0.001
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	36,159	****	****	****	****	1.42	****	0.01	****	0.14 (0.07, 0.36)	40 001
ACEI	36,159	****	****	****	****	10.34	****	-8.91		0.14 (0.07, 0.26)	<0.001
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	36,159	****	****	****	****	1.14	****	-5.77	****	0.16 (0.09, 0.27)	<0.001
ACEI	36,159	****	****	****	****	6.92	****	-5.77		0.10 (0.09, 0.27)	<0.001
Serious Allergies											
Site-Adjusted Analysis	S										
SV	5,684	****	****	****	****	2.67	****	-5.62	****	0.31 (0.13, 0.75)	0.009
ACEI	110,980	****	****	****	****	8.29	****	-3.02		0.31 (0.13, 0.73)	0.009
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	5,545	****	****	****	****	1.92	****	0.65	****	0.10 (0.04 0.03)	0.037
ACEI	5,545	****	****	****	****	10.58	****	-8.65	Ten nen nen nen nen	0.18 (0.04, 0.82)	0.027
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	per= 0.05						
SV	5,545	****	****	****	****	2.73	****	-6.64	****	0.29 (0.11, 0.79)	0.015
ACEI	5,545	****	****	****	****	9.37	****	-0.04		0.29 (0.11, 0.79)	0.015

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 43 of 247

<sup>\*\*\*\*\*</sup>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.



	Number of	Person Years	Average Person Days	Average Person Years	Number of	Incidence Rate per 1,000 Person	Risk per 1,000	Rate Difference per 1,000 Person	Difference in Risk per 1,000	Hazard Ratio (95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Years	New Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Sex: Male											
						Overall					
Site-Adjusted Analysis	5										
SV (14-Day Gap)	27,131	****	****	****	****	0.93	****	Г ОГ	****	0.14 / 0.07 (0.38)	<0.001
ACEI (14-Day Gap)	353,126	****	****	****	****	5.98	****	-5.05		0.14 ( 0.07, 0.28)	<0.001
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-Day Gap)	26,865	****	****	****	****	1.23	****	0.43	****	0.43 ( 0.05 . 0.36)	.0.004
ACEI (14-Day Gap)	26,865	****	****	****	****	10.36	****	-9.13	****	0.12 ( 0.05, 0.26)	<0.001
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-Day Gap)	26,865	****	****	****	****	0.94	****	C 12	****	0.13 / 0.00 0.35)	10,001
ACEI (14-Day Gap)	26,865	****	****	****	****	7.06	****	-6.13		0.13 ( 0.06, 0.25)	<0.001
					0	- 30 Days					
Site-Adjusted Analysis	S										
SV (14-Day Gap)	27,131	****	****	****	****	0.46	****	-14.14	****	0.03 ( 0.00, 0.23)	<0.001
ACEI (14-Day Gap)	353,126	****	****	****	****	14.6	****	-14.14		0.03 ( 0.00, 0.23)	<b>\0.001</b>
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-Day Gap)	26,865	****	****	****	****	0.49	****	-20.49	****	0.03 / 0.00 .0.17)	<0.001
ACEI (14-Day Gap)	26,865	****	****	****	****	20.97	****	-20.49		0.02 ( 0.00, 0.17)	<0.001
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-Day Gap)	26,865	****	****	****	****	0.47	****	10.01	****	0.02 ( 0.00 .0.17)	<0.001
ACEI (14-Day Gap)	26,865	****	****	****	****	20.28	****	-19.81		0.02 ( 0.00, 0.17)	<0.001
					31	- 60 Days					
Site-Adjusted Analysis	S										
SV (14-Day Gap)	24,802	****	****	****	****	1.8	****	-3.8	****	0.32 ( 0.10, 1.01)	0.052
ACEI (14-Day Gap)	325,651	****	****	****	****	5.59	****	-3.0		0.32 (0.10, 1.01)	0.032

cder\_mpl2r\_wp016 Page 44 of 247



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

Medical Product  Fixed Ratio 1:1 Prope  SV (14-Day Gap)  ACEI (14-Day Gap)	Number of New Users nsity Score Ma 22,346 22,346	Person Years at Risk tched Cond *****	Average Person Days at Risk ditional Ana *****	Average Person Years at Risk lysis; Calipe *****	Number of Events er= 0.05 <sup>1</sup> *****	Incidence Rate per 1,000 Person Years 2.26 3.76	Risk per 1,000 New Users	Rate Difference per 1,000 Person Years -1.51	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval) <sup>2</sup> 0.60 ( 0.14, 2.51)	Wald P-Value <sup>2</sup>
Fixed Ratio 1:1 Prope SV (14-Day Gap) ACEI (14-Day Gap)	nsity Score Ma 24,557 24,423	***** ****	enditional A	***** ****	iper= 0.05 ***** ****	1.81 4.05	****	-2.24	****	0.45 ( 0.12, 1.72)	0.241
					61	- 90 Days					
Site-Adjusted Analysi SV (14-Day Gap) ACEI (14-Day Gap) Fixed Ratio 1:1 Prope	16,352 236,828	***** *****	*****  ****	***** *****	***** *****	0.81 4.74	****	-3.92	****	0.17 ( 0.02, 1.25)	0.082
SV (14-Day Gap) ACEI (14-Day Gap) Fixed Ratio 1:1 Prope	10,859 10,859	****	*****	*****	*****	1.31 5.23	****	-3.92	****	0.25 ( 0.03, 2.24)	0.215
SV (14-Day Gap) ACEI (14-Day Gap)	16,184 18,020	****	****	****	*****	0.82 6.52	****	-5.7	****	0.13 ( 0.02, 1.00)	0.05
					91	- 180 Days					
Site-Adjusted Analysi SV (14-Day Gap) ACEI (14-Day Gap)	13,315 203,967	****	****	****	****	0.86 3.5	****	-2.64	****	0.25 ( 0.06, 1.00)	0.05
Fixed Ratio 1:1 Prope SV (14-Day Gap) ACEI (14-Day Gap)	7,652 7,652	****	*****	*****	*****	2.01 2.01	****	0	****	1.00 ( 0.14, 7.10)	1
Fixed Ratio 1:1 Prope SV (14-Day Gap) ACEI (14-Day Gap)	13,180 15,521	**** *****	***** *****	***** *****	*****	0.87 2.92	****	-2.05	****	0.30 ( 0.06, 1.39)	0.123
Cit - Adinoted A					181	- 270 Days					
Site-Adjusted Analysi SV (14-Day Gap) ACEI (14-Day Gap)	7,179 120,304	****	****	****	*****	0.72 3.4	****	-2.68	****	0.21 ( 0.03, 1.51)	0.121
Fixed Ratio 1:1 Prope SV (14-Day Gap)	2,354	*****	ditional Ana ****	lysis; Calipe	er= 0.05 <sup>+</sup> *****	0	****	-10 56	****	-	-

cder\_mpl2r\_wp016 Page 45 of 247



Medical Product  ACEI (14-Day Gap)  Fixed Ratio 1:1 Prope	Number of New Users 2,354	Person Years at Risk ****	Average Person Days at Risk ****	Average Person Years at Risk *****	Number of Events *****	Incidence Rate per 1,000 Person Years 10.56	Risk per 1,000 New Users ****	Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval) <sup>2</sup>	Wald P-Value <sup>2</sup>
SV (14-Day Gap) ACEI (14-Day Gap)	7,102 8,784	*****	****	***** ****	*****	0.73 5.21	****	-4.48	****	0.14 ( 0.02, 1.14)	0.067
					271	- 365 Days					
Site-Adjusted Analysi SV (14-Day Gap) ACEI (14-Day Gap)	4,493 84,166	****	****	****	****	1.06 2.91	*****	-1.85	****	0.35 ( 0.05, 2.52)	0.295
Fixed Ratio 1:1 Prope SV (14-Day Gap) ACEI (14-Day Gap)	1,015 1,015 1,015	***** ****	***** *****	!ysis; Calipe ***** ****	er= 0.05 <sup>1</sup> ***** ****	0 5.59	****	-5.59	****	-	-
Fixed Ratio 1:1 Prope SV (14-Day Gap) ACEI (14-Day Gap)	<b>nsity Score Ma</b> 4,445 5,717	***** ****	***** *****	nalysis; Cal **** ****	iper= 0.05 ***** ****	1.07 0.83	****	0.23	****	1.32 ( 0.08, 21.08)	0.845
Sex: Female						Overall					
Site-Adjusted Analysi SV (14-Day Gap) ACEI (14-Day Gap)	14,867 341,886	****	****	****	****	2.07 7.52	****	-5.45	****	0.26 ( 0.14,  0.47)	<0.001
Fixed Ratio 1:1 Prope SV (14-Day Gap) ACEI (14-Day Gap)	nsity Score Ma 14,820 14,820	***** ****	***** *****	lysis; Calipe ***** *****	er= 0.05 <sup>1</sup> *****	1.62 10.04	****	-8.42	****	0.16 ( 0.06, 0.41)	<0.001
Fixed Ratio 1:1 Prope SV (14-Day Gap) ACEI (14-Day Gap)	nsity Score Ma 14,820 14,820	***** ****	***** *****	nalysis; Cal *****	iper= 0.05 *****	2.07 7.32	****	-5.25	****	0.28 ( 0.14, 0.54)	<0.001
ACLI (14-Day Gap)	17,020					- 30 Days					
Site-Adjusted Analysi	S					-3 - 4,5					
SV (14-Day Gap) ACEI (14-Day Gap)	14,867 341,886	****	****	****	****	1.7 16.09	****	-14.39	****	0.11 ( 0.03, 0.42)	0.001
Fixed Ratio 1:1 Prope											
SV (14-Day Gap) ACEI (14-Day Gap)	14,820 14,820	****	****	*****	****	0.89 15.12	****	-14.23	****	0.06 ( 0.01, 0.44)	0.006

cder\_mpl2r\_wp016 Page 46 of 247



Medical Product Fixed Ratio 1:1 Prope	Number of New Users nsity Score Ma 14,820	Person Years at Risk tched Uncc ****	Average Person Days at Risk onditional A	Average Person Years at Risk nalysis; Cal	Number of Events iper= 0.05	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval) <sup>2</sup>	Wald P-Value <sup>2</sup>
SV (14-Day Gap) ACEI (14-Day Gap)	14,820 14,820	****	****	****	****	1.71 14.57	****	-12.86	****	0.12 ( 0.03, 0.51)	0.004
ACLI (14-Day Gap)	14,020				31	- 60 Days					
Site-Adjusted Analysis	 S										
SV (14-Day Gap)	13,439	****	****	****	****	1.1	****	5.42	****	0.47 / 0.02 .4.22)	0.070
ACEI (14-Day Gap)	312,844	****	****	****	****	6.52	****	-5.42	****	0.17 ( 0.02, 1.22)	0.078
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-Day Gap)	12,080	****	****	****	****	0	****	6.00	****		
ACEI (14-Day Gap)	12,080	****	****	****	****	6.99	****	-6.99	****	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-Day Gap)	13,397	****	****	****	****	1.1	****	-5.29	****	0.17 ( 0.02, 1.45)	0.106
ACEI (14-Day Gap)	13,360	****	****	****	****	6.4	****	-5.29		0.17 (0.02, 1.43)	0.106
					61	- 90 Days					
Site-Adjusted Analysis											
SV (14-Day Gap)	8,921	****	****	****	****	4.49	****	-2.39	****	0.65 ( 0.21, 2.03)	0.456
ACEI (14-Day Gap)	226,281	****	****	****	****	6.88	****			0.03 ( 0.21, 2.03)	0.450
Fixed Ratio 1:1 Prope	nsity Score Ma		ditional Ana	lysis; Calipe							
SV (14-Day Gap)	5,806	****	****	****	****	7.38	****	4.92	****	3.00 ( 0.31, 28.84)	0.341
ACEI (14-Day Gap)	5,806	****	****	****	****	2.46	****	4.52		3.00 ( 0.31, 28.84)	0.541
Fixed Ratio 1:1 Prope	•				•						
SV (14-Day Gap)	8,894	****	****	****	****	4.5	****	1.79	****	1.69 ( 0.28, 10.10)	0.567
ACEI (14-Day Gap)	9,686	****	****	****	****	2.71	****	1.75		1.03 ( 0.20, 10.10)	0.507
					91	- 180 Days					
Site-Adjusted Analysis		ala ala ala ala al-	ale ale ale ale al	ala ala ala ala al	ale ale ale ale		ale ale ale ale				
SV (14-Day Gap)	7,232	****	****	****	****	3.12	****	-2.19	****	0.58 ( 0.21, 1.55)	0.277
ACEI (14-Day Gap)	193,871	****	****	****	****	5.31	****			- ( - , )	
Fixed Ratio 1:1 Prope											
SV (14-Day Gap)	4,049	****	****	****	****	0	****	-12.91	****	-	-
ACEI (14-Day Gap)	4,049	****	****	****	****	12.91	****				
Fixed Ratio 1:1 Prope	•	tched Unco	onditional A	nalysis; Cal	iper= 0.05 ****		****				
SV (14-Day Gap)	7,208	****	****	****	****	3.13	****	_/I Q1	****	N // 2 / N 12 1 21 \	∩ 12 <i>/</i> I

cder\_mpl2r\_wp016 Page 47 of 247



Medical Product ACEI (14-Day Gap)	Number of New Users 8,263	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years 7.45	Risk per 1,000 New Users *****	Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval) <sup>2</sup>	Wald P-Value <sup>2</sup>
, , , , ,	,				181	- 270 Days					
Site-Adjusted Analysis											
SV (14-Day Gap)	3,919	****	****	****	****	1.32	****	-3.54	****	0.30 / 0.04 1.07)	0.100
ACEI (14-Day Gap)	115,308	****	****	****	****	4.86	****	-3.54		0.28 ( 0.04, 1.97)	0.199
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-Day Gap)	1,256	****	****	****	****	4.98	****	0	****	1.00 / 0.00 15.00)	1
ACEI (14-Day Gap)	1,256	****	****	****	****	4.98	****	0		1.00 ( 0.06, 15.99)	1
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.0 <mark>5</mark>						
SV (14-Day Gap)	3,911	****	****	****	****	1.32	****	-3.06	****	** 0.31 ( 0.03,  2.74)	0.289
ACEI (14-Day Gap)	4,690	****	****	****	****	4.38	****	-5.06		0.31 (0.03, 2.74)	0.289

cder\_mpl2r\_wp016 Page 48 of 247



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

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval) <sup>2</sup>	Wald P-Value <sup>2</sup>
					271	- 365 Days					
Site-Adjusted Analysis	S										
SV (14-Day Gap)	2,444	****	****	****	****	0	****	4.24	****		
ACEI (14-Day Gap)	80,651	****	****	****	****	4.21	****	-4.21		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-Day Gap)	538	****	****	****	****	0	****	0	****		
ACEI (14-Day Gap)	538	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unc	onditional A	nalysis; Cali	iper= 0.05						
SV (14-Day Gap)	2,441	****	****	****	****	0	****	4.60	****		
ACEI (14-Day Gap)	3,036	****	****	****	****	4.69	****	-4.69		-	-

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 49 of 247

<sup>&</sup>lt;sup>2</sup>Data presented by a dash are unable to be calculated. This table may not use all data representations.

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



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

						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	<b>Events</b>	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Age Group: 18-44 ye	ears										
Site-Adjusted Analys	sis										
SV	1,538	****	****	****	****	1.95	****	-7.2	****	0.23 (0.03, 1.65)	0.143
ACEI	21,594	****	****	****	****	9.15	****	-7.2		0.23 (0.03, 1.03)	0.143
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	1,408	****	****	****	****	3.99	****	0	****	1.00 (0.00 15.00)	1
ACEI	1,408	****	****	****	****	3.99	****	0		1.00 (0.06, 15.99)	1
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV	1,408	****	****	****	****	2.11	****	-2.13	****	0.53 (0.05, 5.85)	0.601
ACEI	1,408	****	****	****	****	4.24	****	-2.15		0.55 (0.05, 5.65)	0.601
Age Group: 45-54 ye	ears										
Site-Adjusted Analys	sis										
SV	2,863	****	****	****	****	1.01	****	-9.27	****	0.10 (0.01, 0.69)	0.02
ACEI	45,064	****	****	****	****	10.28	****	-9.27		0.10 (0.01, 0.69)	0.02
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	2,789	****	****	****	****	0	****	20.26	****		
ACEI	2,789	****	****	****	****	20.26	****	-20.26	4 4 4 4 4	-	-
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV	2,789	****	****	****	****	1.04	****	-11.43	****	0.09 (0.01 0.63)	0.015
ACEI	2,789	****	****	****	****	12.47	****	-11.43		0.08 (0.01, 0.62)	0.015
Age Group: 55-64 ye	ears										
Site-Adjusted Analys	sis										
SV	5,807	****	****	****	****	1.97	****	6.04	****	0.33 (0.09 .0.50)	0.003
ACEI	97,267	****	****	****	****	8.91	****	-6.94		0.22 (0.08, 0.59)	0.003
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	5,692	****	****	****	****	2.64	****	10.55	****	0.30 (0.00 0.00)	0.011
ACEI	5,692	****	****	****	****	13.19	****	-10.55	4. 4. 4. 4. 4.	0.20 (0.06, 0.69)	0.011

cder\_mpl2r\_wp016 Page 50 of 247



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

						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	<b>Events</b>	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	5,692	****	****	****	****	2.01	****	-7.62	****	0.21 (0.07, 0.62)	0.004
ACEI	5,692	****	****	****	****	9.63	****	-7.02		0.21 (0.07, 0.02)	0.004
Age Group: ≥65 year	rs										
Site-Adjusted Analys	sis										
SV	31,790	****	****	****	****	1.22	****	1 01	****	0.10/0.11 0.22\	<0.001
ACEI	531,087	****	****	****	****	6.03	****	-4.81		0.19 (0.11, 0.32)	<0.001
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	31,082	****	****	****	****	1.5	****	-8.09	****	0.16 (0.08, 0.30)	<0.001
ACEI	31,082	****	****	****	****	9.59	****	-6.09		0.10 (0.06, 0.50)	<0.001
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	31,082	****	****	****	****	1.24	****	-5.16	****	0.18 (0.10, 0.33)	<0.001
ACEI	31,082	****	****	****	****	6.4	****	-5.10		0.16 (0.10, 0.33)	<b>\0.001</b>

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 51 of 247

<sup>&</sup>lt;sup>2</sup>Data presented by a dash are unable to be calculated. This table may not use all data representations.

<sup>\*\*\*\*\*</sup>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.



			Average	Average		Incidence Rate per		Incidence Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Age Group: 18-44											
						Overall					
Site-Adjusted Analysis											
SV (14-day gap)	1,538	****	****	****	****	1.95	****	-7.2	****	0.23 ( 0.03, 1.65)	0.143
ACEI (14-day gap)	21,594	****	****	****	****	9.15	****	7.2		0.23 ( 0.03, 1.03)	0.145
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	1,408	****	****	****	****	3.99	****	0	****	1.00 ( 0.06, 15.99)	1
ACEI (14-day gap)	1,408	****	****	****	****	3.99	****	U		1.00 (0.06, 15.99)	1
Fixed Ratio 1:1 Proper	nsity Score Ma		onditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	1,408	****	****	****	****	2.11	****	-2.13	****	0.53 ( 0.05, 5.85)	0.601
ACEI (14-day gap)	1,408	****	****	****	****	4.24	****	-2.15		0.55 (0.05, 5.65)	0.601
					0	- 30 Days					
Site-Adjusted Analysis	1										
SV (14-day gap)	1,538	****	****	****	****	0	****	-18.03	****	_	_
ACEI (14-day gap)	21,594	****	****	****	****	18.03	****	-10.03			_
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	1,396	****	****	****	****	0	****	-9.47	****		
ACEI (14-day gap)	1,396	****	****	****	****	9.47	****	-9.47		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	1,406	****	****	****	****	0	****	-9.06	****		
ACEI (14-day gap)	1,469	****	****	****	****	9.06	****	-9.06		-	
					31	- 60 Days					
Site-Adjusted Analysis											
SV (14-day gap)	1,414	****	****	****	****	0	****	-8.33	****		
ACEI (14-day gap)	20,001	****	****	****	****	8.33	****	-6.55			
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	1,158	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	1,158	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	nditional A	nalysis; Cali							
SV (14-day gap)	1,293	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	1,256	****	****	****	****	0	****	0		-	-
					61	- 90 Days					

cder\_mpl2r\_wp016 Page 52 of 247



Medical Product Site-Adjusted Analysis	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval) <sup>2</sup>	Wald P-Value <sup>2</sup>
SV (14-day gap)	891	****	****	****	****	0	****				
ACEI (14-day gap)	12,616	****	****	****	****	7.41	****	-7.41	****	-	-
Fixed Ratio 1:1 Proper		tched Conc	litional Ana	lysis: Caline	r= 0.05 <sup>1</sup>	7.71					
SV (14-day gap)	485	****	****	****	****	0	****				
ACEI (14-day gap)	485	****	****	****	****	0	****	0	****	-	-
Fixed Ratio 1:1 Proper		tched Unco	nditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	824	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	817	****	****	****	****	0	****	0		-	-
					91	- 180 Days					
Site-Adjusted Analysis	S										
SV (14-day gap)	673	****	****	****	****	8.49	****	2.65	****	1.82 ( 0.23, 14.38)	0.571
ACEI (14-day gap)	10,173	****	****	****	****	5.84	****	2.03		1.02 ( 0.23, 14.30)	0.571
Fixed Ratio 1:1 Prope	nsity Score Ma										
SV (14-day gap)	294	****	****	****	****	28.34	****	28.34	****	_	_
ACEI (14-day gap)	294	****	****	****	****	0	****	20.34			
Fixed Ratio 1:1 Proper	nsity Score Ma				-						
SV (14-day gap)	624	****	****	****	****	9.12	****	0.13	****	1.10 ( 0.07, 17.82)	0.947
ACEI (14-day gap)	659	****	****	****	****	8.99	****	0.15		1.10 ( 0.07, 17.02)	0.547
					181	- 270 Days					
Site-Adjusted Analysis											
SV (14-day gap)	362	****	****	****	****	0	****	-7.89	****	-	-
ACEI (14-day gap)	5,186	****	****	****	****	7.89	****				

cder\_mpl2r\_wp016 Page 53 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Propen	sity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	71	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	71	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Propen	sity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	338	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	335	****	****	****	****	0	****	U		-	-
					271	- 365 Days					
Site-Adjusted Analysis											
SV (14-day gap)	214	****	****	****	****	0	****	-1.38	****	_	_
ACEI (14-day gap)	3,345	****	****	****	****	1.38	****	-1.56		_	
Fixed Ratio 1:1 Propen	sity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	26	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	26	****	****	****	****	0	****	U		-	-
		tched Unco	onditional A	nalysis; Cal	iper= 0.05						
Fixed Ratio 1:1 Propen	isity Score Ma	terred office					****				
Fixed Ratio 1:1 Propen SV (14-day gap)	205	****	****	****	****	0	****	0	****		
			****	*****	*****	0 0	****	0	****	-	-
SV (14-day gap)	205	****				•		0	****	-	
SV (14-day gap) ACEI (14-day gap) Age Group: 45-54	205 202	****			****	•		0	****	-	-
SV (14-day gap) ACEI (14-day gap) Age Group: 45-54 Site-Adjusted Analysis	205 202	****	****	****	****	0 Overall	****	0	****	-	-
SV (14-day gap) ACEI (14-day gap) Age Group: 45-54	205 202 2,863	****	****	****	****	Overall 1.01	****		****	0.10 ( 0.01   0.69)	0.02
SV (14-day gap) ACEI (14-day gap) Age Group: 45-54  Site-Adjusted Analysis SV (14-day gap) ACEI (14-day gap)	205 202 2,863 45,064	***** ***** *****	****	****	*****	0 Overall	****	-9.27		0.10 ( 0.01, 0.69)	0.02
SV (14-day gap) ACEI (14-day gap) Age Group: 45-54  Site-Adjusted Analysis SV (14-day gap)	205 202 2,863 45,064	*****  ****  ****  tched Cond	****	****	***** ***** er= 0.05 <sup>1</sup>	Overall 1.01	****			0.10 ( 0.01, 0.69)	0.02
SV (14-day gap) ACEI (14-day gap) Age Group: 45-54  Site-Adjusted Analysis SV (14-day gap) ACEI (14-day gap)	205 202 2,863 45,064	***** ***** *****	****	****	*****	Overall 1.01	****	-9.27		0.10 ( 0.01, 0.69)	0.02
SV (14-day gap) ACEI (14-day gap) Age Group: 45-54  Site-Adjusted Analysis SV (14-day gap) ACEI (14-day gap) Fixed Ratio 1:1 Propen SV (14-day gap) ACEI (14-day gap)	205 202 2,863 45,064 <b>nsity Score Ma</b> 2,789 2,789	*****  ****  ****  tched Conc  *****	*****  *****  ditional Anal  *****  *****	*****  ****  ****  lysis; Calipe  *****	*****  ****  er= 0.05 <sup>1</sup> *****  *****	0 Overall 1.01 10.28	****		****	0.10 ( 0.01,  0.69)	0.02
SV (14-day gap) ACEI (14-day gap) Age Group: 45-54  Site-Adjusted Analysis SV (14-day gap) ACEI (14-day gap) Fixed Ratio 1:1 Propen SV (14-day gap) ACEI (14-day gap) Fixed Ratio 1:1 Propen	2,863 45,064 nsity Score Mar 2,789 2,789 nsity Score Mar	*****  ****  ****  tched Conc  *****  tched Uncc	*****  *****  ditional Anal  *****  *****  onditional A	*****  ****  ****  lysis; Calipe  *****	*****  ****  er= 0.05 <sup>1</sup> *****  iper= 0.05	0 Overall 1.01 10.28	*****  ****  ****	-9.27	****	0.10 ( 0.01,  0.69)	0.02
SV (14-day gap) ACEI (14-day gap) Age Group: 45-54  Site-Adjusted Analysis SV (14-day gap) ACEI (14-day gap) Fixed Ratio 1:1 Propen SV (14-day gap) ACEI (14-day gap)	205 202 2,863 45,064 <b>nsity Score Ma</b> 2,789 2,789	*****  ****  ****  tched Conc  *****	*****  *****  ditional Anal  *****  *****	*****  ****  ****  lysis; Calipe  *****	*****  ****  er= 0.05 <sup>1</sup> *****  *****	0 Overall 1.01 10.28	*****	-9.27	****	0.10 ( 0.01, 0.69)	0.02

cder\_mpl2r\_wp016 Page 54 of 247



			A	A		Incidence		Incidence	Difference		
		_	Average	Average		Rate per		Rate	Difference	Hazard Ratio	
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per		144-1-I
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
					0	- 30 Days					
Site-Adjusted Analysi											
SV (14-day gap)	2,863	****	****	****	****	0	****	-23.69	****	_	_
ACEI (14-day gap)	45,064	****	****	****	****	23.69	****	25.05			
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	2,789	****	****	****	****	0	****	-28.18	****		
ACEI (14-day gap)	2,789	****	****	****	****	28.18	****	-20.10		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	2,789	****	****	****	****	0	****	-27.3	****		
ACEI (14-day gap)	2,789	****	****	****	****	27.3	****	-27.3		-	-
					31	- 60 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	2,623	****	****	****	****	0	****	-9.2	****		
ACEI (14-day gap)	41,772	****	****	****	****	9.2	****	-9.2		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	2,337	****	****	****	****	0	****	22.42	****		
ACEI (14-day gap)	2,337	****	****	****	****	22.42	****	-22.42		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	2,566	****	****	****	****	0	****	-22.88	****		
ACEI (14-day gap)	2,531	****	****	****	****	22.88	****	-22.88		-	-
					61	- 90 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	1,674	****	****	****	****	0	****	0.51	****		
ACEI (14-day gap)	27,866	****	****	****	****	9.51	****	-9.51		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	1,024	****	****	****	****	0	****		****		
ACEI (14-day gap)	1,024	****	****	****	****	0	****	0	* * * * *	-	-
( 75-77	, -					-					

cder\_mpl2r\_wp016 Page 55 of 247



			Average	Average		Incidence Rate per		Incidence Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1.000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	,	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Proper	sity Score Ma	tched Unco	nditional A							,	
SV (14-day gap)	1,630	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	1,771	****	****	****	****	0	****	0	4. 4. 4. 4.	-	-
					91	- 180 Days					
<b>Site-Adjusted Analysis</b>											
SV (14-day gap)	1,324	****	****	****	****	0	****	-5.25	****	_	_
ACEI (14-day gap)	22,994	****	****	****	****	5.25	****	-5.25			
Fixed Ratio 1:1 Proper	sity Score Ma	tched Cond	litional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	663	****	****	****	****	0	****	11 40	****		
ACEI (14-day gap)	663	****	****	****	****	11.49	****	-11.49		-	-
Fixed Ratio 1:1 Proper	sity Score Ma	tched Unco	nditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	1,291	****	****	****	****	0	****	-7.87	****		
ACEI (14-day gap)	1,459	****	****	****	****	7.87	****	-7.07		-	-
					181	- 270 Days					
Site-Adjusted Analysis											
SV (14-day gap)	706	****	****	****	****	7.31	****	2.89	****	1.82 ( 0.23, 14.29)	0.569
ACEI (14-day gap)	12,537	****	****	****	****	4.42	****	2.03		1.02 ( 0.23, 14.23)	0.505
Fixed Ratio 1:1 Proper	sity Score Ma	tched Cond	litional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	194	****	****	****	****	0	****	-32.92	****	_	_
ACEI (14-day gap)	194	****	****	****	****	32.92	****	-32.32		-	_
Fixed Ratio 1:1 Proper	sity Score Ma										
SV (14-day gap)	691	****	****	****	****	7.46	****	1	****	1.18 ( 0.07, 19.00)	0.906
ACEI (14-day gap)	789	****	****	****	****	6.45	****			1.18 ( 0.07, 15.00)	0.500
					271	- 365 Days					
Site-Adjusted Analysis											
SV (14-day gap)	449	****	****	****	****	0	****	-5.47	****	_	_
ACEI (14-day gap)	8,412	****	****	****	****	5.47	****	3.47			

cder\_mpl2r\_wp016 Page 56 of 247



Number of Numb				_	_		Incidence		Incidence	- 166		
Number of   Years   Days   Years   Oays   Years   Oays   Years   Oays   Years   Oays   Years   New Users   New Users   New Users   Oays   Oa				Average	Average	_	Rate per		Rate	Difference	Hannad Badin	
Medical Product   New Users   at Risk   at R			Person	Person	Person		1,000	•	Difference	-		
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05		Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	•	
SV (14-day gap)   82   *****   *****   ******   0   ******   0   ******   0   ******   0   ******   0   0							Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
SV (14-day gap)   82   *****   *****   ******   0   ******   0   ******   0   ******   0   ******   0   0	Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
ACEI (14-day gap)   82   ****   ****   *****   0   *****   *****   0   *****			****	****	****	****	0	****	0	****		
SV (14-day gap)   A44	ACEI (14-day gap)	82	****	****	****	****	0	****	U		-	
ACEI (14-day gap) 5.64 **** **** **** **** **** * **** * **** *	Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
Age Group: 55-64    Site-Adjusted Analysis	SV (14-day gap)	444	****	****	****	****	0	****	0	****		
Site-Adjusted Analysis   SV (14-day gap)   5,807   *****   *	ACEI (14-day gap)	514	****	****	****	****	0	****	U		-	
Site-Adjusted Analysis           SV (14-day gap)         5,807         ******         ******         ******         1.97         ******         -6.94         ******         0.22 (0.08, 0.59)         0.003           Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Calipere 0.05           SV (14-day gap)         5,692         ******         ******         ******         13.19         ******         -10.55         ******         0.20 (0.06, 0.69)         0.011           Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Calipere 0.05           SV (14-day gap)         5,692         ******         ******         ******         9.63         ******         -7.62         ******         0.21 (0.07, 0.62)         0.004           SV (14-day gap)         5,692         ******         ******         ******         9.63         ******         -7.62         ******         0.21 (0.07, 0.62)         0.004           Site-Adjusted Analysis           SV (14-day gap)         5,807         ******         ******         ******         2.18         ******         -15.01         ******         0.13 (0.02, 0.92)         0.041           Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Calipere 0.05	Age Group: 55-64											
SV (14-day gap) 5,807 ***** **** **** **** **** **** ****							Overall					
SV (14-day gap)   97,267   ******	Site-Adjusted Analysis	3										
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 ***** ***** ***** 2.64 ***** 13.19 ***** 10.55 ***** 0.20 ( 0.06,  0.69) 0.011  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 ***** **** ***** ***** 9.63 ***** 7.62 ***** 0.21 ( 0.07,  0.62) 0.004  ACEI (14-day gap) 5,692 **** **** **** ***** 9.63 ***** 7.62 ***** 0.21 ( 0.07,  0.62) 0.004  Site-Adjusted Analysis  SV (14-day gap) 97,267 **** **** **** **** 17.19 ***** 15.01 ***** 0.13 ( 0.02,  0.92) 0.041  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 97,267 **** **** ****  2.18 ****  17.19 ***** 17.19 ***** 0.10 ( 0.01,  0.78) 0.028  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 **** **** ***** 23.11 *****  20.8 ***** 0.10 ( 0.01,  0.78) 0.028  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 ***** ***** ***** 23.11 *****  20.8 ***** 0.10 ( 0.01,  0.78) 0.028  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 ***** ***** ***** 2.22 ****** 0.10 ( 0.01,  0.78) 0.028		5,807			****		1.97		-6 94	****	0.22 ( 0.08 0.59)	0.003
SV (14-day gap) 5,692 ***** **** **** **** **** 2.64 *****  ACEI (14-day gap) 5,692 ***** **** **** **** 13.19 ***** -10.55 ***** 0.20 (0.06, 0.69) 0.011  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 ***** **** **** **** 9.63 ***** -7.62 ***** 0.21 (0.07, 0.62) 0.004  ACEI (14-day gap) 5,692 ***** **** **** **** 2.18 ***** -7.62 ***** 0.21 (0.07, 0.62) 0.004  Site-Adjusted Analysis  SV (14-day gap) 5,807 **** **** **** **** **** 17.19 ***** -15.01 ***** 0.13 (0.02, 0.92) 0.041  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 ***** **** **** **** 2.31 ***** -20.8 ***** 0.10 (0.01, 0.78) 0.028  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 ***** **** **** **** 2.31 ***** -20.8 ***** 0.10 (0.01, 0.78) 0.028  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 ***** **** ***** ***** 2.22 ***** 0.10 (0.01, 0.78) 0.028							8.91	****	0.54		0.22 ( 0.00, 0.55)	0.003
SV (14-day gap) 5,692 ***** **** **** **** **** 2.64 *****  ACEI (14-day gap) 5,692 ***** **** **** **** 13.19 ***** -10.55 **** 0.20 (0.06, 0.69) 0.011  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 ***** **** **** **** 9.63 ***** -7.62 ***** 0.21 (0.07, 0.62) 0.004  ACEI (14-day gap) 5,692 ***** **** **** **** 2.18 ***** -7.62 ***** 0.21 (0.07, 0.62) 0.004  Site-Adjusted Analysis  SV (14-day gap) 5,807 **** **** **** **** 17.19 ***** -15.01 ***** 0.13 (0.02, 0.92) 0.041  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 ***** **** **** 2.31 ***** -20.8 ***** 0.10 (0.01, 0.78) 0.028  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 ***** **** **** **** 2.31 ***** -20.8 ***** 0.10 (0.01, 0.78) 0.028  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 ***** **** **** ***** 2.22 ***** 0.10 (0.01, 0.78) 0.028	Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
ACEI (14-day gap) 5,692 ***** **** ***** 13.19 ***** 10.33 0.20 (0.00, 0.09) 0.011  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 ***** **** ***** 2.01 ***** 7.62 ***** 0.21 (0.07, 0.62) 0.004  ACEI (14-day gap) 5,692 ***** **** **** **** 2.18 ***** 7.62  SV (14-day gap) 5,807 **** **** **** **** 2.18 **** 7.19 **** 7.5.01 ***** 0.13 (0.02, 0.92) 0.041  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 **** **** **** **** 2.31 **** 7.0.8 **** 0.10 (0.01, 0.78) 0.028  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 **** **** ****  2.31 ***** 7.0.8 ***** 0.10 (0.01, 0.78) 0.028  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 **** **** ***** ***** 2.22 *****  7.005 ***** 0.10 (0.01, 0.78) 0.028			****	****	****	****	2.64	****	10 55	****	0.20 ( 0.06 0.60)	0.011
SV (14-day gap) 5,692 ***** **** **** **** **** 9,63 ***** -7.62 ***** 0.21 (0.07, 0.62) 0.004  Site-Adjusted Analysis  SV (14-day gap) 5,807 **** **** **** **** **** 2.18 ***** -15.01 ***** 0.13 (0.02, 0.92) 0.041  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 **** **** **** **** 2.31 ***** -20.8 ***** 0.10 (0.01, 0.78) 0.028  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 **** **** **** **** 2.31 ***** -20.8 ***** 0.10 (0.01, 0.78) 0.028  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 **** **** **** ***** 2.22 *****	ACEI (14-day gap)	5,692	****	****	****	****	13.19	****	-10.55		0.20 ( 0.00, 0.09)	0.011
ACEI (14-day gap) 5,692 ***** **** **** **** **** **** * 2.18 **** **** **** * 2.18 **** **** * 17.19 **** * 15.01 **** * 0.13 (0.02, 0.92) **** * 0.004 **** * 0.13 (0.01, 0.78) * 0.028 **** * 0.004 *** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 *** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 *** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 *** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 *** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 *** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 *** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 *** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 *** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 *** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 *** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 *** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 *** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 **** * 0.004 *** * 0.004 **** * 0.004 **** * 0.004 *** * 0.004 *** * 0.004 ****	Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
Site-Adjusted Analysis   SV (14-day gap)   5,807   ******	SV (14-day gap)	5,692	****	****	****	****	2.01	****	7.62	****	0.21 ( 0.07   0.62)	0.004
Site-Adjusted Analysis  SV (14-day gap) 5,807 ***** ***** ***** ***** 2.18 *****  ACEI (14-day gap) 97,267 ***** **** **** ***** 17.19 ***** -15.01 ***** 0.13 (0.02, 0.92) 0.041  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 ***** **** ***** ***** 23.1 *****  ACEI (14-day gap) 5,692 ***** **** ***** 23.11 *****  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 ***** ***** ***** 23.11 ***** -20.8 ***** 0.10 (0.01, 0.78) 0.028  SV (14-day gap) 5,692 ***** ***** ***** 2.22 ******	ACEI (14-day gap)	5,692	****	****	****	****	9.63	****	-7.02		0.21 (0.07, 0.02)	0.004
SV (14-day gap)       5,807       ******       ******       ******       2.18       ******       -15.01       ******       0.13 (0.02, 0.92)       0.041         Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05         SV (14-day gap)       5,692       ******       ******       *****       2.31       ******       -20.8       ******       0.10 (0.01, 0.78)       0.028         Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05         SV (14-day gap)       5,692       ******       ******       ******       2.22       ******       0.10 (0.01, 0.78)       0.028						0	- 30 Days					
ACEI (14-day gap) 97,267 ***** **** **** **** **** **** ****	Site-Adjusted Analysis											
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 ***** **** **** **** 2.31 ***** -20.8 ***** 0.10 ( 0.01,  0.78) 0.028  ACEI (14-day gap) 5,692 ***** **** **** **** 23.11 ***** -20.8 ***** 0.10 ( 0.01,  0.78) 0.028  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 ***** **** **** ***** 2.22 *****	SV (14-day gap)	5,807	****	****	****	****	2.18	****	-15 O1	****	0 13 ( 0 02 0 92)	0.041
SV (14-day gap)       5,692       *****       *****       *****       2.31       *****       -20.8       *****       0.10 (0.01, 0.78)       0.028         Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05         SV (14-day gap)       5,692       *****       *****       *****       2.22       *****       *****       0.10 (0.01, 0.78)       0.028							17.19	****	15.01		0.13 ( 0.02,  0.32)	0.041
SV (14-day gap)       5,692       *****       *****       *****       2.31       *****       -20.8       *****       0.10 (0.01, 0.78)       0.028         Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05         SV (14-day gap)       5,692       *****       *****       *****       2.22       *****       *****       0.10 (0.01, 0.78)       0.028	Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
ACEI (14-day gap) 5,692 **** **** **** **** 23.11 ****    Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,692 ****    ****    ****    23.11 *****    20.05     *****    0.10 (0.01, 0.78)    0.028			****	****	****	****	2.31	****	20.9	****	0.10 / 0.01 0.70	0.029
SV (14-day gap) 5,692 ***** ***** ***** 2.22 *****	ACEI (14-day gap)	5,692	****	****	****	****	23.11	****	-20.8		0.10 ( 0.01, 0.78)	0.028
3v (14-uay gap) 5,692 -2.22 -20.05 ***** 0.10 ( 0.01 0.78) 0.028	Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
	SV (14-day gap)	5,692	****	****	****	****	2.22	****	20.05	****	0.10 / 0.01 0.70	0.029
	ACEI (14-day gap)	5,692	****	****	****	****	22.27	****	-20.05		0.10 ( 0.01, 0.78)	0.026

cder\_mpl2r\_wp016 Page 57 of 247



				_		Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
					31	- 60 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	5,279	****	****	****	****	0	****	-7.74	****		
ACEI (14-day gap)	89,870	****	****	****	****	7.74	****	-7.74		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	4,725	****	****	****	****	0	****	7.20	****		
ACEI (14-day gap)	4,725	****	****	****	****	7.29	****	-7.29	****	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	5,177	****	****	****	****	0	****	F F 4	****		
ACEI (14-day gap)	5,184	****	****	****	****	5.54	****	-5.54		-	-
					61	- 90 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	3,449	****	****	****	****	7.76	****	0.43	****	1 16 ( 0 20 4 01)	0.042
ACEI (14-day gap)	62,809	****	****	****	****	7.33	****	0.43		1.16 (0.28, 4.81)	0.843
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	2,151	****	****	****	****	13.46	****	6.72	****	2.00 / 0.40, 22.06\	0.574
ACEI (14-day gap)	2,151	****	****	****	****	6.73	****	6.73	****	2.00 ( 0.18, 22.06)	0.571
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	3,385	****	****	****	****	7.91	****	0.70	****	1.16 ( 0.16 . 0.24)	0.000
ACEI (14-day gap)	3,696	****	****	****	****	7.12	****	0.79	4. 4. 4. 4.	1.16 ( 0.16, 8.24)	0.882
	·				91	- 180 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	2,776	****	****	****	****	2.07	****	4.22	****	0.33 / 0.05 3.43\	0.379
ACEI (14-day gap)	52,867	****	****	****	****	6.39	****	-4.32	nan nan nan nan	0.33 ( 0.05, 2.42)	0.278
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	1,452	****	****	****	****	0	****	10.65	****		
ACEI (14-day gap)	1,452	****	****	****	****	10.65	****	-10.65	* * * * *	-	-
( / 5 / )	, -										

cder\_mpl2r\_wp016 Page 58 of 247



	,	•			<u> </u>	Incidence	•	Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	<b>Hazard Ratio</b>	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	•	Person Years	Users	· Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Prope											
SV (14-day gap)	2,728	****	****	****	****	2.11	****	2.22	****	0.00 / 0.04 . 0.04 )	0.400
ACEI (14-day gap)	3,127	****	****	****	****	5.5	****	-3.39	****	0.39 ( 0.04, 3.81)	0.422
, , , ,	,				181	- 270 Days					
Site-Adjusted Analysi	is										
SV (14-day gap)	1,462	****	****	****	****	0	****	6.55	****		
ACEI (14-day gap)	29,794	****	****	****	****	6.55	****	-6.55		-	-
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	414	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	414	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	1,431	****	****	****	****	0	****	-9.19	****		
ACEI (14-day gap)	1,689	****	****	****	****	9.19	****	-9.19		-	-
					271	- 365 Days					
Site-Adjusted Analysi	is										
SV (14-day gap)	919	****	****	****	****	0	****	-6.32	****	_	_
ACEI (14-day gap)	20,223	****	****	****	****	6.32	****	0.52			
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	173	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	173	****	****	****	****	0	****	U		-	
Fixed Ratio 1:1 Prope	ensity Score Ma			•	•						
SV (14-day gap)	898	****	****	****	****	0	****	-4.57	****	_	_
ACEI (14-day gap)	1,058	****	****	****	****	4.57	****	-4.57			
Age Group: 65+											
					-	Overall					
Site-Adjusted Analysi											
SV (14-day gap)	31,790	****	****	****	****	1.22	****	-4.81	****	0.19 ( 0.11, 0.32)	<0.001
ACEI (14-day gap)	531,087	****	****	****	****	6.03	****				
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	31,082	****	****	****	****	1.5	****	-8.09	****	0.16 ( 0.08, 0.30)	<0.001
ACEI (14-day gap)	31,082	****	****	****	****	9.59	****	-0.03		0.10 ( 0.00, 0.30)	/0.001
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						

cder\_mpl2r\_wp016 Page 59 of 247



Medical Product SV (14-day gap) ACEI (14-day gap)	Number of New Users 31,082 31,082	Person Years at Risk *****	Average Person Days at Risk *****	Average Person Years at Risk *****	Number of Events *****	Incidence Rate per 1,000 Person Years 1.24 6.4	Risk per 1,000 New Users *****	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users *****	Hazard Ratio (95% Confidence Interval) <sup>2</sup> 0.18 ( 0.10, 0.33)	Wald P-Value <sup>2</sup> <0.001
					0	- 30 Days					
Site-Adjusted Analysis	5										
SV (14-day gap) ACEI (14-day gap)	31,790 531,087	*****	*****	*****	*****	0.79 14.17	****	-13.38	****	0.06 ( 0.01, 0.22)	<0.001
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap) ACEI (14-day gap)	30,993 30,993	****	*****	****	****	0.84 17.32	*****	-16.47	****	0.05 ( 0.01, 0.20)	<0.001
Fixed Ratio 1:1 Proper	· · · · · · · · · · · · · · · · · · ·	tched Unco	nditional A	nalysis: Cali	ner= 0.05	17.32					
SV (14-day gap)	31,034	****	****	****	****	0.81	****			/	
ACEI (14-day gap)	31,041	****	****	****	****	16.73	****	-15.92	****	0.05 ( 0.01, 0.20)	<0.001
					31	- 60 Days					
Site-Adjusted Analysis											
SV (14-day gap) ACEI (14-day gap)	28,925 486,852	****	****	****	****	2.04 5.4	****	-3.35	****	0.38 ( 0.14, 1.02)	0.055
Fixed Ratio 1:1 Proper		tched Cond	ditional Ana	lvsis: Calipe	r= 0.05 <sup>1</sup>	<u> </u>					
SV (14-day gap)	25,639	****	****	****	****	2.6	****	4.05	****	0.57 / 0.47 .4.05\	0.272
ACEI (14-day gap)	25,639	****	****	****	****	4.56	****	-1.95	<b>ጥጥጥጥ</b>	0.57 ( 0.17, 1.95)	0.372
Fixed Ratio 1:1 Proper	nsity Score Ma				-						
SV (14-day gap) ACEI (14-day gap)	28,289 28,148	****	*****	****	*****	2.09 3.5	****	-1.41	****	0.60 ( 0.17, 2.04)	0.411

cder\_mpl2r\_wp016 Page 60 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
					61	- 90 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	19,259	****	****	****	****	1.38	****	-3.79	****	0.27 ( 0.07, 1.08)	0.064
ACEI (14-day gap)	359,818	****	****	****	****	5.17	****	-3.79		0.27 (0.07, 1.08)	0.004
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	12,705	****	****	****	****	2.23	****	-2.23	****	0.50 ( 0.09, 2.73)	0.423
ACEI (14-day gap)	12,705	****	****	****	****	4.45	****	-2.25		0.50 (0.09, 2.75)	0.423
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	18,847	****	****	****	****	1.41	****	-4.18	****	0.25 ( 0.05, 1.16)	0.077
ACEI (14-day gap)	20,968	****	****	****	****	5.59	****	-4.10		0.23 (0.03, 1.10)	0.077
					91	- 180 Days					
Site-Adjusted Analysi											
SV (14-day gap)	15,774	****	****	****	****	1.44	****	-2.51	****	0.37 (0.14, 0.99)	0.047
ACEI (14-day gap)	311,804	****	****	****	****	3.96	****	-2.31		0.37 (0.14, 0.33)	0.047
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	9,047	****	****	****	****	1.66	****	4.00	****	0.35 / 0.05   1.10)	0.00
ACEI (14-day gap)	9,047	****	****	****	****	6.66	****	-4.99		0.25 ( 0.05, 1.18)	0.08
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	15,448	****	****	****	****	1.47	****	-2.23	****	0.40 ( 0.13, 1.23)	0.108
ACEI (14-day gap)	18,166	****	****	****	****	3.7	****	-2.25		0.40 ( 0.15, 1.25)	0.106
					181	- 270 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	8,568	****	****	****	****	0.6	****	-3.02	****	0.17 ( 0.02, 1.20)	0.075
ACEI (14-day gap)	188,096	****	****	****	****	3.62	****	-3.02		0.17 (0.02, 1.20)	0.073
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	2,837	****	****	****	****	0	****	C C1	****		
ACEI (14-day gap)	2,837	****	****	****	****	6.61	****	-6.61	<b>~ ~ ~ ~ ~</b>	-	-

cder\_mpl2r\_wp016 Page 61 of 247



			Average	Average		Incidence Rate per		Incidence Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	<b>Hazard Ratio</b>	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	per= 0.05						
SV (14-day gap)	8,387	****	****	****	****	0.62	****	-4.25	****	0.13 ( 0.02, 0.99)	0.049
ACEI (14-day gap)	10,439	****	****	****	****	4.87	****	-4.25		0.13 (0.02, 0.99)	0.049
					271	- 365 Days					
Site-Adjusted Analysis	5										
SV (14-day gap)	5,355	****	****	****	****	0.87	****	-2.19	****	0.29 ( 0.04, 2.05)	0.212
ACEI (14-day gap)	132,840	****	****	****	****	3.06	****	-2.19		0.29 (0.04, 2.05)	0.212
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	1,212	****	****	****	****	0	****	4.52	****		
ACEI (14-day gap)	1,212	****	****	****	****	4.52	****	-4.52		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	per= 0.05						
SV (14-day gap)	5,241	****	****	****	****	0.89	****	-1.18	****	0.42 ( 0.04 .4.15)	0.467
ACEI (14-day gap)	6,850	****	****	****	****	2.08	****	-1.18		0.43 ( 0.04, 4.15)	0.467

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 62 of 247

<sup>&</sup>lt;sup>2</sup>Data presented by a dash are unable to be calculated. This table may not use all data representations.

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



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

			Average	Average		Incidence Rate per		Incidence Rate	Difference	Hanand Batic	
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio (95% Confidence	Wald
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	•	
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Race: Unknown											
Site-Adjusted Analy		****	****	****	****		****				
SV	7,029		****		****	0.77	****	-6	****	0.11 (0.03, 0.44)	0.002
ACEI	99,645	****		****		6.76	****				
Fixed Ratio 1:1 Prop	ensity Score Ma										
SV	6,992	****	****	****	****	0	****	-8.33	****	_	_
ACEI	6,992	****	****	****	****	8.33	****	0.55			
Fixed Ratio 1:1 Prop	ensity Score Ma				•						
SV	6,992	****	****	****	****	0.77	****	-6.48	****	0.11 (0.03, 0.47)	0.003
ACEI	6,992	****	****	****	****	7.25	****	-0.46		0.11 (0.03, 0.47)	0.003
Race: American Indi	ian										
Site-Adjusted Analy	sis										
SV	132	****	****	****	****	0	****	-2.38	****	_	_
ACEI	4,529	****	****	****	****	2.38	****	-2.36			
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	litional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	123	****	****	****	****	0	****	0	****		
ACEI	123	****	****	****	****	0	****	0	4. 4. 4. 4. 4.	-	-
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	nditional A	nalysis; Cali	iper= 0.05						
SV	123	****	****	****	****	0	****	0	****		
ACEI	123	****	****	****	****	0	****	0		-	-
Race: Asian											
<b>Site-Adjusted Analy</b>	sis										
SV	519	****	****	****	****	0	****	2.62	****		
ACEI	7,874	****	****	****	****	2.63	****	-2.63	ran ran ran ran	-	-
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	litional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	495	****	****	****	****	0	****	10.10	****		
ACEI	495	****	****	****	****	10.49	****	-10.49	***	-	-

cder\_mpl2r\_wp016 Page 63 of 247



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

						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Prop	ensity Score Ma			nalysis; Cal	•						
SV	495	****	****	****	****	0	****	-5.6	****	_	_
ACEI	495	****	****	****	****	5.6	****	-5.0			
Race: Black											
Site-Adjusted Analy											
SV	5,566	****	****	****	****	4.18	****	-18.39	****	0.17 (0.08, 0.36)	<0.001
ACEI	92,129	****	****	****	****	22.57	****				
Fixed Ratio 1:1 Prop	ensity Score Ma			lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	5,479	****	****	****	****	4.08	****	-30.58	****	0.12 (0.04, 0.33)	<0.001
ACEI	5,479	****	****	****	****	34.66	****	-30.38		0.12 (0.04, 0.33)	<b>\0.001</b>
Fixed Ratio 1:1 Prop	ensity Score Ma			•	•						
SV	5,479	****	****	****	****	4.25	****	-20.53	****	0.16 (0.07, 0.36)	<0.001
ACEI	5,479	****	****	****	****	24.79	****	-20.55		0.10 (0.07, 0.30)	\0.001
Race: Pacific Islande											
Site-Adjusted Analy											
SV	46	****	****	****	****	0	****	-14.36	****	_	_
ACEI	741	****	****	****	****	14.36	****	14.50			
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	39	****	****	****	****	0	****	0	****	_	_
ACEI	39	****	****	****	****	0	****	0		_	
Fixed Ratio 1:1 Prop	ensity Score Ma										
SV	39	****	****	****	****	0	****	0	****	_	_
ACEI	39	****	****	****	****	0	****				
Race: White											
<b>Site-Adjusted Analy</b>	sis										
SV	28,706	****	****	****	****	1.05	****	-3.29	****	0.23 (0.13, 0.41)	<0.001
ACEI	490,094	****	****	****	****	4.34	****	-3.23		0.23 (0.13, 0.41)	<b>\0.001</b>

cder\_mpl2r\_wp016 Page 64 of 247



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

			Average	Average		Incidence Rate per		Incidence Rate	Difference		
Medical Product	Number of New Users	Person Years at Risk	Person Days at Risk	Person Years at Risk	Number of Events	1,000 Person Years	Risk per 1,000 New Users	Difference per 1,000 Person Years	in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval) <sup>2</sup>	Wald P-Value <sup>2</sup>
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>					,	
SV	28,638	****	****	****	****	1.43	****	-4.94	****	0.23 (0.11, 0.46)	<0.001
ACEI	28,638	****	****	****	****	6.37	****	-4.94		0.23 (0.11, 0.40)	<0.001
Fixed Ratio 1:1 Propo	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	28,638	****	****	****	****	1.05	****	-3.28	****	0.23 (0.12, 0.44)	<0.001
ACEI	28,638	****	****	****	****	4.33	****	-3.20		0.23 (0.12, 0.44)	\0.001

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 65 of 247

<sup>&</sup>lt;sup>2</sup>Data presented by a dash are unable to be calculated. This table may not use all data representations.

<sup>\*\*\*\*\*</sup>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.



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	<b>Events</b>	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Race: Unknown											
						Overall					
Site-Adjusted Analysi	S										
SV (14-day gap)	7,029	****	****	****	****	0.77	****	-6	****	0.11 ( 0.03, 0.44)	0.002
ACEI (14-day gap)	99,645	****	****	****	****	6.76	****	-0		0.11 (0.03, 0.44)	0.002
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	6,992	****	****	****	****	0	****	0.22	****		
ACEI (14-day gap)	6,992	****	****	****	****	8.33	****	-8.33	4 4 4 4 4	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	6,992	****	****	****	****	0.77	****	-6.48	****	0.11 / 0.02 0.47)	0.003
ACEI (14-day gap)	6,992	****	****	****	****	7.25	****	-6.48		0.11 ( 0.03, 0.47)	0.003
					0	- 30 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	7,029	****	****	****	****	0	****	-15.99	****		
ACEI (14-day gap)	99,645	****	****	****	****	15.99	****	-13.99		-	_
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	6,992	****	****	****	****	0	****	20.00	****		
ACEI (14-day gap)	6,992	****	****	****	****	20.99	****	-20.99	4 4 4 4 4	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	6,992	****	****	****	****	0	****	20.45	****		
ACEI (14-day gap)	6,992	****	****	****	****	20.15	****	-20.15	and the the the the	-	-
					31	- 60 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	6,335	****	****	****	****	0	****	Г ОГ	****		
ACEI (14-day gap)	91,186	****	****	****	****	5.05	****	-5.05	10.10.10.10.10	-	-

cder\_mpl2r\_wp016 Page 66 of 247



		Person	Average Person	Average Person	Number	Incidence Rate per 1,000	Risk per	Incidence Rate Difference	Difference in Risk per	Hazard Ratio	M-14
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	5,635	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	5,635	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	6,307	****	****	****	****	0	****	2.21	****		
ACEI (14-day gap)	6,232	****	****	****	****	2.31	****	-2.31		-	-
					61	- 90 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	4,314	****	****	****	****	3.09	****	2.22	****	0.50 ( 0.00 4.37)	0.000
ACEI (14-day gap)	64,654	****	****	****	****	5.32	****	-2.23		0.59 ( 0.08, 4.37)	0.608
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	2,742	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	2,742	****	****	****	****	0	****	0	4. 4. 4. 4.	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	4,296	****	****	****	****	3.1	****	0.11	****	4.00 ( 0.07.40.05)	0.067
ACEI (14-day gap)	4,422	****	****	****	****	3	****	0.11	4.4.4.4.4	1.06 ( 0.07, 16.95)	0.967
					91	- 180 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	3,500	****	****	****	****	1.57	****	-2.93	****	0.35 ( 0.05 .3.55)	0.3
ACEI (14-day gap)	53,831	****	****	****	****	4.5	****	-2.93		0.35 ( 0.05, 2.55)	0.3
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	1,845	****	****	****	****	0	****	2.24	****		
ACEI (14-day gap)	1,845	****	****	****	****	3.91	****	-3.91	***	-	-
Fixed Ratio 1:1 Prope		tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	3,487	****	****	****	****	1.57	****	4.54	****	0.05/0.00 0.55	0.007
ACEI (14-day gap)	3,656	****	****	****	****	6.09	****	-4.51	***	0.26 ( 0.03, 2.32)	0.227

cder\_mpl2r\_wp016 Page 67 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
					181	- 270 Days					
Site-Adjusted Analysis	5										
SV (14-day gap)	1,996	****	****	****	****	0	****	-3.81	****		
ACEI (14-day gap)	31,204	****	****	****	****	3.81	****	-3.61		-	
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	584	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	584	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	1,990	****	****	****	****	0	****	-5.12	****		
ACEI (14-day gap)	2,022	****	****	****	****	5.12	****	-5.12		-	-
					271	- 365 Days					
Site-Adjusted Analysis	5										
SV (14-day gap)	1,269	****	****	****	****	0	****	-3.8	****		
ACEI (14-day gap)	21,471	****	****	****	****	3.8	****	-5.6			
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	253	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	253	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	1,264	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	1,259	****	****	****	****	0	****	U		-	-
Race: American India	า										
						Overall					
Site-Adjusted Analysis	i										
SV (14-day gap)	132	****	****	****	****	0	****	-2.38	****		
ACEI (14-day gap)	4,529	****	****	****	****	2.38	****	-2.30		-	-

cder\_mpl2r\_wp016 Page 68 of 247



			Average	Average		Incidence		Incidence Rate	Difference		
		Davaan	U	Average	Number	Rate per	Dieleman	Difference		Hazard Ratio	
	N1	Person	Person	Person		1,000	Risk per		in Risk per	(95% Confidence	Wald
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	•	
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Prope											
SV (14-day gap)	123	****	****	****	****	0	****	0	****	_	_
ACEI (14-day gap)	123	****	****	****	****	0	****	0			_
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	123	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	123	****	****	****	****	0	****	0		_	_
					0	- 30 Days					
<b>Site-Adjusted Analysi</b>	S										
SV (14-day gap)	192	****	****	****	****	0	****	-5.35	****		
ACEI (14-day gap)	5,667	****	****	****	****	5.35	****	-5.55		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	125	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	125	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	193	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	214	****	****	****	****	0	****	U		-	-
					31	- 60 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	117	****	****	****	****	0	****	0	****	_	_
ACEI (14-day gap)	4,188	****	****	****	****	0	****	0		_	_
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	101	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	101	****	****	****	****	0	****	<u> </u>		<u>-</u>	
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	179	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	204	****	****	****	****	0	****	U		-	-

cder\_mpl2r\_wp016 Page 69 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
					61	- 90 Days					
<b>Site-Adjusted Analysis</b>											
SV (14-day gap)	73	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	2,743	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Propen	sity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	49	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	49	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Propen	sity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	72	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	79	****	****	****	****	0	****	U		-	-
					91	- 180 Days					
Site-Adjusted Analysis											
SV (14-day gap)	59	****	****	****	****	0	****	-5	****	_	_
ACEI (14-day gap)	2,256	****	****	****	****	5	****	-5			
Fixed Ratio 1:1 Propen	sity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	33	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	33	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Propen	sity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	59	****	****	****	****	0	****	0	****	_	
ACEI (14-day gap)	65	****	****	****	****	0	****	0		_	_
					181	- 270 Days					
Site-Adjusted Analysis											
SV (14-day gap)	30	****	****	****	****	0	****	0	****	_	_
ACEI (14-day gap)	1,258	****	****	****	****	0	****				
Fixed Ratio 1:1 Propen	sity Score Ma	tched Cond	ditional Ana		er= 0.05 <sup>1</sup>						
SV (14-day gap)	****	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	****	****	****	****	****	0	****	U		-	-

cder\_mpl2r\_wp016 Page 70 of 247



			_	_		Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference	Hannad Batta	
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	31	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	37	****	****	****	****	0	****	U		-	-
					271	365 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	17	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	838	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	****	****	****	****	****	0	****		****		
ACEI (14-day gap)	****	****	****	****	****	0	****	0	***	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	18	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	25	****	****	****	****	0	****	0	4. 4. 4. 4. 4.	-	-
Race: Asian											
						Overall					
Site-Adjusted Analysi	S										
SV (14-day gap)	519	****	****	****	****	0	****	2.62	****		
ACEI (14-day gap)	7,874	****	****	****	****	2.63	****	-2.63	****	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	495	****	****	****	****	0	****		ale ale ale ale		
ACEI (14-day gap)	495	****	****	****	****	10.49	****	-10.49	****	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	495	****	****	****	****	0	****		****		
ACEI (14-day gap)	495	****	****	****	****	5.6	****	-5.6	***	-	-

cder\_mpl2r\_wp016 Page 71 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
					0	- 30 Days					
Site-Adjusted Analysis	S										
SV (14-day gap)	519	****	****	****	****	0	****	-4.83	****	_	_
ACEI (14-day gap)	7,874	****	****	****	****	4.83	****	-4.65			
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	479	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	479	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	488	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	485	****	****	****	****	0	****	U		-	-
					31	- 60 Days					
Site-Adjusted Analysis	S										
SV (14-day gap)	479	****	****	****	****	0	****	-6.01	****		_
ACEI (14-day gap)	7,151	****	****	****	****	6.01	****	-0.01		-	
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	417	****	****	****	****	0	****	-36.79	****		
ACEI (14-day gap)	417	****	****	****	****	36.79	****	-30.79		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	458	****	****	****	****	0	****	-30.83	****		
ACEI (14-day gap)	449	****	****	****	****	30.83	****	-30.63		-	-
					61	- 90 Days					
Site-Adjusted Analysis	S										
SV (14-day gap)	326	****	****	****	****	0	****	-5.15	****		_
ACEI (14-day gap)	5,094	****	****	****	****	5.15	****	-5.15		-	
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	217	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	217	****	****	****	****	0	****	0	ere etc. etc. etc. etc.	-	-

cder\_mpl2r\_wp016 Page 72 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Proper	nsity Score Ma				•						
SV (14-day gap)	320	****	****	****	****	0	****	0	****	_	_
ACEI (14-day gap)	327	****	****	****	****	0	****				
					91	- 180 Days					
Site-Adjusted Analysis	<u> </u>										
SV (14-day gap)	249	****	****	****	****	0	****	0	****	_	_
ACEI (14-day gap)	4,335	****	****	****	****	0	****				
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	litional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	125	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	125	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	nditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	240	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	261	****	****	****	****	0	****	U		-	-
					181	- 270 Days					
Site-Adjusted Analysis											
SV (14-day gap)	131	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	2,369	****	****	****	****	0	****	0			_
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	litional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	31	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	31	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	nditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	127	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	130	****	****	****	****	0	****	0		-	-
					271	- 365 Days					
Site-Adjusted Analysis											
SV (14-day gap)	82	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	1,547	****	****	****	****	0	****	U		-	-

cder\_mpl2r\_wp016 Page 73 of 247



			Average	Average		Incidence Rate per		Incidence Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	<b>Hazard Ratio</b>	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Propen	sity Score Ma	tched Cond	litional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>					•	
SV (14-day gap)	12	****	****	****	****	0	****		****		
ACEI (14-day gap)	12	****	****	****	****	0	****	0	****	-	-
Fixed Ratio 1:1 Propen	sity Score Ma	tched Unco	nditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	82	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	88	****	****	****	****	0	****	0		-	-
Race: Black											
						Overall					
<b>Site-Adjusted Analysis</b>											
SV (14-day gap)	5,566	****	****	****	****	4.18	****	-18.39	****	0.17 ( 0.08, 0.36)	< 0.001
ACEI (14-day gap)	92,129	****	****	****	****	22.57	****	-16.39		0.17 ( 0.08, 0.30)	<b>\0.001</b>
Fixed Ratio 1:1 Propen	sity Score Ma	tched Cond	litional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	5,479	****	****	****	****	4.08	****	-30.58	****	0.13 / 0.04   0.33	<0.001
ACEI (14-day gap)	5,479	****	****	****	****	34.66	****	-30.36		0.12 ( 0.04, 0.33)	<0.001
Fixed Ratio 1:1 Propen	sity Score Ma	tched Unco	nditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	5,479	****	****	****	****	4.25	****	-20.53	****	0.16 ( 0.07, 0.36)	<0.001
ACEI (14-day gap)	5,479	****	****	****	****	24.79	****	-20.55		0.10 ( 0.07, 0.36)	<0.001
					0 -	- 30 Days					
<b>Site-Adjusted Analysis</b>											
SV (14-day gap)	5,566	****	****	****	****	2.27	****	-46.47	****	0.05 ( 0.01, 0.33)	0.002
ACEI (14-day gap)	92,129	****	****	****	****	48.74	****	-40.47		0.03 ( 0.01,  0.33)	0.002
Fixed Datie 1.1 Draman	sity Score Ma	tched Cond	litional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
rixed Katio 1:1 Propen					****	2.20	****				
SV (14-day gap)	5,479	****	****	****	****	2.39		E0 70	****	0.04 ( 0.01 0.29)	0.001
			*****	****	****	2.39 62.18	****	-59.79	****	0.04 ( 0.01, 0.28)	0.001
SV (14-day gap)	5,479 5,479	****	****	****	****			-59.79	****	0.04 ( 0.01, 0.28)	0.001
SV (14-day gap) ACEI (14-day gap)	5,479 5,479	****	****	****	****			-59.79 -57.76	****	0.04 ( 0.01, 0.28)	0.001

cder\_mpl2r\_wp016 Page 74 of 247



Mumber of Number of Numb				_	_		Incidence		Incidence			
Number of   Years   Days   Years   Days   Years   Days   Years   Days   Years   Days   Years   New Users   New U			_	Average	Average		Rate per		Rate	Difference	Hanned Batin	
New Users   at Risk   at Risk   at Risk   at Risk   Events   Years   New Users   Person Years   Users   Interval]   P-Value							1,000	•		-		
Site-Adjusted Analysis   Site-Adjusted Analy		Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	•	
Site-Adjusted Analysis   SV (14-day gap)   5,059   ****   *****   *****   *****   *****   3.08   *****   *****   -14.89   *****   0.17 (0.02, 1.21)   0.076	Medical Product	New Users	at Risk	at Risk	at Risk			New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
SV (14-day gap)   5,059   ***** **** **** **** ****   17.97   *****   14.89   *****   0.17 (0.02, 1.21)   0.076						31	- 60 Days					
Signature   Sign	Site-Adjusted Analysi											
Size	SV (14-day gap)	5,059					3.08		-1/189	****	0 17 ( 0 02 1 21)	0.076
SV (14-day gap)							17.97	****	-14.05		0.17 (0.02, 1.21)	0.070
SV (14-day gap)	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
ACEI (14-day gap) 4,542 ***** ***** ***** ***** 19.77 ***** 1.02  SV (14-day gap) 4,982 ***** ***** ***** ***** 14.65 ***** -11.52 ***** 0.22 (0.03, 1.85) 0.161  Site-Adjusted Analysis  SV (14-day gap) 2,977 ***** **** ***** ***** 18.67 ***** 14.1 ***** 0.25 (0.03, 1.79) 0.167  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper = 0.05  SV (14-day gap) 1,834 **** ***** ***** ***** 15.97 ***** 15.97 ***** 15.97  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper = 0.05  SV (14-day gap) 1,834 ***** ***** ***** ***** 15.97 ***** -15.97 ***** 0.40 (0.04, 3.85) 0.428  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper = 0.05  SV (14-day gap) 2,927 ***** ***** ***** 4.66 *****  -6.85 ***** 0.40 (0.04, 3.85) 0.428  Site-Adjusted Analysis  SV (14-day gap) 3,425 **** **** ***** ***** 11.5 ***** -6.85 ***** 0.40 (0.04, 3.85) 0.428  Site-Adjusted Analysis  SV (14-day gap) 2,268 ***** ***** ***** ***** ***** 11.5 ***** -9.05 ***** 0.38 (0.09, 1.54) 0.176  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper = 0.05  SV (14-day gap) 2,268 ***** ***** ***** ***** 11.5 ***** -9.05 ***** 0.38 (0.09, 1.54) 0.176  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper = 0.05  SV (14-day gap) 1,181 ***** ***** ***** ***** ***** ***** 14.6 ******  -9.05 *****  0.38 (0.09, 1.54) 0.176  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper = 0.05  SV (14-day gap) 1,181 ***** ***** ***** ***** *****							3.95	****	15.00	****	0.20 / 0.02 1.71)	0.142
SV (14-day gap) 4,982 ***** **** **** **** **** **** ****	ACEI (14-day gap)	4,542	****	****	****	****	19.77	****	-15.82		0.20 (0.02, 1.71)	0.142
ACEI (14-day gap) 4,995 **** **** **** **** **** **** * 14.65 **** *-11.52 ***** 0.22 (0.03, 1.85) 0.161    Site-Adjusted Analysis	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
ACEI (14-day gap) 4,995 **** **** **** **** 14.65 **** *11.52 **** 0.22 (0.03, 1.63) 0.101    Site-Adjusted Analysis	SV (14-day gap)	4,982	****	****	****	****	3.13	****	11 52	****	0.22 / 0.02 1.05)	0.161
Site-Adjusted Analysis   SV (14-day gap)   2,977   *****   *****   *****   *****   *****   4.58   *****   *****   *****   18.67   *****   *****   *****   *****   18.67   ******	ACEI (14-day gap)	4,995	****	****	****	****	14.65	****	-11.52		0.22 (0.03, 1.63)	0.161
SV (14-day gap) 2,977 ***** **** **** **** **** 4.58 ***** -14.1 ***** 0.25 (0.03, 1.79) 0.167    Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05						61	- 90 Days					
ACEI (14-day gap) 56,538 **** **** **** **** **** **** **** *	Site-Adjusted Analysi	S										
ACEI (14-day gap) 56,538 **** **** **** **** 18.67 ***** 19.67  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper = 0.05  SV (14-day gap) 1,834 **** **** **** **** 15.97 **** 15.97 **** 15.97  ACEI (14-day gap) 1,834 **** **** **** **** 15.97 **** 15.97 **** 15.97  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper = 0.05  SV (14-day gap) 2,927 **** **** **** **** 4.66 ***** 11.5 ****** 11.5 ****** 11.5 ****** 11.5 ****** 11.5 ***** 11.5 ***** 11.5 ***** 11.5 ****** 11.5 ****** 11.5 ***** 11.5 ***** 11.5 ***** 11.5 ****** 11.5 ****** 11.5 *****	SV (14-day gap)	2,977	****	****	****	****	4.58	****	1/1	****	0.25 ( 0.02 1.70)	0.167
SV (14-day gap) 1,834 **** **** **** **** **** **** * 15.97 ***** *-15.97 ****** *-15.97 ****** *-15.97 ***** *-15.97 ***** *-15.97 ****** *-15.97 ***** *-15.97 ***** *-15.97 ***** *-1	ACEI (14-day gap)	56,538	****	****	****	****	18.67	****	-14.1		0.23 (0.03, 1.79)	0.107
SV (14-day gap) 1,834 **** **** **** **** **** **** * 15.97 **** *-15.97 ****** *-15.97 ****** *-15.97 ***** *-15.97 ***** *-15.97 ****** *-15.97 ***** *-15.97 ***** *-15.97 ***** *-15	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
ACEI (14-day gap) 1,834 **** **** **** **** 15.97 ***** 15.97  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 2,927 **** **** **** **** 4.66 ***** -6.85 **** 0.40 (0.04, 3.85) 0.428  ACEI (14-day gap) 3,425 **** **** **** **** 5.54 *****  SV (14-day gap) 2,268 **** **** **** **** 5.54 **** -9.05 ***** 0.38 (0.09, 1.54) 0.176  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 1,181 **** **** **** **** 7.74 *****							0	****	15.07	****		
SV (14-day gap) 2,927 **** **** **** **** 4.66 *****  ACEI (14-day gap) 3,425 **** **** **** **** **** 11.5 *****  Site-Adjusted Analysis  SV (14-day gap) 2,268 **** **** **** **** 5.54 ****	ACEI (14-day gap)	1,834	****	****	****	****	15.97	****	-15.97		-	-
ACEI (14-day gap) 3,425 **** **** **** **** **** 11.5 **** -6.85 **** 0.40 ( 0.04, 3.85) 0.428    Site-Adjusted Analysis   SV (14-day gap) 2,268 **** **** **** **** **** **** 5.54 ****	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
ACEI (14-day gap) 3,425 **** **** **** **** **** 11.5 ***** 11.5 *****  91 - 180 Days  Site-Adjusted Analysis  SV (14-day gap) 2,268 **** **** **** **** 5.54 **** -9.05 ***** 0.38 (0.09, 1.54) 0.176  ACEI (14-day gap) 47,224 **** **** **** **** 14.6 ***** -9.05  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 1,181 **** **** **** **** 7.74 ***** 0.00 ***** 1.00 (0.06, 15.99) 1	SV (14-day gap)	2,927	****	****	****	****	4.66	****	6.05	****	0.40 ( 0.04 - 2.95 )	0.439
Site-Adjusted Analysis  SV (14-day gap) 2,268 **** **** **** **** 5.54 ****  ACEI (14-day gap) 47,224 **** **** **** **** 14.6 *****  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 1,181 **** **** **** **** 7.74 *****  O	ACEI (14-day gap)	3,425	****	****	****	****	11.5	****	-0.65		0.40 ( 0.04, 3.63)	0.426
SV (14-day gap)       2,268       *****       *****       *****       *****       5.54       *****       -9.05       *****       0.38 (0.09, 1.54)       0.176         Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05¹         SV (14-day gap)       1,181       ******       ******       ******       7.74       ******						91	- 180 Days					
ACEI (14-day gap) 47,224 **** **** **** **** 14.6 **** -9.05 ***** 0.38 (0.09, 1.54) 0.176  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 1,181 **** **** **** **** 7.74 ***** 0.38 (0.09, 1.54) 0.176	Site-Adjusted Analysi	s										
ACEI (14-day gap) 47,224 **** **** **** **** 14.6 **** 15.03 **** 10.38 (0.05, 1.34) ****  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05    SV (14-day gap) 1,181 **** **** **** **** 7.74 ***** 1.00 (0.06, 15.99) 1	SV (14-day gap)	2,268	****	****	****	****	5.54	****	0.05	****	0.20/0.00 1.54\	0.176
SV (14-day gap) 1,181 ***** ***** ***** 7.74 ***** 0 ***** 1.00 ( 0.06, 15.99) 1	ACEI (14-day gap)	47,224	****	****	****	****	14.6	****	-9.05		0.36 (0.03, 1.34)	0.176
SV (14-day gap) 1,181 ***** ***** ***** 7.74 ***** 0 ***** 1,00 ( 0,06, 15,99) 1	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
1 ***** 100006 15 44)							7.74	****	0	****	4.00 / 0.00 45.00\	4
	ACEI (14-day gap)	1,181	****	****	****	****	7.74	****	U	***	1.00 ( 0.06, 15.99)	1

cder\_mpl2r\_wp016 Page 75 of 247



	Number of	Person Years	Average Person Days	Average Person Years	Number of	Incidence Rate per 1,000 Person	Risk per 1.000	Incidence Rate Difference per 1,000	Difference in Risk per 1.000 New	Hazard Ratio (95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	,	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Prope						icuis	14044 03013	T CISOII TCUIS	O3C13	intervary	1 Value
SV (14-day gap)	2,231	****	****	****	****	5.64	****		****		
ACEI (14-day gap)	2,902	****	****	****	****	17.06	****	-11.42	****	0.33 ( 0.07, 1.55)	0.16
, , , , , ,	,				181	- 270 Days					
Site-Adjusted Analysis	S										
SV (14-day gap)	1,029	****	****	****	****	10.3	****	-1.85	****	0.83 ( 0.20, 3.41)	0.799
ACEI (14-day gap)	24,192	****	****	****	****	12.15	****	-1.65		0.65 (0.20, 5.41)	0.799
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	253	****	****	****	****	25.37	****	25.37	****		
ACEI (14-day gap)	253	****	****	****	****	0	****	25.57		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	1,012	****	****	****	****	10.47	****	-8.6	****	0.54 ( 0.10, 2.76)	0.455
ACEI (14-day gap)	1,401	****	****	****	****	19.06	****	-0.0		0.34 ( 0.10, 2.70)	0.455
					271	- 365 Days					
Site-Adjusted Analysis											
SV (14-day gap)	631	****	****	****	****	0	****	-11.59	****	_	_
ACEI (14-day gap)	15,675	****	****	****	****	11.59	****	11.55			
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	106	****	****	****	****	0	****	0	****	_	_
ACEI (14-day gap)	106	****	****	****	****	0	****				
Fixed Ratio 1:1 Prope	nsity Score Ma				•	<u> </u>	<u> </u>	<u> </u>	<u> </u>		
SV (14-day gap)	623	****	****	****	****	0	****	-5.85	****	_	_
ACEI (14-day gap)	831	****	****	****	****	5.85	****	5.05			

cder\_mpl2r\_wp016 Page 76 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Race: Pacific Islander	1									·	
						Overall					
Site-Adjusted Analysi	is										
SV (14-day gap)	46	****	****	****	****	0	****	14.26	****		
ACEI (14-day gap)	741	****	****	****	****	14.36	****	-14.36		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	39	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	39	****	****	****	****	0	****	0	4 4 4 4 4	-	-
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	39	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	39	****	****	****	****	0	****	0		-	-
					0	- 30 Days					
Site-Adjusted Analysi	is										
SV (14-day gap)	66	****	****	****	****	0	****	-33.11	****		
ACEI (14-day gap)	1,001	****	****	****	****	33.11	****	-33.11		-	-
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	39	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	39	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	63	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	106	****	****	****	****	0	****	0		-	-
					31	- 60 Days					
Site-Adjusted Analysi	is										
SV (14-day gap)	43	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	652	****	****	****	****	0	****	U		-	-

cder\_mpl2r\_wp016 Page 77 of 247



		Person	Average Person	Average Person	Number	Incidence Rate per 1,000	Risk per	Incidence Rate Difference	Difference in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	32	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	32	****	****	****	****	0	****	0	4. 4. 4. 4.	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	37	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	32	****	****	****	****	0	****	0		-	-
					61	- 90 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	28	****	****	****	****	0	****	26.52	****		
ACEI (14-day gap)	490	****	****	****	****	26.53	****	-26.53		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	17	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	17	****	****	****	****	0	****	0	4. 4. 4. 4.	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	25	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	27	****	****	****	****	0	****	0		-	-
					91	- 180 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	24	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	424	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	11	****	****	****	****	0	****		****		
ACEI (14-day gap)	11	****	****	****	****	0	****	0	***	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	21	****	****	****	****	0	****		****		
ACEI (14-day gap)	21	****	****	****	****	0	****	0	<b>ጥ ጥ ጥ ጥ</b>	-	-

cder\_mpl2r\_wp016 Page 78 of 247



			_	_		Incidence		Incidence			
		_	Average	Average		Rate per		Rate	Difference	Hazard Ratio	
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per		
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
					181	270 Days					
Site-Adjusted Analysis	5										
SV (14-day gap)	14	****	****	****	****	0	****	-24.49	****	_	_
ACEI (14-day gap)	208	****	****	****	****	24.49	****	-24.43			
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	litional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	****	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	****	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	12	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	****	****	****	****	****	0	****	0		-	-
					271	365 Days					
Site-Adjusted Analysis	5										
SV (14-day gap)	****	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	138	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	****	****	****	****	****	0	****		****		
ACEI (14-day gap)	****	****	****	****	****	0	****	0	***	-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	nditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	****	****	****	****	****	0	****	0	****		
ACEI (14-day gap)	****	****	****	****	****	0	****	0		-	-
Race: White											
						Overall					
Site-Adjusted Analysis	3										
SV (14-day gap)	28,706	****	****	****	****	1.05	****	2.20	****	0.22 / 0.42 . 0.44\	10.001
ACEI (14-day gap)	490,094	****	****	****	****	4.34	****	-3.29	* * * * *	0.23 ( 0.13, 0.41)	<0.001

cder\_mpl2r\_wp016 Page 79 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	28,638	****	****	****	****	1.43	****	-4.94	****	0.22 / 0.11 .0.46\	<0.001
ACEI (14-day gap)	28,638	****	****	****	****	6.37	****	-4.94		0.23 ( 0.11, 0.46)	<0.001
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	28,638	****	****	****	****	1.05	****	2.20	****	0.22 / 0.12 . 0.44\	<0.001
ACEI (14-day gap)	28,638	****	****	****	****	4.33	****	-3.28		0.23 ( 0.12, 0.44)	<0.001
					0	- 30 Days					
Site-Adjusted Analysis	S										
SV (14-day gap)	28,706	****	****	****	****	0.88	****	-8.27	****	0.10 ( 0.02, 0.39)	<0.001
ACEI (14-day gap)	490,094	****	****	****	****	9.15	****	-0.27		0.10 (0.02, 0.39)	<0.001
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	28,638	****	****	****	****	0.91	****	0.14	****	0.00 ( 0.03 . 0.30)	0.001
ACEI (14-day gap)	28,638	****	****	****	****	10.05	****	-9.14		0.09 ( 0.02, 0.39)	0.001
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	28,638	****	****	****	****	0.88	****	-8.84	****	0.00 ( 0.02 0.20)	0.001
ACEI (14-day gap)	28,638	****	****	****	****	9.72	****	-8.84		0.09 ( 0.02, 0.39)	0.001
					31	- 60 Days					
Site-Adjusted Analysis	S										
SV (14-day gap)	26,209	****	****	****	****	1.69	****	-2.48	****	0.41 ( 0.13, 1.28)	0.125
ACEI (14-day gap)	450,620	****	****	****	****	4.16	****	-2.40		0.41 (0.13, 1.26)	0.123
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	23,776	****	****	****	****	2.1	****	1.4	****	0.00 ( 0.14 - 2.51 )	0.404
ACEI (14-day gap)	23,776	****	****	****	****	3.5	****	-1.4	ner ner ner ner	0.60 ( 0.14, 2.51)	0.484
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	26,150	****	****	****	****	1.69	****	1 54	****	0.53/0.13 3.00\	0.357
ACEI (14-day gap)	26,026	****	****	****	****	3.24	****	-1.54		0.52 ( 0.13, 2.08)	0.357

cder\_mpl2r\_wp016 Page 80 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
					61	- 90 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	17,556	****	****	****	****	1.51	****	-2.23	****	0.40 ( 0.10, 1.63)	0.203
ACEI (14-day gap)	333,594	****	****	****	****	3.74	****	-2.23		0.40 ( 0.10, 1.03)	0.203
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	11,888	****	****	****	****	2.37	****	0	****	1.00 ( 0.14, 7.10)	1
ACEI (14-day gap)	11,888	****	****	****	****	2.37	****	U		1.00 ( 0.14, 7.10)	1
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	17,513	****	****	****	****	1.51	****	-3.16	****	0.32 ( 0.07, 1.54)	0.156
ACEI (14-day gap)	19,475	****	****	****	****	4.68	****	-5.10		0.32 (0.07, 1.34)	0.130
					91	- 180 Days					
Site-Adjusted Analysi	s										
SV (14-day gap)	14,448	****	****	****	****	1.18	****	-1.75	****	0.41 ( 0.13, 1.27)	0.121
ACEI (14-day gap)	289,770	****	****	****	****	2.92	****	-1.75		0.41 ( 0.13, 1.27)	0.121
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	8,587	****	****	****	****	1.74	****	4 24	****	0.20 / 0.06   1.20	0.110
ACEI (14-day gap)	8,587	****	****	****	****	6.08	****	-4.34		0.29 ( 0.06, 1.38)	0.118
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	14,411	****	****	****	****	1.18	****	-1.12	****	0.51 ( 0.13, 1.96)	0.324
ACEI (14-day gap)	16,921	****	****	****	****	2.3	****	-1.12		0.51 (0.15, 1.90)	0.524
					181	- 270 Days					
Site-Adjusted Analysi	s										
SV (14-day gap)	7,898	****	****	****	****	0	****	-3.19	****		
ACEI (14-day gap)	176,393	****	****	****	****	3.19	****	-3.13		<u>-</u>	
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	2,800	****	****	****	****	0	****	6.60	****		
ACEI (14-day gap)	2,800	****	****	****	****	6.69	****	-6.69	***	-	-
, , , , , ,	•										

cder\_mpl2r\_wp016 Page 81 of 247



		Person	Average Person	Average Person	Number	Incidence Rate per 1,000	Risk per	Incidence Rate Difference	Difference in Risk per	Hazard Ratio	Wald
Medical Product	Number of	Years	Days	Years	of Events	Person	1,000	per 1,000 Person Years	1,000 New	(95% Confidence Interval) <sup>2</sup>	P-Value <sup>2</sup>
	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	intervaij	P-value
Fixed Ratio 1:1 Prope	nsity Score Ma				•						
SV (14-day gap)	7,872	****	****	****	****	0	****	-3.58	****		
ACEI (14-day gap)	9,890	****	****	****	****	3.58	****	-3.36		-	-
					271	365 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	4,930	****	****	****	****	0.96	****	1.64	****	0.27 / 0.05 (2.65)	0.221
ACEI (14-day gap)	125,154	****	****	****	****	2.59	****	-1.64	de de de de de	0.37 ( 0.05, 2.65)	0.321
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Con	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	1,178	****	****	****	****	0	****	4.62	****		
ACEI (14-day gap)	1,178	****	****	****	****	4.62	****	-4.62	de de de de de	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unc	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	4,916	****	****	****	****	0.96	****	4.2	****	0.44/0.05 4.35\	0.470
ACEI (14-day gap)	6,552	****	****	****	****	2.16	****	-1.2	*********	0.44 ( 0.05, 4.25)	0.479
1											

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 82 of 247

<sup>&</sup>lt;sup>2</sup>Data presented by a dash are unable to be calculated. This table may not use all data representations.

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



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

			Average	Average		Incidence Rate per		Incidence Rate	Difference					
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	<b>Hazard Ratio</b>				
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald			
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval)	P-Value			
<b>Site-Adjusted Analys</b>	sis													
SV	43,777	****	****	****	****	1.35	****	-1.67	****	0.42 (0.27, 0.65)	<0.001			
ARBs	337,157	****	****	****	****	3.01	****	-1.07		0.42 (0.27, 0.65)	<0.001			
Fixed Ratio 1:1 Prop	xed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05 <sup>1</sup>													
SV	43,755	****	****	****	****	1.36	****	-0.84	****	0.62 (0.31, 1.24)	0.174			
ARBs	43,755	****	****	****	****	2.2	****	-0.64		0.02 (0.31, 1.24)	0.174			
Fixed Ratio 1:1 Prop	ensity Score Mat	tched Unco	onditional A	nalysis; Cali	per= 0.05									
SV	43,755	****	****	****	****	1.35	****	-0.87	****	0.59 (0.35, 1.01)	0.053			
ARBs	43,755	****	****	****	****	2.21	****	-0.67		0.59 (0.55, 1.01)	0.055			
<b>Propensity Score Ad</b>	justed Stratified	Analysis; F	Percentiles=	10 <sup>1</sup>										
SV	43,777	****	****	****	****	1.35	****	1.67	****	0.50 (0.33, 0.70)	0.003			
ARBs	337,157	****	****	****	****	3.01	****	-1.67		0.50 (0.32, 0.79)	0.003			

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 83 of 247

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



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

			Average	Average		Incidence Rate per		Incidence Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	<b>Hazard Ratio</b>	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
						Overall					
<b>Site-Adjusted Analysis</b>											
SV (14-day gap)	43,777	****	****	****	****	1.35	****	-1.67	****	0.42 ( 0.27, 0.65)	<0.001
ARBs (14-day gap)	337,157	****	****	****	****	3.01	****	-1.07		0.42 ( 0.27,  0.03)	<b>\0.001</b>
Fixed Ratio 1:1 Propen	sity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	43,755	****	****	****	****	1.36	****	-0.84	****	0.62 ( 0.31, 1.24)	0.174
ARBs (14-day gap)	43,755	****	****	****	****	2.2	****	-0.64		0.62 (0.51, 1.24)	0.174
Fixed Ratio 1:1 Propen	sity Score Ma			nalysis; Cali	iper= 0.05						
SV (14-day gap)	43,755	****	****	****	****	1.35	****	-0.87	****	0.59 ( 0.35, 1.01)	0.053
ARBs (14-day gap)	43,755	****	****	****	****	2.21	****	-0.87		0.59 (0.55, 1.01)	0.055
					0	- 30 Days					
<b>Site-Adjusted Analysis</b>											
SV (14-day gap)	43,777	****	****	****	****	1.15	****	-4.81	****	0.20 ( 0.07, 0.53)	0.001
ARBs (14-day gap)	337,157	****	****	****	****	5.96	****	4.01		0.20 ( 0.07,  0.55)	0.001
Fixed Ratio 1:1 Propen	sity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	43,755	****	****	****	****	1.19	****	-2.38	****	0.33 ( 0.11, 1.03)	0.057
ARBs (14-day gap)	43,755	****	****	****	****	3.57	****	-2.50		0.55 (0.11, 1.05)	0.057
Fixed Ratio 1:1 Propen	sity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	43,755	****	****	****	****	1.15	****	-2.29	****	0.33 ( 0.11, 1.04)	0.058
ARBs (14-day gap)	43,755	****	****	****	****	3.45	****	-2.29		0.55 (0.11, 1.04)	0.038
					31	- 60 Days					
<b>Site-Adjusted Analysis</b>											
SV (14-day gap)	39,842	****	****	****	****	1.49	****	-1.92	****	0.45 ( 0.16, 1.22)	0.116
ARBs (14-day gap)	316,299	****	****	****	****	3.42	****	-1.52		0.73 (0.10, 1.22)	0.110
Fixed Ratio 1:1 Proper	sity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	36,865	****	****	****	****	1.35	****	0	****	1.00 ( 0.20, 4.95)	1
	36,865	****	****	****	****	1.35	****	U		1.00 ( 0.20, 4.95)	1

cder\_mpl2r\_wp016 Page 84 of 247



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

						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Prope	nsity Score Ma			nalysis; Cal							
SV (14-day gap)	39,822	****	****	****	****	1.49	****	-1.25	****	0.55 ( 0.17, 1.84)	0.333
ARBs (14-day gap)	40,510	****	****	****	****	2.74	****	-1.25		0.55 (0.17, 1.64)	0.555
					61	- 90 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	26,195	****	****	****	****	2.04	****	-0.77	****	0.77 ( 0.28, 2.11)	0.606
ARBs (14-day gap)	243,513	****	****	****	****	2.81	****	-0.77		0.77 (0.28, 2.11)	0.000
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Con	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	18,508	****	****	****	****	3.07	****	0	****	1.00 ( 0.25, 4.00)	1
ARBs (14-day gap)	18,508	****	****	****	****	3.07	****	0		1.00 ( 0.25, 4.00)	1
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unc	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	26,181	****	****	****	****	2.04	****	-0.06	****	0.99 ( 0.26, 3.67)	0.982
ARBs (14-day gap)	30,964	****	****	****	****	2.1	****	-0.00		0.99 (0.20, 3.07)	0.362
					91	- 180 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	21,286	****	****	****	****	1.61	****	-0.64	****	0.70 ( 0.31, 1.61)	0.406
ARBs (14-day gap)	214,289	****	****	****	****	2.25	****	-0.04		0.70 (0.31, 1.01)	0.400
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Con	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	13,070	****	****	****	****	1.17	****	0	****	1.00 / 0.14 7.10)	1
ARBs (14-day gap)	13,070	****	****	****	****	1.17	****	0		1.00 ( 0.14, 7.10)	1
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unc	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	21,278	****	****	****	****	1.61	****	-0.47	****	0.77 ( 0.28, 2.13)	0.62
ARBs (14-day gap)	26,917	****	****	****	****	2.08	****	-0.47		0.77 (0.26, 2.15)	0.62
					181	- 270 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	11,464	****	****	****	****	0.9	****	-1.17	****	0.44 ( 0.11, 1.80)	0.252
ARBs (14-day gap)	130,098	****	****	****	****	2.07	****	-1.1/		0.44 ( 0.11, 1.00)	0.232

cder\_mpl2r\_wp016 Page 85 of 247



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

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval) <sup>2</sup>	Wald P-Value <sup>2</sup>
Fixed Ratio 1:1 Prope	nsity Score Ma										
SV (14-day gap)	4,037	****	****	****	****	0	****	0	****	_	_
ARBs (14-day gap)	4,037	****	****	****	****	0	****	0			
Fixed Ratio 1:1 Prope	nsity Score Ma			nalysis; Cal	iper= 0.05						
SV (14-day gap)	11,461	****	****	****	****	0.9	****	-0.7	****	0.58 ( 0.11, 3.00)	0.518
ARBs (14-day gap)	15,621	****	****	****	****	1.6	****	-0.7		0.38 ( 0.11, 3.00)	0.518
					271	- 365 Days					
Site-Adjusted Analysis	S										
SV (14-day gap)	7,161	****	****	****	****	0.66	****	-0.9	****	0.42 ( 0.06 - 2.10)	0.412
ARBs (14-day gap)	92,668	****	****	****	****	1.56	****	-0.9		0.43 ( 0.06, 3.19)	0.412
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Con	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	1,737	****	****	****	****	0	****		****		
ARBs (14-day gap)	1,737	****	****	****	****	0	****	0	***	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unc	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	7,159	****	****	****	****	0.66	****	0.33	****	0.70 ( 0.07 . 0.00)	) 0.036
ARBs (14-day gap)	10,561	****	****	****	****	0.89	****	-0.23		0.78 ( 0.07, 8.60)	0.839
1									•	•	•

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 86 of 247

<sup>&</sup>lt;sup>2</sup>Data presented by a dash are unable to be calculated. This table may not use all data representations.

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



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

				_		Incidence		Incidence	-:cc		
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval)	P-Value
No Angioedema (-183	3, -1)										
Site-Adjusted Analysi	is										
SV	43,717	****	****	****	****	1.09	****	-1.34	****	0.43 (0.27, 0.70)	<0.001
ARBs	336,332	****	****	****	****	2.43	****	-1.54		0.43 (0.27, 0.70)	<0.001
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	43,685	****	****	****	****	1.05	****	0.04	****	0.52/0.24 1.12\	0.1
ARBs	43,685	****	****	****	****	1.99	****	-0.94		0.53 (0.24, 1.13)	0.1
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	43,685	****	****	****	****	1.09	****	-0.91	****	0.53 (0.30, 0.95)	0.032
ARBs	43,685	****	****	****	****	2.01	****	-0.91		0.55 (0.50, 0.95)	0.032
Angioedema (-183, -1	L)										
Site-Adjusted Analysi	is										
SV	60	****	****	****	****	174.67	****	-96.96	****	0.58 (0.21, 1.59)	0.29
ARBs	825	****	****	****	****	271.63	****	-90.90		0.36 (0.21, 1.39)	0.29
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	48	****	****	****	****	215.52	****	107.76	****	0.67./0.44. 3.60\	0.657
ARBs	48	****	****	****	****	323.28	****	-107.76	4. 4. 4. 4. 4.	0.67 (0.11, 3.99)	0.657
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	48	****	****	****	****	209.86	****	25.24	****	1 26 (0 20 6 00)	0.696
ARBs	48	****	****	****	****	174.52	****	35.34	THE THE THE THE	1.36 (0.30, 6.09)	0.686

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 87 of 247

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



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

		Person	Average Person	Average Person	Number	Incidence Rate per 1,000	Risk per	Incidence Rate Difference	Difference in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	•	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
No Angioedema (-183		at NISK	at NISK	at NISK	Events	Tears	New Osers	Person rears	Osers	iiiteivaij	r-value
110 Aligiocacilia ( 103	·, ±,					Overall					
Site-Adjusted Analysis						<del>overun</del>					
SV (14-day gap)	43,717	****	****	****	****	1.09	****				
ARBs (14-day gap)	336,332	****	****	****	****	2.43	****	-1.34	****	0.43 ( 0.27, 0.70)	<0.001
Fixed Ratio 1:1 Proper		tched Cond	litional Ana	lvsis: Caline	r= 0.05 <sup>1</sup>						
SV (14-day gap)	43,685	****	****	****	****	1.05	****				
ARBs (14-day gap)	43,685	****	****	****	****	1.99	****	-0.94	****	0.53 ( 0.24, 1.13)	0.1
Fixed Ratio 1:1 Proper		tched Unco	nditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	43,685	****	****	****	****	1.09	****		****		
ARBs (14-day gap)	43,685	****	****	****	****	2.01	****	-0.91	****	0.53 ( 0.30, 0.95)	0.032
, , , , , ,	·				0	- 30 Days					
Site-Adjusted Analysis	S										
SV (14-day gap)	43,717	****	****	****	****	0.58	****	-3.51	****	0.14 ( 0.04, 0.58)	0.007
ARBs (14-day gap)	336,332	****	****	****	****	4.08	****	-5.51		0.14 ( 0.04, 0.38)	0.007
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	43,685	****	****	****	****	0.6	****	2.20	****	0.30 ( 0.04 , 0.01)	0.020
ARBs (14-day gap)	43,685	****	****	****	****	2.98	****	-2.38		0.20 ( 0.04, 0.91)	0.038
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	43,685	****	****	****	****	0.58	****	-2.3	****	0.20 ( 0.04, 0.91)	0.038
ARBs (14-day gap)	43,685	****	****	****	****	2.88	****	-2.5		0.20 ( 0.04, 0.91)	0.038
					31	- 60 Days					
Site-Adjusted Analysis											
SV (14-day gap)	39,788	****	****	****	****	1.49	****	-1.49	****	0.51 (0.19, 1.41)	0.194
ARBs (14-day gap)	315,576	****	****	****	****	2.98	****	1.75		0.51 ( 0.15, 1.41)	0.154
Fixed Ratio 1:1 Proper	nsity Score Ma		ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	36,810	****	****	****	****	1.35	****	0	****	1.00 ( 0.20, 4.95)	1
ARBs (14-day gap)	36,810	****	****	****	****	1.35	****			1.00 ( 0.20, 4.33)	
Fixed Ratio 1:1 Proper	nsity Score Ma				•						
SV (14-day gap)	39,758	****	****	****	****	1.5	****	-1.25	****	0.55 ( 0.17, 1.84)	0.333
ARBs (14-day gap)	40,450	****	****	****	****	2.75	****	1.23		0.55 ( 0.17, 1.04)	0.555
					61	- 90 Days					

cder\_mpl2r\_wp016 Page 88 of 247



Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval) <sup>2</sup>	Wald P-Value <sup>2</sup>
Site-Adjusted Analysis		****	****	****	****	1.50	****				
SV (14-day gap)	26,157	****	****	****	****	1.53	****	-0.7	****	0.72 ( 0.22, 2.33)	0.586
ARBs (14-day gap)	242,996					2.23	****				
Fixed Ratio 1:1 Proper	nsity Score Ma										
SV (14-day gap)	18,487	****	****	****	****	2.3	****	-0.77	****	0.75 ( 0.17, 3.35)	0.706
ARBs (14-day gap)	18,487	****	****	****	****	3.07	****	-0.77		0.73 (0.17, 3.33)	0.700
Fixed Ratio 1:1 Proper	nsity Score Ma				•						
SV (14-day gap)	26,139	****	****	****	****	1.53	****	-0.15	****	0.91 ( 0.20, 4.09)	0.907
ARBs (14-day gap)	30,921	****	****	****	****	1.68	****	-0.13		0.91 (0.20, 4.09)	0.907
					91	- 180 Days					
Site-Adjusted Analysis	3										
SV (14-day gap)	21,255	****	****	****	****	1.34	****	-0.66	****	0.67 ( 0.27, 1.65)	0.382
ARBs (14-day gap)	213,845	****	****	****	****	2	****	-0.00		0.67 (0.27, 1.65)	0.362
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	litional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	13,057	****	****	****	****	1.17	****		****	4.00 (0.44 7.40)	4
ARBs (14-day gap)	13,057	****	****	****	****	1.17	****	0	****	1.00 ( 0.14, 7.10)	1
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	nditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	21,245	****	****	****	****	1.34	****	0.74	****	0.64/0.00 4.00\	0.400
ARBs (14-day gap)	26,883	****	****	****	****	2.08	****	-0.74	****	0.64 ( 0.22, 1.89)	0.422
					181	- 270 Days					
Site-Adjusted Analysis	3										
SV (14-day gap)	11,447	****	****	****	****	0.9	****	0.04	****	0.40 ( 0.42 - 2.04 )	0.210
ARBs (14-day gap)	129,815	****	****	****	****	1.85	****	-0.94	and the contract of	0.49 ( 0.12, 2.01)	0.319

cder\_mpl2r\_wp016 Page 89 of 247



			Average	Average		Incidence Rate per	n: 1	Incidence Rate	Difference	Hazard Ratio	
	Number of	Person Years	Person	Person	Number of	1,000	Risk per	Difference	in Risk per	(95% Confidence	Wald
Medical Product	New Users	at Risk	Days at Risk	Years at Risk		Person Years	1,000	per 1,000	1,000 New Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
					Events	rears	New Osers	Person Years	Users	intervaij	P-value
Fixed Ratio 1:1 Prope		*****	*****	iysis; Calipe	er= 0.05 *****		****				
SV (14-day gap)	4,033					0		0	****	-	-
ARBs (14-day gap)	4,033	****	****	****	*****	0	****				
Fixed Ratio 1:1 Prope											
SV (14-day gap)	11,442	****	****	****	****	0.9	****	-0.38	****	0.72 ( 0.13, 3.92)	0.701
ARBs (14-day gap)	15,602	****	****	****	****	1.28	****	0.55		0.72 ( 0.13) 0.32)	0.701
					271	- 365 Days					
Site-Adjusted Analysis											
SV (14-day gap)	7,150	****	****	****	****	0.66	****	-0.75	****	0.48 ( 0.07, 3.57)	0.477
ARBs (14-day gap)	92,474	****	****	****	****	1.41	****	-0.73		0.48 ( 0.07, 3.37)	0.477
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	1,736	****	****	****	****	0	****		****		
ARBs (14-day gap)	1,736	****	****	****	****	0	****	0	****	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	7,147	****	****	****	****	0.66	****	2.22	****	0.70 ( 0.07 . 0.61)	2.24
ARBs (14-day gap)	10,551	****	****	****	****	0.89	****	-0.23	****	0.78 ( 0.07, 8.61)	0.84
Angioedema (-183, -1											
						Overall					
Site-Adjusted Analysis	s										
SV (14-day gap)	60	****	****	****	****	174.67	****	05.05	****	0.50 / 0.24 .4.50	0.20
ARBs (14-day gap)	825	****	****	****	****	271.63	****	-96.96	****	0.58 ( 0.21, 1.59)	0.29
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lvsis: Caline	er= 0.05 <sup>1</sup>						
SV (14-day gap)	48	****	****	****	****	215.52	****				
ARBs (14-day gap)	48	****	****	****	****	323.28	****	-107.76	****	0.67 (0.11, 3.99)	0.657
Fixed Ratio 1:1 Prope		tched Unco	onditional A	nalvsis: Cal	iper= 0.05	3_35					
SV (14-day gap)	48	****	****	****	****	209.86	****				
ARBs (14-day gap)	48	****	****	****	****	174.52	****	35.34	****	1.36 ( 0.30, 6.09)	0.686
, indo (1-7 day gap)	-10					1,7.52					

cder\_mpl2r\_wp016 Page 90 of 247



Medical Product   Number   Person   Person   Days   Varis   Organisation   Person   Person   Person   Person   Person   Person   1,000   Person   1,000   Person							Incidence		Incidence			
Number of   Years   Days   Years   Of   Person   1,000   per 1,000   Users   Users   Users   Otal   P-Value   P-Value				Average	Average		Rate per		Rate	Difference		
Medical Product   New Users   at Risk   at Risk   at Risk   at Risk   events   Vears   New Users   Person Years   Users   Interval]   P-Value			Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per		
Site-Adjusted Analysis		Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	•	
Site-Adjusted Analysis	Medical Product	New Users	at Risk	at Risk	at Risk			New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
SV (14-day gap)   681						0	- 30 Days					
ARBS (14-day gap)   So   So   So   So   So   So   So   S	Site-Adjusted Analysi	S										
This case   This		681	****	****	****	****	49.13		-86.01	****	0.49 ( 0.12 2.01 )	0 322
SV (14-day gap)   785   ****   ****   ****   ****   90.29   ****   0   ****   1.00 (0.14, 7.10)   1		•					135.14	****	-80.01		0.49 (0.12, 2.01)	0.322
SV (14-day gap)   785   ****   ****   ****   ****   90.29   ****   0   ****   1.00 (0.14, 7.10)   1	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Con	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
ARBs (14-day gap) 785 ***** ***** ***** 90.29 ***** 0 1.00 (0.14, 7.10) 1  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Calipers 0.05  SV (14-day gap) 4,532 ***** **** **** ***** 11.37 **** 5.15 **** 1.01 (0.14, 7.15) 0.995  Site-Adjusted Analysis  SV (14-day gap) 54 **** **** **** **** **** 195.01 ***** -195.01 ****			****	****			90.29	****	0	****	1.00 / 0.14 7.10)	1
SV (14-day gap)	ARBs (14-day gap)	785	****	****	****	****	90.29	****	U		1.00 ( 0.14, 7.10)	1
10.12   11.37   11.3	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unc	onditional A	nalysis; Cal	iper= 0.05						
ARBs (14-day gap) 6,990 ***** **** **** **** **** **** ****	SV (14-day gap)	4,532	****	****	****	****	16.52	****	Г 1Г	****	1.01/0.14 7.15)	0.005
Site-Adjusted Analysis	ARBs (14-day gap)	6,990	****	****	****	****	11.37	****	5.15		1.01 (0.14, 7.15)	0.995
SV (14-day gap) 54 **** **** **** **** **** 195.01 ***** -						31	- 60 Days					
ARBs (14-day gap) 725 ***** ***** ***** 195.01 ***** -195.01 ****** -195.01 ***** -195.01 ****** -195.01 ***** -195.01 ***** -19	Site-Adjusted Analysi	s										
ARBs (14-day gap) 725 **** **** **** **** 195.01 ****	SV (14-day gap)	54	****	****	****	****	0	****	105.01	****		
SV (14-day gap) 98 **** **** **** **** 0 ***** 0 ***** 0 ***** 1	ARBs (14-day gap)	725	****	****	****	****	195.01	****	-195.01		-	-
SV (14-day gap) 98 **** **** **** **** 0 ***** 0 ***** 0 ***** 1	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Con	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
ARBs (14-day gap) 98 **** **** **** **** 0 ***** 0 *****  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 455 **** **** **** 0 ***** 0 *****  ARBs (14-day gap) 519 **** **** **** 0 *****  61 - 90 Days  Site-Adjusted Analysis  SV (14-day gap) 38 **** **** **** **** 354.61 *****  ARBs (14-day gap) 522 **** **** **** **** 276.04 *****  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 23 **** **** **** 0 ***** 0 ***** 0 ***** 0 ***** 0 ***** 0 ***** 0 ***** 0 ***** 0 ***** 0 ******		98	****	****	****	****	0	****		****		
SV (14-day gap)   455   ****   ****   *****   *****   0   *****	ARBs (14-day gap)	98	****	****	****	****	0	****	U	4. 4. 4. 4. 4.	-	-
ARBs (14-day gap) 519 **** **** **** **** 0 ***** 0 ***** 0 *****  Site-Adjusted Analysis  SV (14-day gap) 38 **** **** **** **** 354.61 **** 78.57 **** 1.41 (0.18, 10.92) 0.743  ARBs (14-day gap) 522 **** **** **** **** 276.04 **** 78.57 **** 1.41 (0.18, 10.92) 0.743  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 23 **** **** **** 0 ***** -666.67 *****	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unc	onditional A	nalysis; Cal	iper= 0.05						
ARBs (14-day gap) 519 **** **** **** **** 0 *****    Site-Adjusted Analysis   SV (14-day gap) 38	SV (14-day gap)	455	****	****	****	****	0	****	0	****		
Site-Adjusted Analysis         SV (14-day gap)       38       *****       *****       *****       354.61       *****       78.57       *****       1.41 (0.18, 10.92)       0.743         ARBs (14-day gap)       522       *****       *****       *****       276.04       *****       78.57       *****       1.41 (0.18, 10.92)       0.743         Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05¹         SV (14-day gap)       23       *****       ******       ******       0       ******       -666.67       *****       -       -	ARBs (14-day gap)	519	****	****	****	****	0	****	U		-	-
SV (14-day gap)       38       *****       *****       *****       *****       354.61       *****       78.57       *****       1.41 (0.18, 10.92)       0.743         ARBs (14-day gap)       522       *****       *****       *****       276.04       *****       78.57       *****       1.41 (0.18, 10.92)       0.743         Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05¹         SV (14-day gap)       23       *****       ******       ******       0       ******       -666.67       *****       -						61	- 90 Days					
ARBs (14-day gap) 522 **** **** **** **** 276.04 **** 78.57 **** 1.41 (0.18, 10.92) 0.743  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 23 **** **** **** **** 0 ***** -666.67 *****	Site-Adjusted Analysi	S										
ARBs (14-day gap) 522 **** **** **** 276.04 **** 76.37 1.41 (0.18, 10.32) 0.743  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 23 **** **** **** 0 ***** -666.67 ***** -	SV (14-day gap)	38	****	****	****	****	354.61	****	70 57	****	1 /1 / 0 10 10 02\	0.742
SV (14-day gap) 23 ***** ***** ***** 0 ***** -666 67 *****	ARBs (14-day gap)	522	****	****	****	****	276.04	****	/8.5/		1.41 ( 0.18, 10.92)	0.743
SV (14-day gap) 23 ***** ***** ***** 0 ***** -666 67 *****	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Con	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
-hhh h / ******							0	****	666.67	****		
	ARBs (14-day gap)	23	****	****	****	****	666.67	****	-666.67	* * * * *	-	-

cder\_mpl2r\_wp016 Page 91 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	<b>Hazard Ratio</b>	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	32	****	****	****	****	420.17	****	25.55	****	1 14 / 0 07 19 21\	0.024
ARBs (14-day gap)	34	****	****	****	****	384.62	****	35.55		1.14 ( 0.07, 18.31)	0.924
					91	- 180 Days					
Site-Adjusted Analysis	S										
SV (14-day gap)	31	****	****	****	****	173.31	****	54.52	****	1.48 ( 0.19, 11.65)	0.711
ARBs (14-day gap)	449	****	****	****	****	118.79	****	54.52		1.48 ( 0.13, 11.03)	0.711
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	14	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	14	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	26	****	****	****	****	191.2	****	191.2	****	_	_
ARBs (14-day gap)	29	****	****	****	****	0	****	191.2		-	
					181	- 270 Days					
Site-Adjusted Analysis											
SV (14-day gap)	19	****	****	****	****	0	****	-106.5	****	_	_
ARBs (14-day gap)	285	****	****	****	****	106.5	****	100.5			
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	****	****	****	****	****	0	****	0	****	_	_
ARBs (14-day gap)	****	****	****	****	****	0	****	U		-	
Fixed Ratio 1:1 Proper	nsity Score Ma				iper= 0.05						
SV (14-day gap)	18	****	****	****	****	0	****	0	****	_	_
ARBs (14-day gap)	15	****	****	****	****	0	****	0			_
					271	- 365 Days					
Site-Adjusted Analysis											
SV (14-day gap)	12	****	****	****	****	0	****	-67.2	****	_	_
ARBs (14-day gap)	197	****	****	****	****	67.2	****	-07.2			

cder\_mpl2r\_wp016 Page 92 of 247



			A.,	Avenage		Incidence		Incidence	Difference		
	Number of	Person Years	Average Person Days	Average Person Years	Number of	Rate per 1,000 Person	Risk per 1,000	Rate Difference per 1,000	in Risk per 1,000 New	Hazard Ratio (95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	****	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	****	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	11	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	****	****	****	****	****	0	****	* 0		-	-

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 93 of 247

<sup>&</sup>lt;sup>2</sup>Data presented by a dash are unable to be calculated. This table may not use all data representations.

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



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

			_	_		Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval)	P-Value
No Angioedema (eve	er, -1)										
<b>Site-Adjusted Analys</b>	sis										
SV	43,178	****	****	****	****	0.98	****	-1.05	****	0.46 (0.29 0.79)	0.004
ARBs	329,798	****	****	****	****	2.03	****	-1.05		0.46 (0.28, 0.78)	0.004
Fixed Ratio 1:1 Propo	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	42,832	****	****	****	****	0.96	****	0.75	****	0.56 (0.35, 4.37)	0.167
ARBs	42,832	****	****	****	****	1.71	****	-0.75		0.56 (0.25, 1.27)	0.167
Fixed Ratio 1:1 Propo	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	42,832	****	****	****	****	0.98	****	-0.74	****	0.56 (0.30, 1.04)	0.066
ARBs	42,832	****	****	****	****	1.72	****	-0.74		0.56 (0.50, 1.04)	0.066
Angioedema (ever, -	1)										
Site-Adjusted Analys	sis										
SV	599	****	****	****	****	27.13	****	-20.81	****	0.51 (0.22, 1.15)	0.104
ARBs	7,359	****	****	****	****	47.94	****	-20.61		0.51 (0.22, 1.15)	0.104
Fixed Ratio 1:1 Propo	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	591	****	****	****	****	36.79	****	0	****	4.00 (0.30, 3.45)	1
ARBs	591	****	****	****	****	36.79	****	0	T T T T	1.00 (0.29, 3.45)	1
Fixed Ratio 1:1 Propo	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	591	****	****	****	****	27.53	****	2 77	****	0.95 (0.30, 3.47)	0.772
ARBs	591	****	****	****	****	30.3	****	-2.77	nan nan nan nan	0.85 (0.30, 2.47)	0.772

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 94 of 247

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



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

			Average	Average		Incidence Rate per		Incidence Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference		Hazard Ratio	
	Normala are af					•	•		in Risk per		المارماليا
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval)	P-Value
No Serious Allergies											
Site-Adjusted Analysi											
SV	37,847	****	****	****	****	1.17	****	-1.41	****	0.43 (0.26, 0.71)	< 0.001
ARBs	282,725	****	****	****	****	2.59	****	1.71		0.45 (0.20, 0.71)	10.001
<b>Fixed Ratio 1:1 Prope</b>	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	37,637	****	****	****	****	1.07	****	-0.72	****	0.60 (0.36, 1.37)	0.226
ARBs	37,637	****	****	****	****	1.79	****	-0.72		0.60 (0.26, 1.37)	0.226
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	37,637	****	****	****	****	1.18	****	-0.94	****	0.54 (0.30, 0.99)	0.045
ARBs	37,637	****	****	****	****	2.12	****	-0.94		0.54 (0.50, 0.99)	0.045
Serious Allergies											
Site-Adjusted Analysi	is										
SV	5,930	****	****	****	****	2.56	****	2.02	****	0.42 (0.19. 1.06)	0.069
ARBs	54,432	****	****	****	****	5.5	****	-2.93		0.43 (0.18, 1.06)	0.068
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	5,774	****	****	****	****	2.65	****	4	****	0.60/0.44.0.54\	0.404
ARBs	5,774	****	****	****	****	4.42	****	-1.77	~ ~ <b>^ ^ ^</b>	0.60 (0.14, 2.51)	0.484
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	5,774	****	****	****	****	2.64	****	0.41	****	0.00 (0.27, 2.72)	0.001
ARBs	5,774	****	****	****	****	3.05	****	-0.41	4, 4, 4, 4, 4,	0.86 (0.27, 2.73)	0.801

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 95 of 247

<sup>\*\*\*\*\*</sup>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.



Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval) <sup>2</sup>	Wald P-Value <sup>2</sup>
Sex: Male											
						Overall					
Site-Adjusted Analysi											
SV (14-Day Gap)	28,311	****	****	****	****	0.99	****	-1.9	****	0.33 ( 0.17,  0.62)	<0.001
ARB (14-Day Gap)	149,252	****	****	****	****	2.9	****	1.5		0.55 (0.17, 0.02)	١٥.001
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-Day Gap)	27,999	****	****	****	****	0.82	****	1.40	****	0.30 ( 0.13 . 0.00)	0.040
ARB (14-Day Gap)	27,999	****	****	****	****	2.3	****	-1.48		0.36 ( 0.13, 0.99)	0.048
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-Day Gap)	27,999	****	****	****	****	1.01	****	1 74	****	0.36 ( 0.10 , 0.73)	0.005
ARB (14-Day Gap)	27,999	****	****	****	****	2.74	****	-1.74		0.36 ( 0.18, 0.73)	0.005
					0	- 30 Days					
Site-Adjusted Analysi	S										
SV (14-Day Gap)	28,311	****	****	****	****	0.89	****	-4.13	****	0.10 ( 0.04 0.72)	0.016
ARB (14-Day Gap)	149,252	****	****	****	****	5.02	****	-4.13		0.18 ( 0.04, 0.73)	0.016
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-Day Gap)	27,999	****	****	****	****	0.93	****		****		
ARB (14-Day Gap)	27,999	****	****	****	****	4.18	****	-3.25	****	0.22 ( 0.05, 1.03)	0.054
Fixed Ratio 1:1 Prope		tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-Day Gap)	27,999	****	****	****	****	0.9	****		****	0.00 / 0.05 / 1.55	0.055
ARB (14-Day Gap)	27,999	****	****	****	****	4.04	****	-3.14	****	0.22 ( 0.05, 1.03)	0.055
7 2500	,				31	- 60 Days					
Site-Adjusted Analysi	S										
SV (14-Day Gap)	25,869	****	****	****	****	1.73	****	4.45	****	0.62 / 0.40 . 2.62\	0.427
ARB (14-Day Gap)	139,781	****	****	****	****	2.88	****	-1.15	<b>~ ~ ~ ~ ~</b>	0.62 ( 0.19, 2.03)	0.427

cder\_mpl2r\_wp016 Page 96 of 247



		Person	Average Person	Average Person	Number	Incidence Rate per 1,000	Risk per	Rate Difference per 1,000	Difference in Risk per	Hazard Ratio	W-14
	Number of	Years	Days	Years	of	Person	1,000	Person	1,000	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Years	New Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-Day Gap)	23,643	****	****	****	****	1.41	****	1.41	****	_	
ARB (14-Day Gap)	23,643	****	****	****	****	0	****	1.41		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV (14-Day Gap)	25,578	****	****	****	****	1.75	****	-0.94	****	0.66 ( 0.16, 2.76)	0.569
ARB (14-Day Gap)	25,890	****	****	****	****	2.69	****	-0.94		0.00 (0.10, 2.70)	0.569
					61	- 90 Days					
Site-Adjusted Analysi	S										
SV (14-Day Gap)	16,938	****	****	****	****	0.79	****	1.63	****	0.24 / 0.05   2.54)	0.204
ARB (14-Day Gap)	107,343	****	****	****	****	2.41	****	-1.62		0.34 ( 0.05, 2.54)	0.294
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-Day Gap)	11,771	****	****	****	****	1.2	****	4.2	****	0.50/0.05 5.54)	0.574
ARB (14-Day Gap)	11,771	****	****	****	****	2.41	****	-1.2	****	0.50 ( 0.05, 5.51)	0.571
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	nditional A	nalysis; Cal	iper= 0.05						
SV (14-Day Gap)	16,736	****	****	****	****	0.8	****	4.40	****	0.40./0.04.0.07\	0.404
ARB (14-Day Gap)	19,728	****	****	****	****	1.98	****	-1.18	****	0.40 ( 0.04, 3.87)	0.431
` ' '	·				91	- 180 Days					
Site-Adjusted Analysis	S										
SV (14-Day Gap)	13,783	****	****	****	****	0.83	****	1.02	****	0.20 / 0.07 (1.21)	0.00
ARB (14-Day Gap)	94,209	****	****	****	****	2.76	****	-1.93		0.29 ( 0.07, 1.21)	0.09
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-Day Gap)	8,328	****	****	****	****	0	****		ate ale ale ate		
ARB (14-Day Gap)	8,328	****	****	****	****	2.79	****	-2.79	****	-	-
Fixed Ratio 1:1 Prope		tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-Day Gap)	13,619	****	****	****	****	0.84	****	2.4.4	****	0.05/0.05 4.15	0.000
	-,	****	****	****	****	3.29	****	-2.44	***	0.26 ( 0.06, 1.19)	0.083

cder\_mpl2r\_wp016 Page 97 of 247



		Average	Average		Incidence Rate per		Rate Difference	Difference in			
		Person	Person	Person	Number	1,000	Risk per	per 1,000	Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	Person	1.000	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Years	New Users	` Interval) <sup>2</sup>	P-Value <sup>2</sup>
Medical Froduct	New Osers	ut max	at mak	ut Hisk		- 270 Days	New Osers	10013	itew Osers	intervary	1 Value
Site-Adjusted Analysi	s										
SV (14-Day Gap)	7,405	****	****	****	****	0.7	****				
ARB (14-Day Gap)	56,410	****	****	****	****	1.83	****	-1.13	****	0.38 ( 0.05, 2.83)	0.345
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-Day Gap)	2,559	****	****	****	****	0	****		****		
ARB (14-Day Gap)	2,559	****	****	****	****	0	****	0	****	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unc	onditional A	nalysis; Cal	iper= 0.05						
SV (14-Day Gap)	7,315	****	****	****	****	0.71	****	-1.83	****	0.29 ( 0.03, 2.48)	0.258
ARB (14-Day Gap)	9,864	****	****	****	****	2.54	****	-1.65		0.29 (0.03, 2.46)	0.236
					271	- 365 Days					
Site-Adjusted Analysi	s										
SV (14-Day Gap)	4,632	****	****	****	****	1.03	****	-1.13	****	0.47 ( 0.06, 3.53)	0.464
ARB (14-Day Gap)	39,969	****	****	****	****	2.15	****	1.15		0.47 (0.00, 3.33)	0.404
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Con	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-Day Gap)	1,127	****	****	****	****	0	****	0	****	_	_
ARB (14-Day Gap)	1,127	****	****	****	****	0	****				
Fixed Ratio 1:1 Prope	•				•						
SV (14-Day Gap)	4,575	****	****	****	****	1.04	****	0.33	****	1.53 ( 0.10, 24.43)	0.764
ARB (14-Day Gap)	6,649	****	****	****	****	0.71	****	0.55		1.55 ( 5.15, 2 1. 15)	0.701
Sex: Female											
an a H						Overall					
Site-Adjusted Analysi		****	****	****	****		ate ate ate ate				
SV (14-Day Gap)	15,466					2	****	-1.11	****	0.60 ( 0.33, 1.09)	0.096
ARB (14-Day Gap)	187,905	****	****	****	****	3.1	****			, , , , , , , , , , , , , , , , , , , ,	

cder\_mpl2r\_wp016 Page 98 of 247



Number of   Years   Days   Years   of   Person   1,000		Hazard Ratio	Difference in Risk per	Rate Difference per 1,000	Risk per	Incidence Rate per 1,000	Number	Average Person	Average Person	Person		
New Users   at Risk   at	Wald	(95% Confidence		•	-	-					Number of	
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05	P-Value <sup>2</sup>	•			,				•			Medical Product
SV (14-Day Gap)   15,267   *****   *****   *****   *****   1.77   *****   *****   *****   2.06   *****   *****   *****   2.06   *****   *****   *****   2.06   *****   *****   *****   *****   2.06   *****   *****   *****   *****   2.06   *****   *****   *****   *****   2.06   ******	1 Value	intervalj	New Osers	Tears	IVEW OSEIS	1 Cui 3						
ARB (14-Day Gap) 15,267 ***** **** ***** ***** 2.06 ***** *0.29 **** 0.86 (0.29, 2.55 ****    Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-Day Gap) 15,267 **** **** **** **** **** 2.02 ****    ARB (14-Day Gap) 15,267 **** **** **** **** **** ****    SV (14-Day Gap) 15,466 **** **** **** **** **** ****    SV (14-Day Gap) 187,905 **** **** **** **** ****    Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05    SV (14-Day Gap) 15,267 **** **** ****    ARB (14-Day Gap) 15,267 **** **** ****    ARB (14-Day Gap) 15,267 **** **** ****    ARB (14-Day Gap) 15,267 ****    SV (14-Day Gap) 15,267 ****    ARB (14-Day Gap) 15,267 ****    SV (14-Day Gap) 15,267 ****    Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05    SV (14-Day Gap) 15,267 ****    SV (14-Day Gap) 15,267 ****    SV (14-Day Gap) 15,267 ****    ARB (14-Day Gap) 15,267 ****    SV (14-Day Gap) 15,267 ****    ARB (14-Day Gap) 15,267 ****    SV (14-Day Gap) 15,267 ****    ARB (14-Day Gap) 15,267 ****    SV (14-Day Gap) 15,267 ****    SV (14-Day Gap) 15,267 ****    ARB (14-Day Gap) 15,267 ****    SV (14-Day Gap) 15,267 ****    SV (14-Day Gap) 15,267 ****    SV (14-Day Gap) 15,267 ****    ARB (14-Day Gap) 176,518 ****    SV (14-Day Gap) 12,817 ****    SV (14-Day Gap					****	1 77			****	****		
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-Day Gap) 15,267 ***** ***** ***** ***** 2.02 ****** 0.68 ***** 1.45 ( 0.60, 3.50	0.782	0.86 ( 0.29, 2.55)	****	-0.29	****		****	****	****	****	,	, , , ,
SV (14-Day Gap) 15,267 ***** ***** ***** ***** ***** 2.02 ****** 0.68 ***** 1.45 ( 0.60, 3.50						2.00	per= 0.05	nalvsis: Cali	nditional A	ched Unco		
ARB (14-Day Gap) 15,267 ***** ***** ***** ***** 1.34 ***** 0.68 ***** 1.45 (0.60, 3.50 ***** 1.45 (0.60, 3.50 ***** 1.45 (0.60, 3.50 ***** 1.45 (0.60, 3.50 ***** 1.45 (0.60, 3.50 ***** 1.45 (0.60, 3.50 ***** 1.45 (0.60, 3.50 ***** 1.45 (0.60, 3.50 ***** 1.45 (0.60, 3.50 ***** 1.45 (0.60, 3.50 ***** 1.45 (0.60, 3.50 ***** 1.45 (0.60, 3.50 ***** 1.45 (0.60, 3.50 ***** 1.45 (0.60, 3.50 ***** 1.64 ***** 1.64 ***** 1.64 ***** 1.64 ***** 1.65 ****** 1.65 ****** 1.65 ***** 1.65 ****** 1.65 ***** 1.65 ****** 1.65 ****** 1.65 *****			ale ale ale ale		****	2.02					•	
Site-Adjusted Analysis         SV (14-Day Gap)       15,466       ******       ******       ******       1.64       ******       -5.07       ******       0.25 ( 0.06, 1.01         Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05         SV (14-Day Gap)       15,267       ******       ******       ******       1.71       ******       -0.85       ******       0.67 ( 0.11, 3.99         Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05         SV (14-Day Gap)       15,267       ******       ******       ******       1.66       ******       -0.81       ******       0.67 ( 0.11, 3.99         Site-Adjusted Analysis         SV (14-Day Gap)       13,973       ******       ******       ******       1.06       ******       -2.78       ******       0.28 ( 0.04, 2.00         Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05         SV (14-Day Gap)       176,518       ******       ******       ******       1.06       ******       -2.78       ******       0.28 ( 0.04, 2.00         Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05         SV (14-Day Gap)       12,817	0.41	1.45 (0.60, 3.50)	****	0.68	****		****	****	****	****	•	, , , ,
SV (14-Day Gap) 15,466 ***** **** **** **** **** 1.64 ***** -5.07 ***** 0.25 (0.06, 1.01 ARB (14-Day Gap) 187,905 ***** **** **** **** **** 6.71 ***** -5.07 ***** 0.25 (0.06, 1.01 ARB (14-Day Gap) 187,905 **** **** **** ****						- 30 Days	0 -					( 17 22/17
ARB (14-Day Gap) 187,905 **** **** **** **** **** **** **** *						•					3	Site-Adjusted Analysis
ARB (14-Day Gap) 187,905 ***** **** **** **** 6.71 ***** 5.07  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-Day Gap) 15,267 **** **** **** **** 2.56 ***** -0.85 **** 0.67 ( 0.11, 3.99 ARB (14-Day Gap) 15,267 **** **** **** **** 1.71 ***** -0.85  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-Day Gap) 15,267 **** **** **** **** 1.66 ***** -0.81 ***** 0.67 ( 0.11, 3.99 ARB (14-Day Gap) 15,267 **** **** **** **** 1.06 ***** -0.81 ***** 0.67 ( 0.11, 3.99 ARB (14-Day Gap) 15,267 **** **** **** **** 3.84 **** -2.78 ***** 0.28 ( 0.04, 2.00 ARB (14-Day Gap) 176,518 **** **** **** **** 3.84 **** -2.78 ***** 0.33 ( 0.03, 3.20 ARB (14-Day Gap) 12,817 **** **** **** **** 3.86 ***** -2.57 ***** 0.33 ( 0.03, 3.20 ARB (14-Day Gap) 12,817 ***** **** **** ***** 3.86 ***** -2.57 ***** 0.33 ( 0.03, 3.20 ARB (14-Day Gap) 12,817 ***** ***** ***** ***** 3.86 ***** ***** 0.38 ( 0.04, 3.00 ARB (14-Day Gap) 12,817 ***** ***** ***** ***** 3.86 ***** ***** 0.33 ( 0.03, 3.20 ARB (14-Day Gap) 12,817 ***** ***** ***** ***** ***** 3.86 ****** ***** 0.33 ( 0.03, 3.20 ARB (14-Day Gap) 12,817 ***** ***** ***** ***** ***** 3.86 ******	0.051	0.35 / 0.05 (1.01)	****	F 07	****	1.64	****	****	****	****	15,466	SV (14-Day Gap)
SV (14-Day Gap) 15,267 **** **** **** **** **** 2.56 **** -0.85 **** 0.67 (0.11, 3.99 ARB (14-Day Gap) 15,267 **** **** **** **** **** 2.56 **** -0.85 **** 0.67 (0.11, 3.99 Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper = 0.05  SV (14-Day Gap) 15,267 **** **** **** **** 1.66 ***** -0.81 ***** 0.67 (0.11, 3.99 ARB (14-Day Gap) 15,267 **** **** **** **** 2.47 **** -0.81 ***** 0.67 (0.11, 3.99 ARB (14-Day Gap) 13,973 **** **** **** **** **** 3.60 Days  Site-Adjusted Analysis  SV (14-Day Gap) 13,973 **** **** **** **** 3.84 **** -2.78 **** 0.28 (0.04, 2.00 ARB (14-Day Gap) 176,518 **** **** **** **** 3.84 **** -2.78 ***** 0.33 (0.03, 3.20 ARB (14-Day Gap) 12,817 **** **** **** **** 3.86 **** -2.57 ***** 0.33 (0.03, 3.20 ARB (14-Day Gap) 12,817 **** **** **** **** 3.86 ***** -2.57 ***** 0.33 (0.03, 3.20 ARB (14-Day Gap) 12,817 ***** **** **** **** 3.86 *****	0.051	0.25 (0.06, 1.01)		-5.07	****	6.71	****	****	****	****	187,905	ARB (14-Day Gap)
SV (14-Day Gap) 15,267 **** **** **** **** **** 2.56 **** -0.85 **** 0.67 (0.11, 3.99 ARB (14-Day Gap) 15,267 **** **** **** **** **** 2.56 **** -0.85 **** 0.67 (0.11, 3.99 Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper = 0.05  SV (14-Day Gap) 15,267 **** **** **** **** 1.66 ***** -0.81 ***** 0.67 (0.11, 3.99 ARB (14-Day Gap) 15,267 **** **** **** **** 2.47 ***** -0.81 ***** 0.67 (0.11, 3.99 ARB (14-Day Gap) 13,973 ***** **** **** **** **** 1.06 ***** -2.78 ***** 0.28 (0.04, 2.00 ARB (14-Day Gap) 176,518 **** **** **** **** 3.84 **** -2.78 **** 0.28 (0.04, 2.00 ARB (14-Day Gap) 12,817 **** **** **** **** 3.86 **** 0.33 (0.03, 3.20 ARB (14-Day Gap) 12,817 **** **** **** **** 3.86 ***** 0.33 (0.03, 3.20 ARB (14-Day Gap) 12,817 **** **** **** **** 3.86 ***** 0.33 (0.03, 3.20 ARB (14-Day Gap) 12,817 ***** **** **** **** 3.86 ***** ****							r= 0.05 <sup>1</sup>	ysis; Calipe	litional Anal	ched Cond	nsity Score Mat	Fixed Ratio 1:1 Proper
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-Day Gap) 15,267 ***** ***** ***** 1.66 ***** -0.81 ***** 0.67 (0.11, 3.99  ARB (14-Day Gap) 15,267 ***** **** **** **** 1.06 ***** -0.81 ***** 0.67 (0.11, 3.99  Site-Adjusted Analysis  SV (14-Day Gap) 13,973 **** **** **** **** 1.06 ***** -2.78 ***** 0.28 (0.04, 2.00  ARB (14-Day Gap) 176,518 **** **** **** **** 3.84 **** -2.78  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-Day Gap) 12,817 **** **** **** **** 1.29 ***** -2.57 ***** 0.33 (0.03, 3.20)  ARB (14-Day Gap) 12,817 **** **** **** **** 3.86 ***** -2.57 ***** 0.33 (0.03, 3.20)	0.657	0.67/0.11 3.00\	****	0.05	****	1.71						
SV (14-Day Gap) 15,267 **** **** **** **** 1.66 ***** -0.81 **** 0.67 (0.11, 3.99 ****	0.657	0.67 (0.11, 3.99)		-0.85	****	2.56	****	****	****	****	15,267	ARB (14-Day Gap)
ARB (14-Day Gap) 15,267 ***** **** **** **** 2.47 ***** -0.81 ***** 0.67 (0.11, 3.99 ***** 5.47 ****							per= 0.05	nalysis; Cali	nditional A	ched Unco	nsity Score Mat	Fixed Ratio 1:1 Proper
ARB (14-Day Gap) 15,267 **** **** **** **** 2.47 **** **** **** 5.81 5.057 (6.11, 3.99	0.657	0.67 / 0.11 2.00\	****	0.91	****	1.66	****	****	****	****	15,267	SV (14-Day Gap)
Site-Adjusted Analysis         SV (14-Day Gap)       13,973       *****       *****       *****       1.06       *****       -2.78       *****       0.28 (0.04, 2.00       2.00         ARB (14-Day Gap)       176,518       *****       *****       *****       3.84       *****       -2.78       ******       0.28 (0.04, 2.00         Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05¹         SV (14-Day Gap)       12,817       *****       *****       *****       1.29       *****       -2.57       *****       0.33 (0.03, 3.20         ARB (14-Day Gap)       12,817       *****       *****       *****       3.86       *****       -2.57       ******       0.33 (0.03, 3.20	0.657	0.67 (0.11, 3.99)		-0.61	****	2.47	****	****	****	****	15,267	ARB (14-Day Gap)
SV (14-Day Gap)       13,973       *****       *****       *****       1.06       ******       -2.78       *****       0.28 ( 0.04, 2.00         ARB (14-Day Gap)       176,518       *****       *****       *****       3.84       *****       -2.78       *****       0.28 ( 0.04, 2.00         Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05 <sup>1</sup> SV (14-Day Gap)       12,817       *****       *****       *****       1.29       *****       -2.57       *****       0.33 ( 0.03, 3.20         ARB (14-Day Gap)       12,817       *****       *****       *****       3.86       *****       -2.57       ******       0.33 ( 0.03, 3.20						- 60 Days	31					
ARB (14-Day Gap) 176,518 ***** **** **** **** 3.84 ***** -2.78 ***** 0.28 (0.04, 2.00												Site-Adjusted Analysis
ARB (14-Day Gap) 1/6,518 ***** 3.84 *****  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-Day Gap) 12,817 ***** ***** ***** 1.29 ***** -2.57 ***** 0.33 ( 0.03, 3.20 ***** 3.86 ******	0.202	0.28 ( 0.04 2.00)	****	-2 78		1.06					•	SV (14-Day Gap)
SV (14-Day Gap)       12,817       *****       *****       *****       1.29       *****       -2.57       *****       0.33 ( 0.03, 3.20         ARB (14-Day Gap)       12,817       *****       *****       *****       3.86       *****       -2.57       *****       0.33 ( 0.03, 3.20	0.202	0.20 ( 0.04, 2.00)		2.70	****	3.84						
ARB (14-Day Gap) 12,817 ***** ***** ***** 3.86 ***** -2.57 ***** 0.33 ( 0.03, 3.20							r= 0.05 <sup>1</sup>	ysis; Calipe	litional Anal	ched Cond	nsity Score Mat	Fixed Ratio 1:1 Proper
ARB (14-Day Gap) 12,817 ***** ***** ***** 3.86 ***** -2.37 0.55 (0.05, 5.20	0.341	0.22 / 0.02 .2.20)	****	2 57	****	1.29						
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis: Caliper= 0.05	0.541	0.33 (0.03, 3.20)		-2.37	****	3.86	****	****	****	****	12,817	ARB (14-Day Gap)
							per= 0.05	nalysis; Cali	nditional A	ched Unco	nsity Score Mat	Fixed Ratio 1:1 Proper
SV (14-Day Gap) 13,795 ***** ***** ***** 1.07 ***** -1.86 ***** 0.37 (0.04, 3.58	0.392	0.37 ( 0.04, 3.58)	****	-1 86	****	1.07	****	****	****	****	13,795	SV (14-Day Gap)
ARB (14-Day Gap) 14,173 ***** ***** ***** 2.93 ***** -1.86 0.57 (0.04, 5.58	0.332	0.37 (0.04, 3.36)		-1.00	****	2.93	****	****	****	****	14,173	ARB (14-Day Gap)

cder\_mpl2r\_wp016 Page 99 of 247



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

						Incidence		Rate	Difference		
			Average	Average		Rate per		Difference	in		
		Person	Person	Person	Number	1,000	Risk per	per 1,000	Risk per	<b>Hazard Ratio</b>	
	Number of	Years	Days	Years	of	Person	1,000	Person	1,000	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Years	New Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
					61	- 90 Days				·	
Site-Adjusted Analysi	s					•					
SV (14-Day Gap)	9,257	****	****	****	****	4.33	****	1.2	****	1 47 / 0 45 4 90\	0.533
ARB (14-Day Gap)	136,170	****	****	****	****	3.13	****	1.2	4 4 4 4	1.47 ( 0.45, 4.80)	0.522
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-Day Gap)	6,544	****	****	****	****	4.32	****		ale ale ale ale	/	
ARB (14-Day Gap)	6,544	****	****	****	****	2.16	****	2.16	****	2.00 ( 0.18, 22.06)	0.571
Fixed Ratio 1:1 Prope		tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-Day Gap)	9,145	****	****	****	****	4.38	****	2	****	4 00 / 0 24 44 20)	0.400
ARB (14-Day Gap)	10,897	****	****	****	****	2.38	****	2	****	1.88 ( 0.31, 11.28)	0.488
` ' '	·				91 -	- 180 Days					
Site-Adjusted Analysi	s										
SV (14-Day Gap)	7,503	****	****	****	****	3.02	****	1.16	****	1.66 (0.50, 4.63)	0.220
ARB (14-Day Gap)	120,080	****	****	****	****	1.86	****	1.16		1.66 ( 0.59, 4.63)	0.338
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-Day Gap)	4,666	****	****	****	****	1.61	****	1.51	****		
ARB (14-Day Gap)	4,666	****	****	****	****	0	****	1.61	****	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV (14-Day Gap)	7,419	****	****	****	****	3.05	****	2.05	****		
ARB (14-Day Gap)	9,505	****	****	****	****	0	****	3.05		-	-
					181	- 270 Days					
Site-Adjusted Analysi	S										
SV (14-Day Gap)	4,060	****	****	****	****	1.28	****	-0.98	****	0.57 ( 0.08, 4.19)	0.582
ARB (14-Day Gap)	73,690	****	****	****	****	2.25	****	-0.96		0.57 (0.06, 4.19)	0.362
ixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-Day Gap)	1,493	****	****	****	****	0	****	-	****		
ARB (14-Day Gap)	1,493	****	****	****	****	0	****	0	<b>ጥ ጥ ጥ ጥ</b>	-	-
Fixed Ratio 1:1 Prope		tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-Day Gap)	4,020	****	****	****	****	1.29	****	1 30	****		
ARB (14-Day Gap)	5,591	****	****	****	****	0	****	1.29	4-4-4-4-4-	-	-
· · · · · ·					271	- 365 Days					

cder\_mpl2r\_wp016 Page 100 of 247



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

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval) <sup>2</sup>	Wald P-Value <sup>2</sup>
SV (14-Day Gap)	2,529	****	****	****	****	0	****	1 11	****	,	_
ARB (14-Day Gap)	52,699	****	****	****	****	1.11	****	-1.11		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-Day Gap)	646	****	****	****	****	0	****	0	****		
ARB (14-Day Gap)	646	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unc	onditional A	nalysis; Cal	iper= 0.05						
SV (14-Day Gap)	2,505	****	****	****	****	0	****	1 22	****		
ARB (14-Day Gap)	3,802	****	****	****	****	1.22	****	-1.22		-	<u> </u>

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 101 of 247

<sup>&</sup>lt;sup>2</sup>Data presented by a dash are unable to be calculated. This table may not use all data representations.

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



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

						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Age Group: 18-44 ye	ars										
Site-Adjusted Analys	sis										
SV	1,634	****	****	****	****	1.87	****	-6.02	****	0.27 (0.04, 2.05)	0.207
ARBs	8,500	****	****	****	****	7.89	****	-0.02		0.27 (0.04, 2.03)	0.207
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	1,448	****	****	****	****	3.8	****	2.0	****		
ARBs	1,448	****	****	****	****	0	****	3.8		-	-
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV	1,448	****	****	****	****	2.11	****	-0.02	****	1.00 (0.06, 16.19)	0.998
ARBs	1,448	****	****	****	****	2.13	****	-0.02		1.00 (0.06, 16.19)	0.996
Age Group: 45-54 ye	ars										
Site-Adjusted Analys	sis										
SV	3,068	****	****	****	****	0.95	****	-3.36	****	0.23 (0.03, 1.70)	0.149
ARBs	18,297	****	****	****	****	4.32	****	-5.50		0.23 (0.03, 1.70)	0.149
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	2,938	****	****	****	****	1.72	****	4.72	****	0.50/0.05 5.54)	0.574
ARBs	2,938	****	****	****	****	3.43	****	-1.72	4. 4. 4. 4.	0.50 (0.05, 5.51)	0.571
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV	2,938	****	****	****	****	0.99	****	-1.8	****	0.27 (0.04 .2.57)	0.20
ARBs	2,938	****	****	****	****	2.8	****	-1.8		0.37 (0.04, 3.57)	0.39
Age Group: 55-64 ye	ars										
Site-Adjusted Analys	sis										
SV	6,120	****	****	****	****	1.88	****	2 12	****	0.49 (0.17 1.21)	0.152
ARBs	40,556	****	****	****	****	4	****	-2.12		0.48 (0.17, 1.31)	0.152
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	5,994	****	****	****	****	2.43	****	0	****	4.00 (0.30, 4.05)	
ARBs	5,994	****	****	****	****	2.43	****	0	T T T T T	1.00 (0.20, 4.95)	1

cder\_mpl2r\_wp016 Page 102 of 247



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

			Average	Average		Incidence Rate per		Incidence Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	<b>Hazard Ratio</b>	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	<b>Events</b>	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unc	onditional A	nalysis; Cal	iper= 0.05						
SV	5,994	****	****	****	****	1.91	****	-0.18	****	0.92 (0.25, 3.43)	0.899
ARBs	5,994	****	****	****	****	2.1	****	-0.16		0.92 (0.25, 5.45)	0.699
Age Group: ≥65 year	rs										
Site-Adjusted Analys	sis										
SV	32,955	****	****	****	****	1.26	****	-1.44	****	0.42 (0.26 0.72)	0.001
ARBs	269,804	****	****	****	****	2.71	****	-1.44		0.43 (0.26, 0.72)	0.001
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	32,649	****	****	****	****	1.22	****	0.91	****	0.60 (0.36 1.37)	0.226
ARBs	32,649	****	****	****	****	2.03	****	-0.81		0.60 (0.26, 1.37)	0.226
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unc	onditional A	nalysis; Cal	iper= 0.05						
SV	32,649	****	****	****	****	1.19	****	-0.91	****	0.55 (0.20, 1.02)	0.063
ARBs	32,649	****	****	****	****	2.1	****	-0.91		0.55 (0.29, 1.03)	0.062
1	·	•	•	•	·		•	·		·	

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 103 of 247

<sup>&</sup>lt;sup>2</sup>Data presented by a dash are unable to be calculated. This table may not use all data representations.

<sup>\*\*\*\*\*</sup>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.



			Average	Average		Incidence Rate per		Incidence Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	•	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Age Group: 18-44	New Osers	at NISK	at NISK	at NISK	Events	Tears	New Osers	reison reals	Users	intervalj	r-value
Age Gloup. 10-44						Overall					
Site-Adjusted Analysis	<u> </u>					Overun					
SV (14-day gap)	1,634	****	****	****	****	1.87	****		****		
ARBs (14-day gap)	8,500	****	****	****	****	7.89	****	-6.02	***	0.27 ( 0.04, 2.05)	0.207
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	1,448	****	****	****	****	3.8	****		****		
ARBs (14-day gap)	1,448	****	****	****	****	0	****	3.8	****	-	-
Fixed Ratio 1:1 Proper		tched Unco	nditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	1,448	****	****	****	****	2.11	****	0.03	****	1.00 / 0.00 10 10	0.000
ARBs (14-day gap)	1,448	****	****	****	****	2.13	****	-0.02		1.00 ( 0.06, 16.19)	0.998
					0	- 30 Days					
Site-Adjusted Analysis	s										
SV (14-day gap)	1,788	****	****	****	****	0	****	-5.84	****	_	_
ARBs (14-day gap)	10,999	****	****	****	****	5.84	****	-5.04			
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	1,422	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	1,422	****	****	****	****	0	****	U		-	
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco			•						
SV (14-day gap)	1,605	****	****	****	****	0	****	0	****	_	
ARBs (14-day gap)	1,760	****	****	****	****	0	****	U		-	
					31	- 60 Days					
Site-Adjusted Analysis											
SV (14-day gap)	1,497	****	****	****	****	0	****	-7.65	****	-	_
ARBs (14-day gap)	7,924	****	****	****	****	7.65	****	7.05			

cder\_mpl2r\_wp016 Page 104 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	1,211	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	1,211	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	1,331	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	1,314	****	****	****	****	0	****	U		-	-
					61	- 90 Days					
Site-Adjusted Analysi	s										
SV (14-day gap)	933	****	****	****	****	0	****	-5.33	****		
ARBs (14-day gap)	5,002	****	****	****	****	5.33	****	-5.55		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	492	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	492	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	830	****	****	****	****	0	****	-15.86	****		
ARBs (14-day gap)	854	****	****	****	****	15.86	****	-15.60		-	-
					91	- 180 Days					
Site-Adjusted Analysis											
SV (14-day gap)	704	****	****	****	****	8.2	****	-8.31	****	0.63 ( 0.08, 4.94)	0.66
ARBs (14-day gap)	4,048	****	****	****	****	16.52	****	-0.51		0.03 ( 0.08, 4.54)	0.00
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	288	****	****	****	****	28.03	****	20.02	****		
ARBs (14-day gap)	288	****	****	****	****	0	****	28.03	ner ner ner ner	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	625	****	****	****	****	9.19	****	9.19	****		
ARBs (14-day gap)	662	****	****	****	****	0	****	9.19		-	-

cder\_mpl2r\_wp016 Page 105 of 247



· '					71 7 0	•					
						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	<b>New Users</b>	at Risk	at Risk	at Risk	<b>Events</b>	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value
					181	- 270 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	371	****	****	****	****	0	****	Г 1	****		
ARBs (14-day gap)	1,995	****	****	****	****	5.1	****	-5.1		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	77	****	****	****	****	0	****		****		
ARBs (14-day gap)	77	****	****	****	****	0	****	0	****	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	335	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	296	****	****	****	****	0	****	U		-	-
					271	- 365 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	223	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	1,317	****	****	****	****	0	****	U		-	
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	42	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	42	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	200	****	****	****	****	0	****	0	****		_
ARBs (14-day gap)	199	****	****	****	****	0	****	<u> </u>		<u> </u>	
Age Group: 45-54											
						Overall					
Site-Adjusted Analysi	S										
SV (14-day gap)	3,068	****	****	****	****	0.95	****	-3.36	****	0.23 ( 0.03, 1.70)	0.149
ARBs (14-day gap)	18,297	****	****	****	****	4.32	****	-3.30		0.23 (0.03, 1.70)	0.149

cder\_mpl2r\_wp016 Page 106 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	2,938	****	****	****	****	1.72	****	-1.72	****	0.50/0.05 5.51)	0.571
ARBs (14-day gap)	2,938	****	****	****	****	3.43	****	-1./2		0.50 ( 0.05, 5.51)	0.571
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	2,938	****	****	****	****	0.99	****	1.0	****	0.27 / 0.04 .2.57)	0.20
ARBs (14-day gap)	2,938	****	****	****	****	2.8	****	-1.8		0.37 ( 0.04, 3.57)	0.39
					0	- 30 Days					
Site-Adjusted Analysi	S										
SV (14-day gap)	3,068	****	****	****	****	0	****	-10.27	****		
ARBs (14-day gap)	18,297	****	****	****	****	10.27	****	-10.27		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	2,938	****	****	****	****	0	****	4.45	****		
ARBs (14-day gap)	2,938	****	****	****	****	4.45	****	-4.45		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	2,938	****	****	****	****	0	****	4.2	****		
ARBs (14-day gap)	2,938	****	****	****	****	4.3	****	-4.3		-	-
					31	- 60 Days					
Site-Adjusted Analysi											
SV (14-day gap)	2,806	****	****	****	****	0	****	-4.29	****	_	_
ARBs (14-day gap)	17,086	****	****	****	****	4.29	****	-4.23			_
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	2,467	****	****	****	****	0	****	C 0C	****		
ARBs (14-day gap)	2,467	****	****	****	****	6.86	****	-6.86	and the same and	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	2,693	****	****	****	****	0	****	-5.42	****		
ARBs (14-day gap)	2,684	****	****	****	****	5.42	****	-3.42		-	-

cder\_mpl2r\_wp016 Page 107 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	<b>Events</b>	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
					61	- 90 Days					
Site-Adjusted Analysis	3										
SV (14-day gap)	1,779	****	****	****	****	0	****	0	****		_
ARBs (14-day gap)	11,645	****	****	****	****	0	****	0		-	
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	1,093	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	1,093	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	1,711	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	1,863	****	****	****	****	0	****	U		-	-
					91	- 180 Days					
Site-Adjusted Analysis	3										
SV (14-day gap)	1,412	****	****	****	****	0	****	-3.6	****	_	_
ARBs (14-day gap)	9,740	****	****	****	****	3.6	****	-5.0			
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	729	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	729	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	1,357	****	****	****	****	0	****	-3.83	****		
ARBs (14-day gap)	1,544	****	****	****	****	3.83	****	-5.65		-	-
					181	- 270 Days					
Site-Adjusted Analysis	3										
SV (14-day gap)	744	****	****	****	****	6.99	****	5.05	****	3.89 ( 0.34, 44.69)	0.275
ARBs (14-day gap)	5,203	****	****	****	****	1.94	****	3.03		5.65 ( 0.54, 44.05)	0.273
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	211	****	****	****	****	29.15	****	20.45	****		
ARBs (14-day gap)	211	****	****	****	****	0	****	29.15	<b>~ ~ ~ ~ ~</b>	-	-

cder\_mpl2r\_wp016 Page 108 of 247



			Average	Average		Incidence Rate per		Incidence Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	<b>Hazard Ratio</b>	
	Number of	Years	Days	Years	of	Person	1.000	per 1,000	1.000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	nditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	721	****	****	****	****	7.19	****	7.10	****		
ARBs (14-day gap)	782	****	****	****	****	0	****	7.19	4.4.4.4.4.	-	-
, , , , , , , , , , , , , , , , , , ,					271	- 365 Days					
Site-Adjusted Analysis	3										
SV (14-day gap)	468	****	****	****	****	0	****	-2.69	****		
ARBs (14-day gap)	3,437	****	****	****	****	2.69	****	-2.09		-	
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	litional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	88	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	88	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	nditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	454	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	496	****	****	****	****	0	****	U		-	-
Age Group: 55-64											
						Overall					
Site-Adjusted Analysis											
SV (14-day gap)	6,120	****	****	****	****	1.88	****	-2.12	****	0.48 ( 0.17, 1.31)	0.152
ARBs (14-day gap)	40,556	****	****	****	****	4	****			0.40 (0.17, 1.51)	0.132
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	litional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	5,994	****	****	****	****	2.43	****	0	****	1.00 ( 0.20, 4.95)	1
ARBs (14-day gap)	5,994	****	****	****	****	2.43	****	<u> </u>		1.00 ( 0.20, 4.93)	<b>T</b>
Fixed Ratio 1:1 Proper	-				•						
SV (14-day gap)	5,994	****	****	****	****	1.91	****	-0.18	****	0.92 ( 0.25, 3.43)	0.899
ARBs (14-day gap)	5,994	****	****	****	****	2.1	****	0.10		0.52 (0.25, 5.45)	0.055

cder\_mpl2r\_wp016 Page 109 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
					0 -	- 30 Days					
Site-Adjusted Analysis	3										
SV (14-day gap)	6,120	****	****	****	****	2.07	****	-5.95	****	0.25 ( 0.03, 1.84)	0.173
ARBs (14-day gap)	40,556	****	****	****	****	8.01	****	-5.95		0.23 (0.03, 1.84)	0.173
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	5,994	****	****	****	****	2.18	****	4.26	****	0.33 ( 0.03 3.30)	0.241
ARBs (14-day gap)	5,994	****	****	****	****	6.54	****	-4.36		0.33 ( 0.03, 3.20)	0.341
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	5,994	****	****	****	****	2.11	****	4.10	****	0.33 ( 0.03 3.30)	0.241
ARBs (14-day gap)	5,994	****	****	****	****	6.3	****	-4.19		0.33 ( 0.03, 3.20)	0.341
					31	- 60 Days					
Site-Adjusted Analysis	3										
SV (14-day gap)	5,561	****	****	****	****	0	****	-2.25	****		
ARBs (14-day gap)	37,960	****	****	****	****	2.25	****	-2.25		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	5,036	****	****	****	****	0	****		****		
ARBs (14-day gap)	5,036	****	****	****	****	0	****	0	****	-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	5,453	****	****	****	****	0	****		****		
ARBs (14-day gap)	5,536	****	****	****	****	0	****	0	****	-	-
, , , , ,	·				61	- 90 Days					
Site-Adjusted Analysis	;										
SV (14-day gap)	3,609	****	****	****	****	7.43	****		****	2.55 / 0.60 / 10 / 11	0.131
ARBs (14-day gap)	27,418	****	****	****	****	2.38	****	5.04	4- 4- 4- 4-	3.55 ( 0.68, 18.41)	0.131
Fixed Ratio 1:1 Proper		tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	2,358	****	****	****	****	6.08	****		ale ale ale ale		
								6.08	****		

cder\_mpl2r\_wp016 Page 110 of 247



			_	_		Incidence		Incidence			
		_	Average	Average		Rate per		Rate	Difference	Hazard Ratio	
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per		14/-1-I
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Propen					•						
SV (14-day gap)	3,547	****	****	****	****	7.57	****	7.57	****	_	_
ARBs (14-day gap)	4,002	****	****	****	****	0	****	, .s,			
					91 -	- 180 Days					
Site-Adjusted Analysis											
SV (14-day gap)	2,898	****	****	****	****	1.98	****	-1.4	****	0.61 ( 0.08, 4.69)	0.637
ARBs (14-day gap)	23,333	****	****	****	****	3.39	****	1.7		0.01 ( 0.00, 4.03)	0.037
Fixed Ratio 1:1 Propen	sity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	1,619	****	****	****	****	4.79	****	4.79	****		
ARBs (14-day gap)	1,619	****	****	****	****	0	****	4.79		-	-
Fixed Ratio 1:1 Propen	sity Score Ma	tched Unco	onditional A	nalysis; Cali	per= 0.05						
SV (14-day gap)	2,846	****	****	****	****	2.02	****	0.33	****	1.31 ( 0.08, 20.90)	0.85
ARBs (14-day gap)	3,362	****	****	****	****	1.69	****	0.55		1.51 ( 0.08, 20.90)	0.65
					181	- 270 Days					
<b>Site-Adjusted Analysis</b>											
SV (14-day gap)	1,528	****	****	****	****	0	****	-3.39	****		
ARBs (14-day gap)	13,310	****	****	****	****	3.39	****	-3.39		-	-
Fixed Ratio 1:1 Propen	sity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	483	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	483	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Propen	sity Score Ma	tched Unco	onditional A	nalysis; Cali	per= 0.05						
SV (14-day gap)	1,507	****	****	****	****	0	****	2.72	****		
ARBs (14-day gap)	1,880	****	****	****	****	2.73	****	-2.73		-	-
,,					271	- 365 Days					
Site-Adjusted Analysis						-					
SV (14-day gap)	958	****	****	****	****	0	****	-3.54	****		
ARBs (14-day gap)	9,053	****	****	****	****	3.54	****	-3.34		-	-

cder\_mpl2r\_wp016 Page 111 of 247



	Person	Average Person	Average Person	Number	Incidence Rate per 1,000	Risk per	Incidence Rate Difference	Difference in Risk per	Hazard Ratio	
Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	•	Wald
New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
nsity Score Ma	tched Conc	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
203	****	****	****	****	0	****	0	****		
203	****	****	****	****	0	****	U		-	-
nsity Score Ma	tched Unco	onditional A	nalysis; Cali	per= 0.05						
946	****	****	****	****	0	****	0	****		
1,209	****	****	****	****	0	****	U		-	-
				(	Overall					
S										
32,955	****	****	****	****	1.26	****	1 44	****	0.42 ( 0.26   0.72)	0.001
269,804	****	****	****	****	2.71	****	-1.44		0.43 (0.26, 0.72)	0.001
nsity Score Ma	tched Conc	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
32,649	****	****	****	****	1.22	****	0.04	****	0.60/0.36 4.37)	0.226
32,649	****	****	****	****	2.03	****	-0.81	***	0.60 (0.26, 1.37)	0.226
nsity Score Ma	tched Unco	onditional A	nalysis; Cali	per= 0.05						
32,649	****	****	****	****	1.19	****	0.01	****	0.55 / 0.30 / 4.03\	0.063
32,649	****	****	****	****	2.1	****	-0.91	4. 4. 4. 4. 4.	0.55 (0.29, 1.03)	0.062
				0 -	- 30 Days					
S										
32,955	****	****	****	****	1.15	****	4.22	****	0.22 / 0.07 . 0.60\	0.000
269,804	****	****	****	****	5.36	****	-4.22	4. 4. 4. 4. 4.	0.22 ( 0.07, 0.68)	0.009
nsity Score Ma	tched Conc	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
	****	****	****	****	1.19	****		ale ale ale ale ale		
-	****	****	****	****		****	-1.99	****	0.38 ( 0.10, 1.41)	0.147
	tched Unco	onditional A	nalvsis: Cal	per= 0.05						
			, ,	•						
32,600	****	****	****	****	1.16	****	-1.92	****	0.38 ( 0.10, 1.42)	0.15
	New Users nsity Score Mat 203 203 203 nsity Score Mat 946 1,209  s 32,955 269,804 nsity Score Mat 32,649 32,649 32,649 s 32,649 32,649 s 32,955 269,804 nsity Score Mat 32,556 32,556 32,556	Number of New Users at Risk nsity Score Matched Conc 203 ***** 203 ***** nsity Score Matched Unco 946 ***** 1,209 *****  32,955 ***** 269,804 ***** nsity Score Matched Conc 32,649 ***** nsity Score Matched Unco 32,649 *****	Person   Person   Number of   Years   Days   New Users   at Risk   at Risk   at Risk   shifty Score Matched Conditional Anal   203   ******	Person   P	Person   Person   Person   Number   Number of   Years   Days   Years   Of   New Users   at Risk   at Risk   at Risk   Events   Events   Score   Matched   Conditional   Analysis; Caliper=   0.05	Number of   Years   Days   Years   Of   Person   New Users   at Risk   at Risk   at Risk   Events   Years   O   Person   New Users   at Risk   at Risk   Events   Years   O   Person   New Users   at Risk   at Risk   Events   Years   O   Person   New Users   at Risk   at Risk   Events   Years   O   Person   New Users   At Risk   At Risk   Events   Years   O   Person   New Users   At Risk   At Risk   Events   Years   O   Person   New Users   At Risk   Events   Person   New Users   At Risk   At Risk   Events   Person   New Users   Person   New Users   O   Person   New Users   O   Person   New Users   At Risk   Events   O   Person   Person   New Users   O   Person   New Users   Person   New Users   O   Person   New Users   Person   Person   New Users   Person   Person	Number of   Years   Days   Years   Of   Person   Number of   Years   Days   Years   Of   Person   New Users   At Risk   at Risk   Events   Years   New Users	Number of   Person   Person   Person   Person   Number   1,000   Risk per   Difference   Person   Number of   Years   Days   Years   of   Person   New Users   at Risk   at Risk   Events   Years   New Users   Person Years   Person Years   New Users   Person Years   Person Years   New Users   Person Years   New Users   Person Years   Person	Number of   Person   Person   Person   Person   Person   Number of   1,000   Person   P	Number of   Person   Person

cder\_mpl2r\_wp016 Page 112 of 247



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

Medical Product   Namber of   Person   Number of   Person   Number of   Person   Number of   Person   Person   Person   Number of   Person   1,000   Per				_	_		Incidence		Incidence			
Number of   Years   Days   D			_	•	•		=				Horand Datie	
New Users   at Risk   at							•	•		•		147 11
Site-Adjusted Analysis   SV (14-day gap)   29,979   ****   ****   ****   ****   1.98   *****   ****   3.41   *****   -1.43   *****   0.58 ( 0.21, 1.59 )   0.291				•				•	• ′	•	•	
Site-Adjusted Analysis   SV (14-day gap)   29,979   *****   *****   *****   *****   *****   1.98   *****   *****   1.98   *****   1.43   *****   0.58 (0.21, 1.59)   0.291	Medical Product	New Users	at Risk	at Risk	at Risk			New Users	Person Years	Users	Interval)²	P-Value <sup>2</sup>
SV (14-day gap)   29,979   *****   *****   *****   *****   3.41   *****   3.41   *****   0.58 (0.21, 1.59)   0.291						31	- 60 Days					
Solid   Soli												
Size Aging   25,351		•							-1 43	****	0.58 ( 0.21 1.59)	0 291
SV (14-day gap) 27,574 ***** ***** ***** ***** 1.78 ***** 0 ***** 1.00 (0.20, 4.95) 1  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 29,701 ***** **** ***** ***** 1.99 ***** 1.17 ***** 0.64 (0.19, 2.18) 0.474  ***** 0.64 (0.19, 2.18) 0.474  ***** 0.64 (0.19, 2.18) 0.474  ***** 0.64 (0.19, 2.18) 0.474  ***** 0.64 (0.19, 2.18) 0.474  ***** 0.64 (0.19, 2.18) 0.474  ***** 0.64 (0.11, 1.88) 0.278  ***** 0.46 (0.11, 1.88) 0.278  ***** 0.46 (0.11, 1.88) 0.278  ***** 0.46 (0.11, 1.88) 0.278  ***** 0.46 (0.11, 1.88) 0.278  ***** 0.46 (0.11, 1.88) 0.278  ***** 0.33 (0.03, 3.20) 0.341  ***** 0.33 (0.03, 3.20) 0.341  ***** 0.34 (0.03, 2.79) 0.298  ***** 0.37 (0.03, 2.79) 0.298  ***** 0.38 (14-day gap) 19,699 ***** ***** ***** ***** 0.67 ***** 1.4 *****  1.5 ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ******* 0.31 (0.03, 2.79) 0.298							3.41	****	1.45		0.50 ( 0.21, 1.55)	0.231
SV (14-day gap) 27,574 ***** ***** ***** ***** 1.78 ***** 0 ***** 1.00 (0.20, 4.95) 1  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 29,701 ***** **** ***** ***** 1.99 ***** 1.17 ***** 0.64 (0.19, 2.18) 0.474  ***** 0.64 (0.19, 2.18) 0.474  ***** 0.64 (0.19, 2.18) 0.474  ***** 0.64 (0.19, 2.18) 0.474  ***** 0.64 (0.19, 2.18) 0.474  ***** 0.64 (0.19, 2.18) 0.474  ***** 0.64 (0.11, 1.88) 0.278  ***** 0.46 (0.11, 1.88) 0.278  ***** 0.46 (0.11, 1.88) 0.278  ***** 0.46 (0.11, 1.88) 0.278  ***** 0.46 (0.11, 1.88) 0.278  ***** 0.46 (0.11, 1.88) 0.278  ***** 0.33 (0.03, 3.20) 0.341  ***** 0.33 (0.03, 3.20) 0.341  ***** 0.34 (0.03, 2.79) 0.298  ***** 0.37 (0.03, 2.79) 0.298  ***** 0.38 (14-day gap) 19,699 ***** ***** ***** ***** 0.67 ***** 1.4 *****  1.5 ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ***** 0.31 (0.03, 2.79) 0.298  ******* 0.31 (0.03, 2.79) 0.298	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
ARBs (14-day gap) 27,574 ***** ***** ***** ***** ***** 1.78 ***** 0 1.00 (0.29, 4.93) 1  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 29,701 ***** ***** ***** ***** 1.99 ****** -1.17 ***** 0.64 (0.19, 2.18) 0.474  ARBs (14-day gap) 30,313 ***** ***** ***** ***** 1.99 ****** -1.17 ***** 0.64 (0.19, 2.18) 0.474  SV (14-day gap) 19,875 ***** ***** ***** 1.34 ***** -1.63 ***** 0.46 (0.11, 1.88) 0.278  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05¹  SV (14-day gap) 14,351 ***** **** ***** ***** 0.98 ***** -1.96 ***** 0.33 (0.03, 3.20) 0.341  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 19,699 ***** ***** ***** 0.67 ***** -1.5 ***** 0.31 (0.03, 2.79) 0.298  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 19,699 ***** ***** ***** 0.67 ***** -1.5 ***** 0.31 (0.03, 2.79) 0.298  Site-Adjusted Analysis  SV (14-day gap) 16,273 ***** ***** ***** 1.4 ****** -0.35 ***** 0.81 (0.29, 2.24) 0.687  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05¹  SV (14-day gap) 16,273 ***** ***** ***** 1.75 ***** -0.35 ***** 0.81 (0.29, 2.24) 0.687  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05¹  SV (14-day gap) 10,320 ***** ***** ***** ***** 1.75 *****  0.35 ******  0.81 (0.29, 2.24) 0.687  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05¹  SV (14-day gap) 10,320 ***** ***** ***** ***** ***** 1.75 ******  1.75 ************************************			****	****			1.78	****	0	****	1.00 / 0.20 / 05\	1
SV (14-day gap) 29,701 ***** **** **** **** **** 1.99 ***** -1.17 ***** 0.64 ( 0.19, 2.18) 0.474  *****	ARBs (14-day gap)	27,574	****	****	****	****	1.78	****	U		1.00 ( 0.20, 4.95)	1
Site-Adjusted Analysis   Site-Adjusted Conditional Analysis; Caliper   O.51   Site-Adjusted Analysis   Site-Adjusted Analysis   Site-Adjusted Analysis   Site-Adjusted Analysis   Site-Adjusted Conditional Analysis; Caliper   O.51   Site-Adjusted Conditional Analysis; Caliper   O.51   Site-Adjusted Conditional Analysis; Caliper   O.51   Site-Adjusted Conditional Conditional Analysis; Caliper   O.51   Site-Adjusted Conditional Conditional Analysis; Caliper   O.51   Site-Adjusted Conditional Conditional Conditional Analysis; Caliper   O.51   Site-Adjusted Conditional Conditi	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unc	onditional A	nalysis; Cal	iper= 0.05						
ARBs (14-day gap) 30,313 ***** **** ***** ***** 3.17 ***** ***** 51.17 ***** 5	SV (14-day gap)	29,701	****	****	****	****	1.99	****	1 17	****	0.64/0.10 3.10\	0.474
Site-Adjusted Analysis         SV (14-day gap)       19,875       ******       ******       ******       1.34       ******       -1.63       ******       0.46 ( 0.11, 1.88)       0.278         Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05¹         SV (14-day gap)       14,351       ******       ******       ******       0.98       ******       -1.96       ******       0.33 ( 0.03, 3.20)       0.341         Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05         SV (14-day gap)       19,699       ******       ******       ******       0.67       ******       -1.5       ******       0.31 ( 0.03, 2.79)       0.298         Site-Adjusted Analysis         SV (14-day gap)       16,273       ******       ******       ******       ******       1.4       ******       -0.35       ******       0.81 ( 0.29, 2.24)       0.687         Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05¹         SV (14-day gap)       10,320       ******       ******       ******       -0.35       ******       0.81 ( 0.29, 2.24)       0.687         Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05	ARBs (14-day gap)	30,313	****	****	****	****	3.17	****	-1.1/		0.64 (0.19, 2.18)	0.474
SV (14-day gap) 19,875 ***** ***** ***** ***** ***** 1.34 ***** -1.63 ***** 0.46 (0.11, 1.88) 0.278    Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05						61	- 90 Days					
ARBs (14-day gap) 199,450 **** **** **** **** **** **** **** *	Site-Adjusted Analysi	S										
ARBs (14-day gap) 199,450 **** **** **** **** **** 2.97 ***** *1.05 *0.40 (0.11, 1.86) *0.278  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 14,351 **** **** **** **** **** **** **** *	SV (14-day gap)	19,875	****	****	****	****	1.34	****	1.62	****	0.46 ( 0.11 1.00)	0.270
SV (14-day gap) 14,351 **** **** **** **** **** 2.95 ***** -1.96 ***** 0.33 (0.03, 3.20) 0.341  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 19,699 **** **** **** **** 0.67 ***** -1.5 ***** 0.31 (0.03, 2.79) 0.298  ARBs (14-day gap) 23,789 **** **** **** **** 2.17 ***** -1.5 ***** 0.31 (0.03, 2.79) 0.298  Site-Adjusted Analysis  SV (14-day gap) 16,273 **** **** **** **** **** 1.4 ***** -0.35 ***** 0.81 (0.29, 2.24) 0.687  ARBs (14-day gap) 177,174 **** **** **** **** 1.75 ***** -0.35 ***** 0.81 (0.29, 2.24) 0.687  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 10,320 ***** **** **** ***** 0.73 *****	ARBs (14-day gap)	199,450	****	****	****	****	2.97	****	-1.03		0.46 ( 0.11, 1.88)	0.278
SV (14-day gap) 14,351 **** **** **** **** **** 2.95 ***** -1.96 ***** 0.33 (0.03, 3.20) 0.341  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 19,699 **** **** **** **** 0.67 ***** -1.5 ***** 0.31 (0.03, 2.79) 0.298  ARBs (14-day gap) 23,789 **** **** **** **** 2.17 ***** -1.5 ***** 0.31 (0.03, 2.79) 0.298  Site-Adjusted Analysis  SV (14-day gap) 16,273 **** **** **** **** **** 1.4 ***** -0.35 ***** 0.81 (0.29, 2.24) 0.687  ARBs (14-day gap) 177,174 **** **** **** **** 1.75 ***** -0.35 ***** 0.81 (0.29, 2.24) 0.687  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 10,320 ***** **** **** ***** 0.73 *****	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
ARBs (14-day gap) 14,351 **** **** **** **** 2.95 **** -1.96 **** 0.33 (0.03, 3.20) 0.341  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 19,699 **** **** **** **** 0.67 ***** -1.5 ***** 0.31 (0.03, 2.79) 0.298  ARBs (14-day gap) 23,789 **** **** **** **** 2.17 ***** -1.5 ***** 0.31 (0.03, 2.79) 0.298  Site-Adjusted Analysis  SV (14-day gap) 16,273 **** **** **** **** 1.4 ***** -0.35 ***** 0.81 (0.29, 2.24) 0.687  ARBs (14-day gap) 177,174 **** **** **** **** 1.75 ***** 0.73 ***** 1.00 (0.06, 15, 99) 1  SV (14-day gap) 10,320 **** **** **** ***** 0.73 *****		14,351	****	****	****	****	0.98	****	1.05	****	0.00 ( 0.00 0.00)	0.044
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 19,699 **** **** **** **** **** 0.67 ***** 0.31 (0.03, 2.79) 0.298  ARBs (14-day gap) 23,789 **** **** **** **** 2.17 ***** 0.31 (0.03, 2.79) 0.298  Site-Adjusted Analysis  SV (14-day gap) 16,273 **** **** **** **** 1.4 **** -0.35 ***** 0.81 (0.29, 2.24) 0.687  ARBs (14-day gap) 177,174 **** **** **** **** 1.75 ***** 0.73 ***** 0.81 (0.29, 2.24) 0.687  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 10,320 ***** **** ***** ***** 0.73 *****		14,351	****	****	****	****	2.95	****	-1.96	****	0.33 ( 0.03, 3.20)	0.341
ARBs (14-day gap) 23,789 ***** **** **** **** **** 2.17 ***** -1.5 ***** 0.31 (0.03, 2.79) 0.298    Site-Adjusted Analysis   SV (14-day gap)			tched Unc	onditional A	nalysis; Cal	iper= 0.05						
ARBs (14-day gap) 23,789 **** **** **** **** 2.17 ***** -1.5 ***** 0.31 (0.03, 2.79) 0.298    Site-Adjusted Analysis   SV (14-day gap)		•				•	0.67	****	4.5	****	0.24 / 0.02 .2.70)	0.200
91 - 180 Days       Site-Adjusted Analysis       SV (14-day gap)     16,273     *****     *****     *****     1.4     *****     -0.35     *****     0.81 (0.29, 2.24)     0.687       Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05¹       SV (14-day gap)     10,320     ******     ******     ******     0.73     ******     0     ******     1 00 (0.06, 15, 99)     1		23,789	****	****	****	****	2.17	****	-1.5	****	0.31 (0.03, 2.79)	0.298
SV (14-day gap)       16,273       *****       *****       *****       *****       1.4       *****       -0.35       *****       0.81 (0.29, 2.24)       0.687         Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05¹         SV (14-day gap)       10,320       *****       *****       *****       0.73       *****       0       *****       1 00 (0.06, 15.99)       1	7 7 7 7	,				91	- 180 Days					
SV (14-day gap)       16,273       *****       *****       *****       *****       1.4       *****       -0.35       *****       0.81 (0.29, 2.24)       0.687         Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05¹         SV (14-day gap)       10,320       *****       *****       *****       0.73       *****       0       *****       1 00 (0.06, 15.99)       1	Site-Adjusted Analysi	S					•					
ARBs (14-day gap) 177,174 ***** ***** ***** 1.75 ***** -0.35 0.81 (0.29, 2.24) 0.687  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 10,320 ***** ***** ***** ***** 0.73 ***** 0.73 ***** 1.00 (0.06, 15, 99) 1			****	****	****	****	1.4	****	0.25	****	0.04 / 0.20 . 2.24\	0.607
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05 <sup>1</sup> SV (14-day gap) 10,320 ***** ***** ***** ***** 0.73 ***** 0.73 ***** 1.00 ( 0.06, 15, 99) 1	, , , , ,	•	****	****	****	****	1.75	****	-0.35	T T T T T	0.81 (0.29, 2.24)	0.687
SV (14-day gap) 10,320 ***** ***** ***** 0.73 ***** 0 ***** 1.00 ( 0.06, 15.99) 1			tched Cond	ditional Ana	lvsis: Caline	er= 0.05 <sup>1</sup>						
0 ***** 100(006 15 99) 1							0.73	****				
	ARBs (14-day gap)	10,320	****	****	****	****	0.73	****	0	****	1.00 ( 0.06, 15.99)	1

cder\_mpl2r\_wp016 Page 113 of 247



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

		Person	Average Person	Average Person	Number	Incidence Rate per 1,000	Risk per	Incidence Rate Difference	Difference in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk		Events		•	• •	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Prope				at Risk		Years	New Osers	Person Years	users	intervaij	P-value
	-	****	*****	*****	*****	1 11	****				
SV (14-day gap)	16,124	****	****	****	****	1.41	****	-0.17	****	0.90 (0.25, 3.18)	0.867
ARBs (14-day gap)	20,952	4. 4. 4. 4. 4.	4-4-4-4-	4-4-4-4-4-		1.59	ale de de de				
Cita Adimetad Amaloni					181	- 270 Days					
Site-Adjusted Analysis		****	****	****	****	0.50	****				
SV (14-day gap)	8,822	****	****	****	****	0.59	****	-1.28	****	0.32 (0.04, 2.30)	0.256
ARBs (14-day gap)	109,601					1.87	****				
Fixed Ratio 1:1 Prope	nsity Score Ma			lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	3,325	****	****	****	****	1.87	****	1.87	****		
ARBs (14-day gap)	3,325	****	****	****	****	0	****	1.07		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	8,739	****	****	****	****	0.59	****	1.01	****	0.30 ( 0.04	0.204
ARBs (14-day gap)	12,445	****	****	****	****	1.6	****	-1.01		0.38 ( 0.04, 3.38)	0.384
					271	- 365 Days					
Site-Adjusted Analysis	S										
SV (14-day gap)	5,512	****	****	****	****	0.85	****	0.46	****	0.67 ( 0.00 , 4.04)	0.602
ARBs (14-day gap)	78,866	****	****	****	****	1.31	****	-0.46	****	0.67 ( 0.09, 4.94)	0.693
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	1,436	****	****	****	****	0	****		****		
ARBs (14-day gap)	1,436	****	****	****	****	0	****	0	***	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	5,458	****	****	****	****	0.86	****		ale ale ale ale	/ :	
ARBs (14-day gap)	8,510	****	****	****	****	1.1	****	-0.24	****	0.79 ( 0.07, 8.75)	0.85
1	-,										

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 114 of 247

<sup>&</sup>lt;sup>2</sup>Data presented by a dash are unable to be calculated. This table may not use all data representations.

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



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

						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Race: Unknown											
Site-Adjusted Analys	sis										
SV	7,289	****	****	****	****	0.75	****	-1.77	****	0.30 (0.07, 1.22)	0.092
ARBs	47,812	****	****	****	****	2.51	****	-1.77		0.30 (0.07, 1.22)	0.092
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	7,159	****	****	****	****	0.65	****	1 21	****	0.22 (0.022.20)	0.241
ARBs	7,159	****	****	****	****	1.96	****	-1.31		0.33 (0.03, 3.20)	0.341
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV	7,159	****	****	****	****	0.76	****	-1.32	****	0.38 (0.08, 1.87)	0.232
ARBs	7,159	****	****	****	****	2.08	****	-1.52		0.36 (0.06, 1.67)	0.232
Race: American Indi	an										
Site-Adjusted Analys	sis										
SV	143	****	****	****	****	0	****	-1.36	****		
ARBs	1,947	****	****	****	****	1.36	****	-1.30		-	
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	138	****	****	****	****	0	****	0	****		
ARBs	138	****	****	****	****	0	****	0	4. 4. 4. 4.	-	-
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV	138	****	****	****	****	0	****	0	****		
ARBs	138	****	****	****	****	0	****	U		-	-
Race: Asian											
Site-Adjusted Analys	sis										
SV	511	****	****	****	****	0	****	-0.81	****		
ARBs	7,817	****	****	****	****	0.81	****	-0.01		<u> </u>	
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	484	****	****	****	****	0	****	0	****		
ARBs	484	****	****	****	****	0	****	0	4- 4- 4- 4-	-	-

cder\_mpl2r\_wp016 Page 115 of 247



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

						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV	484	****	****	****	****	0	****	0	****		
ARBs	484	****	****	****	****	0	****	U		-	-
Race: Black											
Site-Adjusted Analys	sis										
SV	5,853	****	****	****	****	4.01	****	-2.79	****	0.54 (0.25, 1.15)	0.11
ARBs	55,815	****	****	****	****	6.8	****	-2.79		0.34 (0.23, 1.13)	0.11
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	5,765	****	****	****	****	3.76	****	0	****	1.00 (0.35, 4.00)	1
ARBs	5,765	****	****	****	****	3.76	****	0		1.00 (0.25, 4.00)	1
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV	5,765	****	****	****	****	4.06	****	0.36	****	1.08 (0.39, 3.00)	0.879
ARBs	5,765	****	****	****	****	3.7	****	0.50		1.06 (0.59, 5.00)	0.679
Race: Pacific Islande	er										
Site-Adjusted Analys	sis										
SV	46	****	****	****	****	0	****	-8.97	****		
ARBs	478	****	****	****	****	8.97	****	-0.37		-	
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	31	****	****	****	****	0	****	0	****		
ARBs	31	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV	31	****	****	****	****	0	****	0	****		
ARBs	31	****	****	****	****	0	****	0		-	-
Race: White											
Site-Adjusted Analy	sis										
SV	29,935	****	****	****	****	1.1	****	-1.3	2 ***** 0.42 (0.24 0.75)	0.004	
ARBs	223,288	****	****	****	****	2.4	****	-1.5		0.42 (0.24, 0.76)	0.004

cder\_mpl2r\_wp016 Page 116 of 247



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

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval) <sup>2</sup>	Wald P-Value <sup>2</sup>
Fixed Ratio 1:1 Prop	ensity Score Ma 29,757	tched Cond	ditional Ana ****	lysis; Calipe	*****	1.03	****		ate ate ate ate		
ARBs	29,757	****	****	****	****	2.21	****	-1.18	****	0.47 (0.19, 1.14)	0.096
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV	29,757	****	****	****	****	1.11	****	-0.97	****	0.51 (0.26, 1.00)	0.051
ARBs	29,757	****	****	****	****	2.08	****	-0.97		0.51 (0.26, 1.00)	0.051

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 117 of 247

<sup>&</sup>lt;sup>2</sup>Data presented by a dash are unable to be calculated. This table may not use all data representations.

<sup>\*\*\*\*\*</sup>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.



	Number of	Person Years	Average Person Days	Average Person Years	Number of	Incidence Rate per 1,000 Person	Risk per 1.000	Incidence Rate Difference per 1,000	Difference in Risk per 1.000 New	Hazard Ratio (95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	,	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Race: Unknown										,	
						Overall					
<b>Site-Adjusted Analysis</b>	1										
SV (14-day gap)	7,289	****	****	****	****	0.75	****	-1.77	****	0.30 ( 0.07, 1.22)	0.092
ARBs (14-day gap)	47,812	****	****	****	****	2.51	****	-1.//		0.30 (0.07, 1.22)	0.092
Fixed Ratio 1:1 Proper	sity Score Ma	tched Cond	litional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	7,159	****	****	****	****	0.65	****	4.24	****	0.22 ( 0.02 2.20)	0.244
ARBs (14-day gap)	7,159	****	****	****	****	1.96	****	-1.31	4 4 4 4 4	0.33 ( 0.03, 3.20)	0.341
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	nditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	7,159	****	****	****	****	0.76	****	-1.32	****	0.30 / 0.00 1.07)	0.232
ARBs (14-day gap)	7,159	****	****	****	****	2.08	****	-1.52		0.38 ( 0.08, 1.87)	0.232
					0	- 30 Days					
<b>Site-Adjusted Analysis</b>											
SV (14-day gap)	7,289	****	****	****	****	0	****	-3.41	****	_	_
ARBs (14-day gap)	47,812	****	****	****	****	3.41	****	-3.41			
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	litional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	7,125	****	****	****	****	0	****	1 05	****		
ARBs (14-day gap)	7,125	****	****	****	****	1.85	****	-1.85		-	
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	nditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	7,209	****	****	****	****	0	****	-1.77	****		
ARBs (14-day gap)	7,398	****	****	****	****	1.77	****	-1.//		-	
					31	- 60 Days					
Site-Adjusted Analysis											
SV (14-day gap)	6,560	****	****	****	****	0	****	-2.52	****		
ARBs (14-day gap)	44,564	****	****	****	****	2.52	****	-2.32		-	_

cder\_mpl2r\_wp016 Page 118 of 247



			Average	Average		Incidence Rate per		Incidence Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Con	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	5,874	****	****	****	****	0	****	-2.82	****		
ARBs (14-day gap)	5,874	****	****	****	****	2.82	****	-2.02		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unc	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	6,446	****	****	****	****	0	****	-4.33	****		
ARBs (14-day gap)	6,520	****	****	****	****	4.33	****	-4.55		-	
					61	90 Days					
Site-Adjusted Analysi											
SV (14-day gap)	4,440	****	****	****	****	3.01	****	1.44	****	2.80 ( 0.31, 25.43)	0.36
ARBs (14-day gap)	33,271	****	****	****	****	1.57	****	1.44		2.80 ( 0.31, 23.43)	0.50
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Con	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	2,963	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	2,963	****	****	****	****	0	****	U		-	
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unc	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	4,367	****	****	****	****	3.06	****	3.06	****		
ARBs (14-day gap)	4,816	****	****	****	****	0	****	3.00		-	
					91	- 180 Days					
Site-Adjusted Analysi											
SV (14-day gap)	3,591	****	****	****	****	1.53	****	-1.76	****	0.47 ( 0.06, 3.53)	0.46
ARBs (14-day gap)	28,540	****	****	****	****	3.29	****	1.70		0.47 ( 0.00, 3.55)	0.40
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Con	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	2,019	****	****	****	****	3.63	****	0	****	1.00 ( 0.06, 15.99)	1
ARBs (14-day gap)	2,019	****	****	****	****	3.63	****	<u> </u>		1.00 ( 0.00, 15.99)	
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unc	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	3,541	****	****	****	****	1.55	****	-1.21	****	0 54 ( 0 05 5 03)	) 0.612
ARBs (14-day gap)	4,059	****	****	****	****	2.76	****	-1.21	***** 0.54 ( 0.05, 5.93)	0.54 (0.05, 5.93)	

cder\_mpl2r\_wp016 Page 119 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
					181	270 Days					
Site-Adjusted Analysis	3										
SV (14-day gap)	2,040	****	****	****	****	0	****	-2.06	****		
ARBs (14-day gap)	16,763	****	****	****	****	2.06	****	-2.00		-	
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	657	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	657	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	2,021	****	****	****	****	0	****	-2.21	****	_	_
ARBs (14-day gap)	2,273	****	****	****	****	2.21	****	-2.21		-	_
					271	365 Days					
Site-Adjusted Analysis	3										
SV (14-day gap)	1,297	****	****	****	****	0	****	-1.16	****	_	_
ARBs (14-day gap)	11,721	****	****	****	****	1.16	****	1.10			
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	292	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	292	****	****	****	****	0	****	U		-	_
Fixed Ratio 1:1 Proper	nsity Score Ma		onditional A	nalysis; Cal	•						
SV (14-day gap)	1,284	****	****	****	****	0	****	0	****	_	_
ARBs (14-day gap)	1,522	****	****	****	****	0	****	0			
Race: American Indiar	า										
						Overall					
Site-Adjusted Analysis	3										
SV (14-day gap)	143	****	****	****	****	0	****	-1.36	****	_	_
ARBs (14-day gap)	1,947	****	****	****	****	1.36	****	1.50			

cder\_mpl2r\_wp016 Page 120 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	litional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	138	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	138	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	nditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	138	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	138	****	****	****	****	0	****	0		-	-
					0 -	- 30 Days					
Site-Adjusted Analysis	3										
SV (14-day gap)	211	****	****	****	****	0	****	-5.6	****		
ARBs (14-day gap)	2,647	****	****	****	****	5.6	****	-5.0		-	
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	litional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	143	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	143	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	nditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	205	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	237	****	****	****	****	0	****	U		-	
					31	- 60 Days					
Site-Adjusted Analysis											
SV (14-day gap)	126	****	****	****	****	0	****	0	****	_	_
ARBs (14-day gap)	1,839	****	****	****	****	0	****	0			
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	litional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	115	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	115	****	****	****	****	0	****	0	nan nan nan nan	-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	nditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	122	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	131	****	****	****	****	0	****	U		-	-

cder\_mpl2r\_wp016 Page 121 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	<b>Events</b>	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
					61	- 90 Days					
Site-Adjusted Analysis	5										
SV (14-day gap)	78	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	1,234	****	****	****	****	0	****	U		-	
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	57	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	57	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	77	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	93	****	****	****	****	0	****	U		-	
					91	- 180 Days					
Site-Adjusted Analysis	5										
SV (14-day gap)	63	****	****	****	****	0	****	0	****	_	_
ARBs (14-day gap)	1,023	****	****	****	****	0	****				
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	40	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	40	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	62	****	****	****	****	0	****	0	****	_	_
ARBs (14-day gap)	81	****	****	****	****	0	****	0			
					181	- 270 Days					
Site-Adjusted Analysis											
SV (14-day gap)	32	****	****	****	****	0	****	0	****	_	_
ARBs (14-day gap)	551	****	****	****	****	0	****				
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	15	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	15	****	****	****	****	0	****	U		-	-

cder\_mpl2r\_wp016 Page 122 of 247



					<u> </u>						
						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	<b>Hazard Ratio</b>	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	per= 0.05						
SV (14-day gap)	33	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	47	****	****	****	****	0	****	0	4 4 4 4 4	-	-
, , , , , ,					271	- 365 Days					
Site-Adjusted Analysis	S										
SV (14-day gap)	18	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	370	****	****	****	****	0	****	0	4 4 4 4 4	-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	****	****	****	****	****	0	****	_	****		
ARBs (14-day gap)	****	****	****	****	****	0	****	0	****	-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	per= 0.05						
SV (14-day gap)	19	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	31	****	****	****	****	0	****	0	4 4 4 4 4	-	-
Race: Asian											
						Overall					
Site-Adjusted Analysis	S										
SV (14-day gap)	511	****	****	****	****	0	****	0.04	****		
ARBs (14-day gap)	7,817	****	****	****	****	0.81	****	-0.81		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	484	****	****	****	****	0	****		****		
ARBs (14-day gap)	484	****	****	****	****	0	****	0	***	-	-
Fixed Ratio 1:1 Proper		tched Unco	onditional A	nalysis; Cali	per= 0.05						
SV (14-day gap)	484	****	****	****	****	0	****	•	****		
ARBs (14-day gap)	484	****	****	****	****	0	****	0	***	-	-

cder\_mpl2r\_wp016 Page 123 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
					0	- 30 Days					
Site-Adjusted Analysis	3										
SV (14-day gap)	509	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	7,782	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	437	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	437	****	****	****	****	0	****	0	4. 4. 4. 4.	-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	448	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	453	****	****	****	****	0	****	U		-	-
					31	- 60 Days					
Site-Adjusted Analysis											
SV (14-day gap)	472	****	****	****	****	0	****	0	****		_
ARBs (14-day gap)	7,373	****	****	****	****	0	****	0		-	
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	405	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	405	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	432	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	442	****	****	****	****	0	****	U		-	_
					61	- 90 Days					
Site-Adjusted Analysis											
SV (14-day gap)	325	****	****	****	****	0	****	-2.16	****	_	_
ARBs (14-day gap)	5,973	****	****	****	****	2.16	****	-2.10		_	
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	251	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	251	****	****	****	****	0	****	U		-	-

cder\_mpl2r\_wp016 Page 124 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	<b>Hazard Ratio</b>	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05					·	
SV (14-day gap)	316	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	376	****	****	****	****	0	****	U		-	-
					91	- 180 Days					
Site-Adjusted Analysis	S										
SV (14-day gap)	247	****	****	****	****	0	****	-1.04	****	_	_
ARBs (14-day gap)	5,297	****	****	****	****	1.04	****	-1.04			
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	158	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	158	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	235	****	****	****	****	0	****	0	****		_
ARBs (14-day gap)	326	****	****	****	****	0	****	0			
					181	- 270 Days					
Site-Adjusted Analysis											
SV (14-day gap)	135	****	****	****	****	0	****	-1.55	****	_	_
ARBs (14-day gap)	3,218	****	****	****	****	1.55	****				
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	60	****	****	****	****	0	****	0	****	_	_
ARBs (14-day gap)	60	****	****	****	****	0	****	0			
Fixed Ratio 1:1 Proper	nsity Score Ma				•						
SV (14-day gap)	128	****	****	****	****	0	****	0	****	_	_
ARBs (14-day gap)	177	****	****	****	****	0	****				
					271	- 365 Days					
Site-Adjusted Analysis											
SV (14-day gap)	87	****	****	****	****	0	****	0	****	-	_
ARBs (14-day gap)	2,249	****	****	****	****	0	****	J			

cder\_mpl2r\_wp016 Page 125 of 247



Person Person Person Number 1,000 Risk per Difference in Risk per Hazard Ratio  Number of Years Days Years of Person 1,000 per 1,000 1,000 New (95% Confidence Wald Medical Product New Users at Risk at Risk at Risk Events Years New Users Person Years Users Interval) <sup>2</sup> P-Value  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper = 0.05 <sup>1</sup> SV (14-day gap) 31 **** **** **** **** 0 ***** 0 *****  ARBs (14-day gap) 31 **** **** **** **** 0 ***** 0 *****  SV (14-day gap) 31 **** **** **** 0 ***** 0 ***** 0 ***** 0 *****  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper = 0.05  SV (14-day gap) 83 **** **** **** 0 ***** 0 ***** 0 ***** 0 ***** 0 ***** 0 ***** 0 ***** 0 ***** 0 ***** 0 ******							Incidence		Incidence			
Number of   Years   Days   Years   of   Person   1,000   per 1,000   1,000   New   (95% Confidence   Mald Medical Product   New Users   at Risk   at Risk   at Risk   Events   Years   New Users   Person Years   Users   Users   Interval)   P-Value				Average	Average		Rate per		Rate	Difference		
Medical Product   New Users   at Risk   at Risk   at Risk   at Risk   Events   Years   New Users   Person Years   Users   Interval]   P-Value			Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per		
Second   S		Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	•	
Sy (14-day gap)   31	Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Sy (14-day gap)   31	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
ARBs (14-day gap)   31			****	****	****	****	0	****	0	****		
SV (14-day gap)   83	ARBs (14-day gap)	31	****	****	****	****	0	****	U		-	-
ARBs (14-day gap) 115 **** **** **** **** 4.01 ***** 0 ***** 0.54 (0.25, 1.15) 0.11  Sive Adjusted Analysis  SV (14-day gap) 5,853 **** **** **** **** 4.01 ***** 0 ***** 0.54 (0.25, 1.15) 0.11  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper = 0.05  SV (14-day gap) 5,765 **** **** **** **** 4.06 ***** 0 ***** 1.00 (0.25, 4.00) 1  ARBs (14-day gap) 5,765 **** **** **** **** 4.06 ***** 0 ***** 1.08 (0.39, 3.00) 0.879  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper = 0.05  SV (14-day gap) 5,765 **** **** **** **** 4.06 ***** 0.36 ***** 1.08 (0.39, 3.00) 0.879  Site-Adjusted Analysis  SV (14-day gap) 5,765 **** **** **** **** 1.3.65 **** 1.1.49 **** 0.16 (0.02, 1.14) 0.067  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper = 0.05  Site-Adjusted Analysis  SV (14-day gap) 5,853 **** **** **** **** 1.3.65 **** -11.49 **** 0.16 (0.02, 1.14) 0.067  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper = 0.05  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper = 0.05  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper = 0.05  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper = 0.05  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper = 0.05  SV (14-day gap) 5,765 **** **** **** ****  2.26 ***** -2.26 ***** 0.50 (0.05, 5.51) 0.571  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper = 0.05  SV (14-day gap) 5,765 ****  ****  *****  *****  2.26 *****  -2.26 *****  0.50 (0.05, 5.51) 0.571	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
ARBs (14-day gap) 115 **** **** **** **** 0 ***** 0 ***** 0 ****	SV (14-day gap)	83	****	****	****	****	0	****	0	****		
Site-Adjusted Analysis	ARBs (14-day gap)	115	****	****	****	****	0	****	U		-	-
Site-Adjusted Analysis	Race: Black											
SV (14-day gap)   5,853   *****   *****   *****   *****   *****   4.01   ******   -2.79   *****   0.54 (0.25, 1.15)   0.11							Overall					
ARBs (14-day gap) 55,815 **** **** **** **** **** * 6.8 **** ****	Site-Adjusted Analysis	S										
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05¹  SV (14-day gap) 5,765 ***** **** **** **** 3.76 ***** 0 ***** 1.00 (0.25, 4.00) 1  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 **** **** **** **** **** 4.06 ***** 0.36 ***** 1.08 (0.39, 3.00) 0.879  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 **** **** **** **** **** 3.7 ***** 0.36 ***** 1.08 (0.39, 3.00) 0.879  Site-Adjusted Analysis  SV (14-day gap) 5,853 ***** **** **** **** 2.16 ***** -11.49 ***** 0.16 (0.02, 1.14) 0.067  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05¹  SV (14-day gap) 5,765 ***** **** **** **** 2.26 ***** -2.26 ***** 0.50 (0.05, 5.51) 0.571  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 ***** **** **** **** 4.52 **** -2.26 ***** 0.50 (0.05, 5.51) 0.571  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 ***** **** **** ****  4.52 ****  -2.26 ***** 0.50 (0.05, 5.51) 0.571  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 ***** **** **** ***** ***** 2.19 *****  4.52 *****  0.50 (0.04, 5.46) 0.566	SV (14-day gap)	5,853	****	****	****	****	4.01	****	-2 70	****	054/025 115)	0.11
SV (14-day gap) 5,765 ***** **** **** **** **** 3.76 ***** 0 ***** 1.00 (0.25, 4.00) 1  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 **** **** **** **** 4.06 ***** 0.36 ***** 1.08 (0.39, 3.00) 0.879  ARBs (14-day gap) 5,765 **** **** **** **** **** 2.16 ***** 13.65 **** 11.49 **** 0.16 (0.02, 1.14) 0.067  Site-Adjusted Analysis  SV (14-day gap) 5,853 **** **** **** **** **** 13.65 **** 11.49 **** 0.16 (0.02, 1.14) 0.067  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 **** **** **** **** 2.26 ***** -2.26 ***** 0.50 (0.05, 5.51) 0.571  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 **** **** **** **** 4.52 ****  2.19 *****  2.26 ***** 0.50 (0.04, 5.46) 0.566							6.8	****	-2.79		0.54 ( 0.25, 1.15)	0.11
SV (14-day gap) 5,765 ***** **** **** **** **** 3.76 ***** 0 ***** 1.00 (0.25, 4.00) 1  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 **** **** **** **** 4.06 ***** 0.36 ***** 1.08 (0.39, 3.00) 0.879  ARBs (14-day gap) 5,765 **** **** **** **** **** 2.16 ***** 13.65 **** 11.49 **** 0.16 (0.02, 1.14) 0.067  Site-Adjusted Analysis  SV (14-day gap) 5,853 **** **** **** **** **** 13.65 **** 11.49 **** 0.16 (0.02, 1.14) 0.067  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 **** **** **** **** 2.26 ***** -2.26 ***** 0.50 (0.05, 5.51) 0.571  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 **** **** **** **** 4.52 ****  2.19 *****  2.26 ***** 0.50 (0.04, 5.46) 0.566	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
ARBs (14-day gap) 5,765 **** **** **** **** 3.76 ***** 0.100 (0.23, 4.00) 1  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 **** **** **** **** 4.06 ***** 0.36 ***** 1.08 (0.39, 3.00) 0.879  ARBs (14-day gap) 5,765 **** **** **** **** 2.16 **** 0.36 ***** 0.16 (0.02, 1.14) 0.067  ARBs (14-day gap) 5,853 **** **** **** **** 13.65 **** 11.49 ***** 0.16 (0.02, 1.14) 0.067  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 **** **** **** **** 2.26 ***** 0.50 (0.05, 5.51) 0.571  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 **** **** **** **** 4.52 ****			****	****	****	****	3.76	****	0	****	1.00 / 0.25 / 4.00)	1
SV (14-day gap) 5,765 **** **** **** **** **** 4.06 **** 0.36 ***** 1.08 (0.39, 3.00) 0.879  ***** O-30 Days  ***** O.50 Days  ***** O.50 (0.02, 1.14) 0.067  ***** O.50 (0.05, 5.51) 0.571  ***** O.50 (0.05, 5.51) 0.571  ***** O.50 (0.05, 5.51) 0.571  ***** O.50 (0.04, 5.46) 0.566  ***** O.50 (0.04, 5.46) 0.566  ***** O.50 (0.04, 5.46) 0.566	ARBs (14-day gap)	5,765	****	****	****	****	3.76	****	U		1.00 ( 0.23, 4.00)	1
ARBs (14-day gap) 5,765 **** **** **** **** **** 3.7 **** 0.36 ***** 1.08 (0.39, 3.00) 0.879    Site-Adjusted Analysis	Fixed Ratio 1:1 Prope	nsity Score Ma			nalysis; Cal	•						
ARBS (14-day gap) 5,765 ***** **** **** 3.7 ****  O - 30 Days  Site-Adjusted Analysis  SV (14-day gap) 5,853 **** **** **** **** 2.16 ***** -11.49 ***** 0.16 (0.02, 1.14) 0.067  ARBS (14-day gap) 55,815 **** **** **** **** 13.65 ***** -11.49 ***** 0.16 (0.02, 1.14) 0.067  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 **** **** **** **** 2.26 ***** -2.26 ***** 0.50 (0.05, 5.51) 0.571  ARBS (14-day gap) 5,765 **** **** **** **** 4.52 ****  0.50 (0.05, 5.51) 0.571  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 **** **** **** **** 2.19 *****  0.50 (0.04 5.46) 0.566	SV (14-day gap)	5,765	****	****	****	****	4.06	****	0.26	****	1.09 ( 0.20 2.00)	0.970
Site-Adjusted Analysis  SV (14-day gap) 5,853 **** **** **** **** **** 13.65 **** -11.49 **** 0.16 (0.02, 1.14) 0.067  ARBs (14-day gap) 55,815 **** **** **** **** 2.26 *****  SV (14-day gap) 5,765 **** **** **** **** 2.26 **** -2.26 ***** 0.50 (0.05, 5.51) 0.571  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 **** **** **** **** 4.52 ****  -2.26 ***** 0.50 (0.05, 5.51) 0.571  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 **** **** **** ****	ARBs (14-day gap)	5,765	****	****	****	****	3.7	****	0.30		1.06 (0.39, 3.00)	0.879
SV (14-day gap) 5,853 **** **** **** **** **** 13.65 **** -11.49 **** 0.16 (0.02, 1.14) 0.067  ARBs (14-day gap) 55,815 **** **** **** **** 13.65 ****  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 **** **** **** **** 2.26 ***** -2.26 ***** 0.50 (0.05, 5.51) 0.571  ARBs (14-day gap) 5,765 **** **** **** **** **** 4.52 ****						0	- 30 Days					
ARBs (14-day gap) 55,815 **** **** **** **** **** **** 13.65 **** -11.49 **** 0.16 (0.02, 1.14) 0.067  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 **** **** **** **** **** 4.52 **** -2.26 ***** 0.50 (0.05, 5.51) 0.571  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 **** **** **** **** **** 2.19 ***** -2.17 ***** 0.50 (0.04, 5.46) 0.566	Site-Adjusted Analysis	S										
ARBs (14-day gap) 55,815 **** **** **** **** 13.65 ****  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 **** **** **** **** 2.26 **** 4.52 **** 0.50 (0.05, 5.51) 0.571  ARBs (14-day gap) 5,765 **** **** **** **** **** 2.19 ***** 2.19 ***** 0.50 (0.04, 5.46) 0.566	SV (14-day gap)	5,853	****	****	****	****	2.16	****	-11 //Q	****	0.16 ( 0.02 1.14)	0.067
SV (14-day gap)       5,765       *****       *****       *****       *****       2.26       *****       -2.26       *****       0.50 (0.05, 5.51)       0.571         ARBs (14-day gap)       5,765       *****       *****       *****       4.52       *****       -2.26       ******       0.50 (0.05, 5.51)       0.571         Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05         SV (14-day gap)       5,765       *****       ******       ******       2.19       ******       -2.17       ******       0.50 (0.04, 5.46)       0.566	ARBs (14-day gap)	55,815	****	****	****	****	13.65	****	-11.45		0.10 ( 0.02, 1.14)	0.007
SV (14-day gap)       5,765       *****       *****       *****       *****       2.26       *****       -2.26       *****       0.50 (0.05, 5.51)       0.571         ARBs (14-day gap)       5,765       *****       *****       *****       4.52       *****       -2.26       ******       0.50 (0.05, 5.51)       0.571         Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05         SV (14-day gap)       5,765       *****       ******       ******       2.19       ******       -2.17       ******       0.50 (0.04, 5.46)       0.566	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
ARBs (14-day gap) 5,765 **** **** **** **** 4.52 ****    Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 **** **** ****    SV (14-day gap) 5,765 ****    -2.17 **** 0.50 (0.04, 5.46) 0.566							2.26	****	2.26	****	0.50/0.05 5.51	0.571
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 5,765 ***** ***** ***** 2.19 *****  -2 17 ***** 0.50 (0.04, 5.46) 0.566	ARBs (14-day gap)	5,765	****	****	****	****	4.52	****	-2.26		0.50 ( 0.05, 5.51)	0.571
3v (14-day gap) -2.17 ***** 0.50 (0.04 5.46) 0.566		nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
	SV (14-day gap)	5,765	****	****	****	****	2.19	****	2 17	****	0.50 ( 0.04 . 5.46)	0.566
	ARBs (14-day gap)	5,765	****	****	****	****	4.36	****	-2.17	*** *** *** ***	0.50 ( 0.04, 5.46)	0.566

cder\_mpl2r\_wp016 Page 126 of 247



			_	_		Incidence		Incidence	D:#		
		_	Average	Average		Rate per		Rate	Difference	Hazard Ratio	
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per		347 11
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
					31	- 60 Days					
Site-Adjusted Analysis											
SV (14-day gap)	5,322	****	****	****	****	2.94	****	-4.46	****	0.40 ( 0.05, 2.93)	0.366
ARBs (14-day gap)	52,284	****	****	****	****	7.4	****	4.40		0.40 ( 0.03, 2.33)	0.500
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	4,860	****	****	****	****	3.66	****	-3.66	****	0.50 ( 0.05, 5.51)	0.571
ARBs (14-day gap)	4,860	****	****	****	****	7.32	****	-5.00		0.50 ( 0.05, 5.51)	0.571
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	5,243	****	****	****	****	2.98	****	-2.41	****	0.54 ( 0.05, 5.99)	0.618
ARBs (14-day gap)	5,333	****	****	****	****	5.39	****	-2.41		0.54 (0.05, 5.55)	0.018
					61	- 90 Days					
Site-Adjusted Analysis											
SV (14-day gap)	3,101	****	****	****	****	4.4	****	-2.21	****	0.68 ( 0.09, 5.08)	0.707
ARBs (14-day gap)	37,460	****	****	****	****	6.61	****	-2.21		0.08 (0.09, 5.08)	0.707
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	1,993	****	****	****	****	7.33	****	7.22	****		
ARBs (14-day gap)	1,993	****	****	****	****	0	****	7.33	44444	-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	3,058	****	****	****	****	4.46	****	2.40	****	0.63 ( 0.06 6.93)	0.000
ARBs (14-day gap)	3,789	****	****	****	****	6.93	****	-2.48		0.62 ( 0.06, 6.83)	0.696
, , , ,					91	- 180 Days					
Site-Adjusted Analysis											
SV (14-day gap)	2,361	****	****	****	****	5.3	****	1.07	****	1 20 / 0 20	0.724
ARBs (14-day gap)	32,147	****	****	****	****	4.23	****	1.07	4. 4. 4. 4.	1.29 ( 0.30, 5.45)	0.734
Fixed Ratio 1:1 Proper		tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
				, -,							
SV (14-day gap)	1,289	****	****	****	****	6.83	****	6.83	****		

cder\_mpl2r\_wp016 Page 127 of 247



Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval) <sup>2</sup>	Wald P-Value <sup>2</sup>
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	nditional A	nalysis; Cali	iper= 0.05					-	
SV (14-day gap) ARBs (14-day gap)	2,333 3,196	****	*****	*****	*****	5.37 1.88	****	3.49	****	2.88 ( 0.26, 31.78)	0.388
					181	- 270 Days					
Site-Adjusted Analysis	S										
SV (14-day gap) ARBs (14-day gap)	1,072 17,235	****	*****	****	*****	9.93 4.18	****	5.76	****	2.36 ( 0.54, 10.37)	0.257
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	303	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	303	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	nditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	1,058	****	****	****	****	10.05	****	6.84	****	3.03 ( 0.27, 33.45)	0.365
ARBs (14-day gap)	1,640	****	****	****	****	3.21	****	0.64		3.03 ( 0.27, 33.43)	0.505
					271	365 Days					
Site-Adjusted Analysis											
SV (14-day gap)	650	****	****	****	****	0	****	-2.9	****	_	_
ARBs (14-day gap)	11,241	****	****	****	****	2.9	****	-2.5			
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	115	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	115	****	****	****	****	0	****			<u>-</u>	
Fixed Ratio 1:1 Proper	nsity Score Ma				•			_			
SV (14-day gap)	643	****	****	****	****	0	****	0	****	_	_
ARBs (14-day gap)	1,001	****	****	****	****	0	****	O			

cder\_mpl2r\_wp016 Page 128 of 247



			_	_		Incidence		Incidence	-:		
		_	Average	Average		Rate per		Rate	Difference	Hazard Ratio	
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per		344-1-I
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Race: Pacific Islander											
						Overall					
Site-Adjusted Analysis											
SV (14-day gap)	46	****	****	****	****	0	****	-8.97	****	_	_
ARBs (14-day gap)	478	****	****	****	****	8.97	****	-0.37		_	
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	31	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	31	****	****	****	****	0	****	0	4. 4. 4. 4. 4.	-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	31	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	31	****	****	****	****	0	****	0		-	-
					0	- 30 Days					
Site-Adjusted Analysis	3										
SV (14-day gap)	69	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	1,590	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	29	****	****	****	****	0	****		****		
ARBs (14-day gap)	29	****	****	****	****	0	****	0	***	-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05	-					
SV (14-day gap)	65	****	****	****	****	0	****		****		
ARBs (14-day gap)	111	****	****	****	****	0	****	0	***	-	-
, , , , , , , , , , , ,					31	- 60 Days					
Site-Adjusted Analysis	3					•					
SV (14-day gap)	43	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	446	****	****	****	****	0	****	0	<b>ጥ ጥ ጥ ጥ</b>	-	-

cder\_mpl2r\_wp016 Page 129 of 247



						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	28	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	28	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	29	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	30	****	****	****	****	0	****	0		-	-
					61	- 90 Days					
Site-Adjusted Analysis											
SV (14-day gap)	30	****	****	****	****	0	****	-34.86	****		
ARBs (14-day gap)	359	****	****	****	****	34.86	****	-34.60		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	13	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	13	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	18	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	23	****	****	****	****	0	****	U		-	-
					91 -	- 180 Days					
Site-Adjusted Analysis											
SV (14-day gap)	27	****	****	****	****	0	****	-17.55	****	_	_
ARBs (14-day gap)	335	****	****	****	****	17.55	****	-17.55			_
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	12	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	12	****	****	****	****	0	****	0	THE THE THE THE	-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	17	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	21	****	****	****	****	0	****	U		-	-

cder\_mpl2r\_wp016 Page 130 of 247



			_	_		Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference	Hannad Bakka	
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
					181	- 270 Days					
Site-Adjusted Analysis											
SV (14-day gap)	15	****	****	****	****	0	****	0	****	_	_
ARBs (14-day gap)	194	****	****	****	****	0	****				
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	****	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	****	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	12	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	14	****	****	****	****	0	****	U		-	_
					271	365 Days					
Site-Adjusted Analysis											
SV (14-day gap)	****	****	****	****	****	0	****	0	****	_	_
ARBs (14-day gap)	138	****	****	****	****	0	****	0			
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	****	****	****	****	****	0	****	0	****		,
ARBs (14-day gap)	****	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Proper	nsity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV (14-day gap)	****	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	12	****	****	****	****	0	****	U		-	-
Race: White											
						Overall					
Site-Adjusted Analysis	3										
SV (14-day gap)	29,935	****	****	****	****	1.1	****	-1.3	****	0.42 ( 0.24, 0.76)	0.004
ARBs (14-day gap)	223,288	****	****	****	****	2.4	****	-1.3		0.42 (0.24, 0.76)	0.004

cder\_mpl2r\_wp016 Page 131 of 247



			Average	Average		Incidence Rate per		Incidence Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	<b>Hazard Ratio</b>	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Proper	nsity Score Mat	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	29,757	****	****	****	****	1.03	****	-1.18	****	0.47/0.10 1.14)	0.096
ARBs (14-day gap)	29,757	****	****	****	****	2.21	****	-1.18		0.47 ( 0.19, 1.14)	0.096
Fixed Ratio 1:1 Proper	nsity Score Mat	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	29,757	****	****	****	****	1.11	****	-0.97	****	0.51 ( 0.26, 1.00)	0.051
ARBs (14-day gap)	29,757	****	****	****	****	2.08	****	-0.97		0.31 (0.20, 1.00)	0.031
					0	- 30 Days					
Site-Adjusted Analysis	3										
SV (14-day gap)	29,935	****	****	****	****	1.26	****	-3.54	****	0.26 ( 0.08, 0.83)	0.023
ARBs (14-day gap)	223,288	****	****	****	****	4.8	****	-5.54		0.20 ( 0.08, 0.83)	0.023
Fixed Ratio 1:1 Proper	nsity Score Mat	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	29,757	****	****	****	****	1.31	****	2.61	****	0.33 ( 0.00 1.33)	0.000
ARBs (14-day gap)	29,757	****	****	****	****	3.92	****	-2.61		0.33 ( 0.09, 1.23)	0.099
Fixed Ratio 1:1 Proper	nsity Score Mat	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	29,757	****	****	****	****	1.27	****	2.52	****	0.22 / 0.00 1.24)	0.101
ARBs (14-day gap)	29,757	****	****	****	****	3.79	****	-2.52		0.33 ( 0.09, 1.24)	0.101
					31	- 60 Days					
Site-Adjusted Analysis	3										
SV (14-day gap)	27,322	****	****	****	****	1.62	****	-1.19	****	0.58 ( 0.18, 1.87)	0.36
ARBs (14-day gap)	209,796	****	****	****	****	2.81	****	-1.19		0.38 ( 0.18, 1.87)	0.30
Fixed Ratio 1:1 Proper	nsity Score Mat	tched Cond	litional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV (14-day gap)	25,245	****	****	****	****	1.3	****	0.65	****	2.00 / 0.10, 22.00\	0.571
ARBs (14-day gap)	25,245	****	****	****	****	0.65	****	0.65	and the same and	2.00 ( 0.18, 22.06)	0.571
Fixed Ratio 1:1 Proper	nsity Score Mat	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
		****	****	****	****	1.62	****				
SV (14-day gap)	27,160	****	****	4.4.4.4.4.		1.63		-0.36	****	0.82 (0.18, 3.66)	0.792

cder\_mpl2r\_wp016 Page 132 of 247



Medical Product							Incidence		Incidence			
Number of   Years   Days   Years   Days   Years   Of   Person   1,000   per 1,000   Jogo   New   Users   Person   Vears   Days   Person   New Users   Person   Vears   Days   Person   New Users   Person   Vears   Days   Person   New Users   Person   Vears   Days   Person   New Users   Person   Vears   Days   Person   New Users   Person   Vears   Days   Person   New Users   Person   Vears   Days   Person   New Users   Person   Vears   Days   Person   Vears				Average	Average		Rate per		Rate	Difference		
Medical Product   New Users   at Risk   at R			Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per		
Site-Adjusted Analysis   SV (14-day gap)   18,222   ****   ******		Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	•	
Site-Adjusted Analysis   SV (14-day gap)   18,222   ****   ****   *****   *****   1.46   *****   *****   0.68 (0.16, 2.84)   0.592	Medical Product	New Users	at Risk	at Risk	at Risk			New Users	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
SV (14-day gap)   18,222   *****   *****   *****   *****   1.46   ******   2.18   *****   *****   0.68 (0.16, 2.84)   0.592						61	90 Days					
165,220   ******	Site-Adjusted Analysi	S										
Time   This	SV (14-day gap)	18,222	****	****	****	****	1.46	****	-0.72	****	0.68 ( 0.16 2.84)	0.502
SV (14-day gap)   13,131   ******	ARBs (14-day gap)	165,220	****	****	****	****	2.18	****	-0.72		0.08 ( 0.10, 2.04)	0.392
SV (14-day gap)   13,131   ******	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
ARBs (14-day gap) 13,131 ***** **** **** **** **** 3.21 ***** **** ****  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 18,107 **** **** **** **** 1.47 ***** -0.33 ***** 0.83 (0.14, 4.94) 0.833  *****							1.07	****	2.14	****	0.22 ( 0.02	0.241
SV (14-day gap) 18,107 ***** **** **** ***** 1.47 ***** -0.33 ***** 0.83 (0.14, 4.94) 0.833  Site-Adjusted Analysis  SV (14-day gap) 14,999 **** **** **** **** 1.14 ***** -0.55 **** 0.67 (0.21, 2.16) 0.505  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05¹  SV (14-day gap) 9,524 **** **** **** ***** 0.79 ***** 0 ***** 1.00 (0.06, 15.99) 1  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 9,524 **** **** **** ***** 0.79 ***** 0 ***** 0 ***** 0.66 (0.15, 2.18) 0.407  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 14,904 **** **** **** ***** 1.15 ***** 0.89 ***** 0.56 (0.15, 2.18) 0.407  ARBs (14-day gap) 19,006 **** **** **** ***** 1.73 ***** -1.73 ****** -1.73 ***** -1.73 ***** -1.73 ***** -1.73 *****	ARBs (14-day gap)	13,131	****	****	****	****	3.21	****	-2.14		0.33 ( 0.03, 3.20)	0.341
Solution	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unc	onditional A	nalysis; Cal	iper= 0.05						
ARBs (14-day gap) 21,598 **** **** **** **** 1.8 ***** **** 5.03 (0.14, 4.34) 0.833 (0.14	SV (14-day gap)	18,107	****	****	****	****	1.47	****	0.22	****	0.03 ( 0.14 .4.04)	0 022
Site-Adjusted Analysis         SV (14-day gap)       14,999       ******       ******       ******       1.14       ******       -0.55       ******       0.67 ( 0.21, 2.16)       0.505         Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05         SV (14-day gap)       9,524       ******       ******       ******       0.79       ******       0       ******       1.00 ( 0.06, 15.99)       1         Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05         SV (14-day gap)       14,904       ******       ******       ******       1.15       ******       -0.89       ******       0.56 ( 0.15, 2.18)       0.407         ARBs (14-day gap)       8,170       ******       ******       ******       ******       0       ******       -1.73       ******       -1.73       ******       -1.73       ******       -1.73       ******       -1.99       ******       -1.99       ******       -1.99       ******       -1.99       *******       -1.99       *******       -1.99       ******       -1.99       *******       -1.99       *******       -1.99       *******       -1.99       ********       -1.99       *******       -1	ARBs (14-day gap)	21,598	****	****	****	****	1.8	****	-0.55		0.65 (0.14, 4.94)	0.655
SV (14-day gap) 14,999 ***** **** **** **** **** 1.14 ***** -0.55 ***** 0.67 (0.21, 2.16) 0.505  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 9,524 **** **** **** **** **** 0.79 ***** 0 ***** 1.00 (0.06, 15.99) 1  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 9,524 **** **** **** **** **** **** 0.79 ***** 0 ***** 1.00 (0.06, 15.99) 1  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 14,904 **** **** **** ****  1.15 ***** -0.89 ***** 0.56 (0.15, 2.18) 0.407  ARBs (14-day gap) 19,006 **** **** ****  *****  2.03 ***** -1.73 ****** -1.73 ***** -1.73 ***** -1.73 ***** -1.73 ***** -1.73 ***** -1.73 ***** -1.73 ***** -1.73 ***** -1.73 ***** -1.73 ***** -1.73 ***** -1.73 ***** -1.73 ***** -1.73 ***** -1.73 ***** -1.73 ****** -1.73 ****** -1.73 ****** -1.73 ***** -1.73 ***** -1.73 ***** -1.73 ***** -1.73 *						91	- 180 Days					
ARBs (14-day gap) 146,951 ***** **** **** **** **** **** ****	Site-Adjusted Analysi	S										
ARBs (14-day gap) 146,951 **** **** **** **** **** 1.69 **** **** **** 1.69 **** **** **** **** **** **** **** *	SV (14-day gap)	14,999	****	****	****	****	1.14	****	0.55	****	0.67 ( 0.21 - 2.16)	0.505
SV (14-day gap) 9,524 ***** **** **** **** **** 0.79 ***** 0 ***** 1.00 (0.06, 15.99) 1  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 14,904 **** **** **** **** 1.15 ***** -0.89 ***** 0.56 (0.15, 2.18) 0.407  ARBs (14-day gap) 19,006 **** **** **** **** **** 2.03 ***** -0.89 ***** 0.56 (0.15, 2.18) 0.407  Site-Adjusted Analysis  SV (14-day gap) 8,170 ***** **** **** **** **** 1.73 *****	ARBs (14-day gap)	146,951	****	****	****	****	1.69	****	-0.55		0.07 (0.21, 2.10)	0.303
SV (14-day gap) 9,524 ***** **** **** **** **** 0.79 ***** 0 ***** 1.00 (0.06, 15.99) 1  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 14,904 **** **** **** **** 1.15 ***** -0.89 ***** 0.56 (0.15, 2.18) 0.407  ARBs (14-day gap) 19,006 **** **** **** **** **** 2.03 ***** -0.89 ***** 0.56 (0.15, 2.18) 0.407  Site-Adjusted Analysis  SV (14-day gap) 8,170 ***** **** **** **** **** 1.73 *****	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
ARBs (14-day gap) 9,524 **** **** **** **** 0.79 ***** 0 1.00 (0.00, 13.99) 1  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV (14-day gap) 14,904 **** **** **** **** 1.15 ****   ARBs (14-day gap) 19,006 **** **** **** **** 2.03 *****     Site-Adjusted Analysis  SV (14-day gap) 8,170 ****   ARBs (14-day gap) 92,144 ****   ARBs (14-day gap) 92,144 ****   ARBs (14-day gap) 93,108 ****    Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 3,108 ****    SV (14-day gap) 3,108 ****    ARBs (14-day gap) 3,108 *****    ARBs (14-day gap		9,524	****	****	****	****	0.79	****	0	****	4.00 / 0.00 45.00\	4
SV (14-day gap) 14,904 ***** **** **** **** **** 2.03 ***** -0.89 ***** 0.56 (0.15, 2.18) 0.407  ARBs (14-day gap) 19,006 ***** **** **** **** 2.03 ***** -0.89 ***** 0.56 (0.15, 2.18) 0.407  I81 - 270 Days  Site-Adjusted Analysis  SV (14-day gap) 8,170 ***** **** **** ***** 0 ***** -1.73 ***** -1.73 ***** -1.73  ARBs (14-day gap) 92,144 **** **** **** **** **** 1.73 ***** -1.	ARBs (14-day gap)	9,524	****	****	****	****	0.79	****	U		1.00 (0.06, 15.99)	1
ARBs (14-day gap) 19,006 ***** **** **** **** **** 2.03 ***** -0.89 ***** 0.56 ( 0.15, 2.18) 0.407    Site-Adjusted Analysis   SV (14-day gap) 8,170 ***** **** **** **** **** **** 0 ***** -1.73 ***** -1.73 *****	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unc	onditional A	nalysis; Cal	iper= 0.05						
ARBs (14-day gap) 19,006 ***** **** **** **** 2.03 ***** 50.89 50.50 (0.13, 2.16) 50.407    181 - 270 Days	SV (14-day gap)	14,904	****	****	****	****	1.15	****	0.00	****	0.56 / 0.15   2.19)	0.407
Site-Adjusted Analysis         SV (14-day gap)       8,170       *****       *****       0       *****       -1.73       *****       -1.73       *****       -1.73       *****       -1.73       *****       -1.73       *****       -1.73       *****       -1.73       *****       -1.73       *****       -1.73       *****       -1.73       *****       -1.73       *****       -1.73       *****       -1.73       *******       -1.73       ******       -1.73 <t< td=""><td>ARBs (14-day gap)</td><td>19,006</td><td>****</td><td>****</td><td>****</td><td>****</td><td>2.03</td><td>****</td><td>-0.89</td><td></td><td>0.56 (0.15, 2.18)</td><td>0.407</td></t<>	ARBs (14-day gap)	19,006	****	****	****	****	2.03	****	-0.89		0.56 (0.15, 2.18)	0.407
SV (14-day gap) 8,170 ***** **** **** **** 0 ***** -1.73 ***** -1.73 *****  ARBs (14-day gap) 92,144 ***** **** **** **** 1.73 *****  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 3,108 ***** ***** ***** 0 ******						181	- 270 Days					
ARBs (14-day gap) 92,144 ***** **** **** 1.73 *****  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 3,108 ***** ***** ***** 0 ******	Site-Adjusted Analysi	S										
ARBs (14-day gap) 92,144 **** **** **** **** 1.73 *****  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV (14-day gap) 3,108 **** **** **** ***** 0 *****	SV (14-day gap)	8,170	****	****	****	****	0	****	1 72	****		
SV (14-day gap) 3,108 ***** ***** ***** 0 ***** -1 99 *****	ARBs (14-day gap)	92,144	****	****	****	****	1.73	****	-1./3		-	<u> </u>
SV (14-day gap) 3,108 ***** ***** ***** 0 ***** -1 99 *****	Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
-1 99 *****							0	****	1.00	****		
	ARBs (14-day gap)	3,108	****	****	****	****	1.99	****	-1.99	* * * * *	-	-

cder\_mpl2r\_wp016 Page 133 of 247



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

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval) <sup>2</sup>	Wald P-Value <sup>2</sup>
Fixed Ratio 1:1 Propen	sity Score Mat				•						
SV (14-day gap)	8,117	****	****	****	****	0	****	-1.31	****	_	_
ARBs (14-day gap)	11,357	****	****	****	****	1.31	****	-1.51		_	<u>-</u>
					271	- 365 Days					
<b>Site-Adjusted Analysis</b>											
SV (14-day gap)	5,100	****	****	****	****	0.93	****	0.54	****	0.65 ( 0.00 , 4.00)	0.671
ARBs (14-day gap)	66,959	****	****	****	****	1.47	****	-0.54		0.65 ( 0.09, 4.80)	0.671
Fixed Ratio 1:1 Propen	sity Score Mat	tched Cond	litional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV (14-day gap)	1,370	****	****	****	****	0	****	0	****		
ARBs (14-day gap)	1,370	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Propen	sity Score Mat	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV (14-day gap)	5,063	****	****	****	****	0.93	****	0.26	****	0.00 / 0.07 .0.70)	0.053
ARBs (14-day gap)	7,812	****	****	****	****	1.19	****	-0.26		0.80 ( 0.07, 8.78)	0.852

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 134 of 247

<sup>&</sup>lt;sup>2</sup>Data presented by a dash are unable to be calculated. This table may not use all data representations.

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



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

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Site-Adjusted Analysi	is										
SV	41,998	****	****	****	****	1.11	****	-5.8	****	0.15 (0.09, 0.25)	<0.001
ACEI	695,012	****	****	****	****	6.91	****	-3.6		0.13 (0.09, 0.23)	<0.001
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	41,998	****	****	****	****	1.5	****	-9.97	****	0.12 (0.07 0.25)	<0.001
ACEI	41,998	****	****	****	****	11.48	****	-9.97		0.13 (0.07, 0.25)	<0.001
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	41,998	****	****	****	****	1.11	****	6.00	****	0.14 (0.09 0.25)	<0.001
ACEI	41,998	****	****	****	****	7.2	****	-6.09		0.14 (0.08, 0.25)	<0.001

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 135 of 247

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



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

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
		at KISK	at NISK	at NISK	Events	rears	New Osers	Person rears	Users	intervaij	P-value
Site-Adjusted Analysi	S										
SV	43,777	****	****	****	****	1.14	****	1.0	****	0.35 (0.21, 0.58)	<0.001
ARBs	337,157	****	****	****	****	3.04	****	-1.9		0.55 (0.21, 0.56)	<0.001
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	43,755	****	****	****	****	1.26	****	1.12	****	0.53 (0.34, 4.43)	0.1
ARBs	43,755	****	****	****	****	2.39	****	-1.13	4. 4. 4. 4.	0.53 (0.24, 1.13)	0.1
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	per= 0.05						
SV	43,755	****	****	****	****	1.14	****	1 12	****	0.49 (0.27 0.99)	0.017
ARBs	43,755	****	****	****	****	2.27	****	-1.13		0.48 (0.27, 0.88)	0.017

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 136 of 247

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



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

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Site-Adjusted Analysi		ut Misk	at Nisk	ut Misk	LVCIICS	Tears	IVEW OSCIS	T CISOII TCUIS	Oscis	intervaly	T-Value
SV	41,998	****	****	****	****	0.6	****		****	0.00 (0.15, 0.54)	2.221
ACEI	695,012	****	****	****	****	2	****	-1.4	****	0.28 (0.15, 0.54)	<0.001
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	41,998	****	****	****	****	0.68	****	2.04	****	0.25 (0.10, 0.61)	0.003
ACEI	41,998	****	****	****	****	2.72	****	-2.04		0.25 (0.10, 0.61)	0.002
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	41,998	****	****	****	****	0.6	****	-1.47	****	0.28 (0.13, 0.58)	<0.001
ACEI	41,998	****	****	****	****	2.07	****	-1.47		0.20 (0.13, 0.30)	<b>\0.001</b>

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 137 of 247

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



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

			Average	Average		Incidence Rate per		Incidence Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	<b>Hazard Ratio</b>	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
No Angioedema	(-183, -1)									·	
<b>Site-Adjusted Anal</b>	lysis										
SV	41,941	****	****	****	****	0.53	****	-1.39	****	0.26 (0.12, 0.52)	<0.001
ACEI	694,148	****	****	****	****	1.93	****	-1.39		0.26 (0.13, 0.52)	<0.001
Fixed Ratio 1:1 Pro	pensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	41,930	****	****	****	****	0.57	****	2.16	****	0.31 (0.09, 0.55)	0.001
ACEI	41,930	****	****	****	****	2.72	****	-2.16		0.21 (0.08, 0.55)	0.001
Fixed Ratio 1:1 Pro	pensity Score Ma	tched Unco	onditional A	nalysis; Cali	per= 0.05						
SV	41,930	****	****	****	****	0.53	****	-1.54	****	0.25 (0.11, 0.53)	<0.001
ACEI	41,930	****	****	****	****	2.08	****	-1.54		0.25 (0.11, 0.55)	\0.001
Angioedema (-183	• •										
Site-Adjusted Anal	lysis										
SV	57	****	****	****	****	44.8	****	-30.56	****	0.74 (0.10, 5.47)	0.767
ACEI	864	****	****	****	****	75.37	****	-30.30		0.74 (0.10, 3.47)	0.707
Fixed Ratio 1:1 Pro	pensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	42	****	****	****	****	0	****	0	****		
ACEI	42	****	****	****	****	0	****	U		-	
Fixed Ratio 1:1 Pro	pensity Score Ma			nalysis; Cali							
SV	42	****	****	****	****	0	****	0	****		
ACEI	42	****	****	****	****	0	****	<u> </u>		-	

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 138 of 247

<sup>&</sup>lt;sup>2</sup>Data presented by a dash are unable to be calculated. This table may not use all data representations.

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



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

			Average	Average		Incidence		Incidence Rate	Difference		
		Davaan	U	Average	Number	Rate per	Diele man			Hazard Ratio	
		Person	Person	Person		1,000	Risk per	Difference	in Risk per		
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval)	P-Value
No Angioedema (ev											
Site-Adjusted Analys	sis										
SV	41,427	****	****	****	****	0.54	****	-1.21	****	0.29 (0.15, 0.59)	< 0.001
ACEI	687,692	****	****	****	****	1.75	****	-1.21		0.25 (0.15, 0.55)	<b>\0.001</b>
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	41,416	****	****	****	****	0.57	****	1.05	****	0.33 (0.00, 0.00)	0.003
ACEI	41,416	****	****	****	****	2.53	****	-1.95		0.23 (0.09, 0.60)	0.003
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	41,416	****	****	****	****	0.54	****	-1.44	****	0.26 (0.12, 0.57)	<0.001
ACEI	41,416	****	****	****	****	1.98	****	-1.44		0.26 (0.12, 0.57)	<0.001
Angioedema (ever, -	-1)										
Site-Adjusted Analys	sis										
SV	571	****	****	****	****	4.77	****	-23.95	****	0.17 (0.02 1.10)	0.074
ACEI	7,320	****	****	****	****	28.72	****	-25.95		0.17 (0.02, 1.19)	0.074
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	437	****	****	****	****	11.58	****	11 50	****	0.50/0.05 5.54\	0.574
ACEI	437	****	****	****	****	23.17	****	-11.58	4. 4. 4. 4.	0.50 (0.05, 5.51)	0.571
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	437	****	****	****	****	6.31	****	F 2F	****	0 50 (0 05 5 52)	0.572
ACEI	437	****	****	****	****	11.66	****	-5.35		0.50 (0.05, 5.53)	0.573

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 139 of 247

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



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

						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	<b>New Users</b>	at Risk	at Risk	at Risk	<b>Events</b>	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval)	P-Value
No Serious Allergies											
Site-Adjusted Analysis	s										
SV	36,314	****	****	****	****	0.38	****	-1.47	****	0.19 (0.08, 0.46)	<0.001
ACEI	584,032	****	****	****	****	1.85	****	-1.47		0.19 (0.06, 0.46)	<0.001
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	36,159	****	****	****	****	0.52	****	1.04	****	0.24 (0.07, 0.62)	0.005
ACEI	36,159	****	****	****	****	2.45	****	-1.94	4. 4. 4. 4. 4.	0.21 (0.07, 0.62)	0.005
<b>Fixed Ratio 1:1 Prope</b>	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	per= 0.05						
SV	36,159	****	****	****	****	0.38	****	-1.52	****	0.19 (0.07, 0.49)	<0.001
ACEI	36,159	****	****	****	****	1.9	****	-1.52		0.19 (0.07, 0.49)	<0.001
Serious Allergies											
Site-Adjusted Analysis	S										
SV	5,684	****	****	****	****	2.14	****	-0.78	****	0.70 (0.26, 1.90)	0.489
ACEI	110,980	****	****	****	****	2.92	****	-0.76		0.70 (0.26, 1.90)	0.469
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	5,545	****	****	****	****	1.92	****	4.02	****	0.50 (0.00, 0.70)	0.422
ACEI	5,545	****	****	****	****	3.84	****	-1.92	T T T T T	0.50 (0.09, 2.73)	0.423
Fixed Ratio 1:1 Prope	·	tched Unco	nditional A	nalysis; Cali	per= 0.05						
SV	5,545	****	****	****	****	2.19	****	1.26	****	0.63 (0.19, 3.10)	0.465
ACEI	5,545	****	****	****	****	3.45	****	-1.26	and the same same	0.63 (0.18, 2.16)	0.465

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 140 of 247

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



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

			<b>A</b>	<b>0</b>		Incidence		Incidence	D:ffa.ramaa		
		D	Average	Average	N1	Rate per	Dialona.	Rate	Difference	Hannal Bakka	
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval)	P-Value
Sex: Male											
Site-Adjusted Analys	sis										
SV	27,131	****	****	****	****	0.31	****	-1.26	****	0.18 (0.06, 0.57)	0.003
ACEI	353,126	****	****	****	****	1.57	****	-1.20		0.10 (0.00, 0.37)	0.003
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	26,865	****	****	****	****	0.53	****	-2.28	****	0.19 (0.05, 0.64)	0.008
ACEI	26,865	****	****	****	****	2.81	****	-2.20		0.19 (0.05, 0.04)	0.008
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	26,865	****	****	****	****	0.31	****	-1.52	****	0.16 (0.05, 0.54)	0.003
ACEI	26,865	****	****	****	****	1.83	****	-1.52		0.10 (0.03, 0.34)	0.003
Sex: Female											
<b>Site-Adjusted Analys</b>	sis										
SV	14,867	****	****	****	****	1.13	****	-1.32	****	0.44 (0.20, 0.98)	0.045
ACEI	341,886	****	****	****	****	2.45	****	-1.32		0.44 (0.20, 0.36)	0.045
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	14,820	****	****	****	****	0.97	****	1.62	****	0.30 (0.10, 1.44)	0.147
ACEI	14,820	****	****	****	****	2.59	****	-1.62	71 71 71 71	0.38 (0.10, 1.41)	0.147
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco		nalysis; Cali							
SV	14,820	****	****	****	****	1.13	****	-1.25	****	0.47 (0.18, 1.21)	0.117
ACEI	14,820	****	****	****	****	2.38	****	-1.25		U.47 (U.10, 1.21)	0.117

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 141 of 247

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

						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	<b>Events</b>	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Age Group: 18-44 ye	ears										
Site-Adjusted Analy	sis										
SV	1,538	****	****	****	****	0	****	-3.36	****		
ACEI	21,594	****	****	****	****	3.36	****	-5.50		-	
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	1,408	****	****	****	****	0	****	0	****		
ACEI	1,408	****	****	****	****	0	****	0		-	-
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV	1,408	****	****	****	****	0	****	0	****		
ACEI	1,408	****	****	****	****	0	****	U		-	-
Age Group: 45-54 ye	ears										
Site-Adjusted Analys	sis										
SV	2,863	****	****	****	****	0	****	-2.79	****		
ACEI	45,064	****	****	****	****	2.79	****	-2.79		-	
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	2,789	****	****	****	****	0	****	Г ГЭ	****		
ACEI	2,789	****	****	****	****	5.52	****	-5.52		-	-
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV	2,789	****	****	****	****	0	****	-2.87	****		
ACEI	2,789	****	****	****	****	2.87	****	-2.87		-	-
Age Group: 55-64 ye	ears										
Site-Adjusted Analys	sis										
SV	5,807	****	****	****	****	1.48	****	-1.77	****	0.47 (0.15, 1.46)	0.191
ACEI	97,267	****	****	****	****	3.25	****	-1.//		0.47 (0.13, 1.40)	0.191
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	5,692	****	****	****	****	1.76	****	2.51	****	0.22 (0.07. 1.05)	0.170
ACEI	5,692	****	****	****	****	5.27	****	-3.51	and the the the the	0.33 (0.07, 1.65)	0.178

cder\_mpl2r\_wp016 Page 142 of 247



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

Medical Product         New Users         at Risk         at Risk         at Risk         at Risk         Events         Years         New Users         Person Years         Users         Interval)²         P           Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05           SV         5,692         ******         ******         ******         1.51         ******         -3.07         ******         0.32 (0.09, 1.18)           Age Group: ≥65 years           Site-Adjusted Analysis           SV         31,790         ******         ******         ******         0.52         ******         0.29 (0.13, 0.64)	Wald -Value <sup>2</sup>
Medical Product         New Users         at Risk         at Risk         at Risk         Events         Years         New Users         Person Years         Users         Interval)²         P           Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05           SV         5,692         ******         ******         ******         1.51         ******         -3.07         ******         0.32 (0.09, 1.18)           ACEI         5,692         ******         ******         ******         4.58         ******         -3.07         ******         0.32 (0.09, 1.18)           Age Group: ≥65 years         Site-Adjusted Analysis         Site-Adjusted Analysis         ******         0.52         ******         0.29 (0.13, 0.64)	
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV 5,692 ***** ***** ***** 1.51 *****  ACEI 5,692 ***** **** ***** 4.58 *****  Age Group: ≥65 years  Site-Adjusted Analysis  SV 31,790 ***** ***** ***** ***** 0.52 *****  -1 17 ***** 0.29 (0.13 0.64)	2مبراد/
SV       5,692       *****       *****       *****       1.51       *****       -3.07       *****       0.32 (0.09, 1.18)         Acel       5,692       *****       *****       *****       4.58       *****       -3.07       *****       0.32 (0.09, 1.18)         Age Group: ≥65 years         Site-Adjusted Analysis         SV       31,790       *****       *****       *****       0.52       *****       -1.17       *****       0.29 (0.13, 0.64)	Value
ACEI 5,692 **** **** **** **** 4.58 **** -3.07 ***** 0.32 (0.09, 1.18)  Age Group: ≥65 years  Site-Adjusted Analysis  SV 31,790 **** **** **** **** 0.52 *****  -1 17 ***** 0.29 (0.13, 0.64)	
ACEI 5,692 **** **** **** 4.58 **** 5.07 0.32 (0.03, 1.18)  Age Group: ≥65 years  Site-Adjusted Analysis  SV 31,790 **** **** **** **** 0.52 *****  -1 17 ***** 0.29 (0.13, 0.64)	0.007
Site-Adjusted Analysis       SV     31,790     *****     *****     *****     0.52     *****       -1 17     *****     0.29 (0.13, 0.64)	0.087
SV 31,790 ***** ***** ***** 0.52 ***** -1 17 ***** 0.29 (0.13 0.64)	
31,790 0.32 -1 17 **** 0.29 (0.13 0.64)	
	0.002
ACEI 531,087 ***** ***** ***** 1.69 *****	0.002
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05 <sup>1</sup>	
SV 31,082 ***** ***** ***** 0.6 ***** 1.2 **** 0.32 (0.11, 1.03)	0.057
ACEI 31,082 **** **** **** **** 1.8 **** -1.2 ***** 0.33 (0.11, 1.03)	0.057
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05	
SV 31,082 ***** ***** ***** 0.53 ***** 1.02 ***** 0.22 (0.12 0.92)	0.017
ACEI 31,082 **** **** **** 1.56 **** -1.03 ***** 0.33 (0.13, 0.82)	0.017

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 143 of 247

<sup>&</sup>lt;sup>2</sup>Data presented by a dash are unable to be calculated. This table may not use all data representations.

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

			Average	Average		Incidence Rate per		Incidence Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	•	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Race: Unknown										,	
Site-Adjusted Analy	rsis										
SV	7,029	****	****	****	****	0	****	-1.93	****		
ACEI	99,645	****	****	****	****	1.93	****	-1.93		-	
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	6,992	****	****	****	****	0	****	2.47	****		
ACEI	6,992	****	****	****	****	3.47	****	-3.47		-	-
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV	6,992	****	****	****	****	0	****	-3.05	****		
ACEI	6,992	****	****	****	****	3.05	****	-5.05		-	-
Race: American Ind	ian										
<b>Site-Adjusted Analy</b>	rsis										
SV	132	****	****	****	****	0	****	0	****	_	_
ACEI	4,529	****	****	****	****	0	****				
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	123	****	****	****	****	0	****	0	****		
ACEI	123	****	****	****	****	0	****	U		-	
Fixed Ratio 1:1 Prop	ensity Score Ma			nalysis; Cal							
SV	123	****	****	****	****	0	****	0	****	_	_
ACEI	123	****	****	****	****	0	****			_	
Race: Asian											
Site-Adjusted Analy											
SV	519	****	****	****	****	0	****	-0.98	****	_	_
ACEI	7,874	****	****	****	****	0.98	****	0.50			
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	495	****	****	****	****	0	****	0	****		
ACEI	495	****	****	****	****	0	****	U		-	-

cder\_mpl2r\_wp016 Page 144 of 247



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

			Average	Average		Incidence Rate per		Incidence Rate	Difference	Harand Bakin	
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	NA/alal
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Prope					•						
SV	495	****	****	****	****	0	****	0	****	-	_
ACEI	495	****	****	****	****	0	****				
Race: Black											
Site-Adjusted Analys											
SV	5,566	****	****	****	****	2.99	****	-4.36	****	0.38 (0.16, 0.93)	0.033
ACEI	92,129	****	****	****	****	7.35	****	4.50		0.50 (0.10, 0.55)	0.055
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	5,479	****	****	****	****	2.03	****	-6.1	****	0.25 (0.05 1.10)	0.08
ACEI	5,479	****	****	****	****	8.14	****	-0.1		0.25 (0.05, 1.18)	0.08
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	5,479	****	****	****	****	3.04	****	2.14	****	0.47.(0.17. 1.24)	0.157
ACEI	5,479	****	****	****	****	6.18	****	-3.14		0.47 (0.17, 1.34)	0.157
Race: Pacific Islander	r										
<b>Site-Adjusted Analys</b>	sis										
SV	46	****	****	****	****	0	****	2.50	****		
ACEI	741	****	****	****	****	3.59	****	-3.59	4. 4. 4. 4. 4.	-	-
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	39	****	****	****	****	0	****		****		
ACEI	39	****	****	****	****	0	****	0	***	-	-
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	39	****	****	****	****	0	****		****		
ACEI	39	****	****	****	****	0	****	0	<b>ተተተተ</b>	-	-
Race: White											
Site-Adjusted Analys											
	SIS										
SV	28,706	****	****	****	****	0.38	****	-0.83	****	0.29 (0.11, 0.79)	0.015

cder\_mpl2r\_wp016 Page 145 of 247



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

			Average	Average		Incidence Rate per		Incidence Rate	Difference		
Medical Product	Number of New Users	Person Years at Risk	Person Days at Risk	Person Years at Risk	Number of Events	1,000 Person Years	Risk per 1,000 New Users	Difference per 1,000 Person Years	in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval) <sup>2</sup>	Wald P-Value <sup>2</sup>
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>					,	
SV	28,638	****	****	****	****	0.48	****	-1.11	****	0.30 (0.08, 1.09)	0.067
ACEI	28,638	****	****	****	****	1.59	****	-1.11		0.30 (0.08, 1.09)	0.007
Fixed Ratio 1:1 Propo	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	28,638	****	****	****	****	0.38	****	-0.87	****	0.29 (0.10, 0.88)	0.028
ACEI	28,638	****	****	****	****	1.25	****	-0.67		0.29 (0.10, 0.88)	0.026

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 146 of 247

<sup>&</sup>lt;sup>2</sup>Data presented by a dash are unable to be calculated. This table may not use all data representations.

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



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

			Average	Average		Incidence Rate per		Incidence Rate	Difference		
Medical Product	Number of New Users	Person Years at Risk	Person Days at Risk	Person Years at Risk	Number of Events	1,000 Person Years	Risk per 1,000	Difference per 1,000 Person Years	in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Site-Adjusted Analysi		at RISK	at RISK	at RISK	Events	rears	New Osers	Person rears	Users	interval)	P-value
		****	****	****	****	0.50	****				
SV	43,777					0.58		-0.32	****	0.61 (0.31, 1.20)	0.15
ARBs	337,157	****	****	****	****	0.9	****	0.32		0.01 (0.31, 1.20)	0.15
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	43,755	****	****	****	****	0.63	****	-0.1	****	0.96 (0.30, 3.55)	0.782
ARBs	43,755	****	****	****	****	0.73	****	-0.1		0.86 (0.29, 2.55)	0.782
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	per= 0.05						
SV	43,755	****	****	****	****	0.58	****	0.05	****	0.00 (0.30, 3.13)	0.003
ARBs	43,755	****	****	****	****	0.63	****	-0.05		0.90 (0.38, 2.13)	0.802

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 147 of 247

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



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

Number of Numb							Incidence		Incidence			
Number of   Vears   Days   Years   of   Person   1,000   per 1,000   1,000   New   (95% Confidence   Person   No   Name   Name				Average	Average		Rate per		Rate	Difference		
Medical Product   New Users   at Risk   at Risk   at Risk   at Risk   Events   Years   New Users   Person Years   Users   Interval]   P-Value			Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per		
No Angioedema (-183, -1)		Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	•	
Site-Adjusted Analysis	Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	<b>Person Years</b>	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
SV 43,717 ***** ***** ***** ***** 0.51 ***** -0.26 ***** 0.63 (0.31, 1.29) 0.208  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05¹  SV 43,685 ***** **** ***** ***** 0.52 ***** -0.21 ***** 0.71 (0.23, 2.25) 0.566  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV 43,685 **** **** ****  ***** 0.51 ***** -0.21 ***** 0.71 (0.23, 2.25) 0.566  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV 43,685 ****  ****  *****  ***** 0.51 *****  -0.12 ***** 0.80 (0.33, 1.97) 0.631  Angioedema (-183, -1)  Site-Adjusted Analysis  SV 60 *****  *****  *****  *****  *****	No Angioedema (-18	83, -1)										
ARBS 336,332 ***** **** **** ***** ***** 0.70.6 ***** 0.63 (0.31, 1.29) 0.208    Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05\frac{1}{2}	<b>Site-Adjusted Analys</b>	sis										
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05¹	SV	43,717	****	****	****	****	0.51	****	0.26	****	0.62 (0.21 1.20)	0.200
SV 43,685 **** **** **** **** **** 0.52 ****	ARBs	336,332	****	****	****	****	0.78	****	-0.26		0.03 (0.31, 1.29)	0.208
SV 43,685 **** **** **** **** **** **** 0.52 ***** -0.21 ***** 0.71 (0.23, 2.25) 0.566    Rabs	Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
ARBs 43,685 **** **** **** **** 0.73 **** 0.73 **** 0.71 (0.23, 2.23) 0.300  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV 43,685 **** **** **** **** 0.51 **** 0.63 **** 0.63 **** 0.80 (0.33, 1.97) 0.631  Angioedema (-183, -1)  Site-Adjusted Analysis  SV 60 **** **** **** **** **** 52.37 **** -11.71 ***** 0.77 (0.10, 5.77) 0.8  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV 48 **** **** **** **** 90.09 ***** 90.09 *****  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV 48 **** **** **** ****							0.52	****	0.31	****	0.74 (0.22, 2.25)	0.566
SV       43,685       *****       *****       *****       *****       0.51       *****       -0.12       *****       0.80 (0.33, 1.97)       0.631         ARBs       43,685       *****       *****       *****       0.63       *****       -0.12       ******       0.80 (0.33, 1.97)       0.631         Angioedema (-183, -1)       Site-Adjusted Analysis         SV       60       ******       ******       ******       40.67       ******       -11.71       ******       0.77 (0.10, 5.77)       0.8         Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05         SV       48       ******       ******       ******       90.09       ******       -       -       -         Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05         SV       48       ******       ******       ******       48.19       ******       -       -       -         Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05         SV       48       ******       ******       ******       48.19       ******       -       -       -	ARBs	43,685	****	****	****	****	0.73	****	-0.21		0.71 (0.23, 2.25)	0.566
ARBs 43,685 **** **** **** **** **** 0.63 ***** -0.12 ***** 0.80 (0.33, 1.97) 0.631  Angioedema (-183, -1)  Site-Adjusted Analysis  SV 60 **** **** **** **** **** 52.37 ***** -11.71 ***** 0.77 (0.10, 5.77) 0.8  ARBs 825 **** **** **** **** 52.37 ***** -11.71 ***** 0.77 (0.10, 5.77) 0.8  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV 48 **** **** **** **** 0 ***** 90.09 ***** 90.09 *****  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV 48 **** **** ****	Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
ARBs 43,685 **** **** **** **** 0.63 **** -0.12 0.80 (0.33, 1.37) 0.031  Angioedema (-183, -1)  Site-Adjusted Analysis  SV 60 ***** **** **** **** 40.67 ***** -11.71 ***** 0.77 (0.10, 5.77) 0.8  ARBs 825 **** **** **** **** 52.37 ***** -11.71 ***** 0.77 (0.10, 5.77) 0.8  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05	SV	43,685	****	****	****	****	0.51	****	0.12	****	0.90 (0.22 1.07)	0.621
Site-Adjusted Analysis         SV       60       ******       ******       ******       40.67       ******       ******       0.77 (0.10, 5.77)       0.8         Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05         SV       48       ******       ******       ******       90.09       ******       -	ARBs	43,685	****	****	****	****	0.63	****	-0.12		0.60 (0.55, 1.57)	0.031
SV 60 ***** **** **** **** **** **** ****	Angioedema (-183, -	-1)										
ARBS 825 **** **** **** **** 52.37 **** -11.71 ***** 0.77 (0.10, 5.77) 0.8  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV 48 **** **** **** **** 90.09 ***** 90.09 *****  ARBS 48 **** **** **** **** 48.19 *****  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV 48 **** **** **** **** 48.19 *****	Site-Adjusted Analys	sis										
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV	SV	60	****	****	****	****	40.67	****	-11 71	****	0.77 (0.10 5.77)	0.8
SV       48       *****       *****       *****       90.09       *****       90.09       *****       -	ARBs	825	****	****	****	****	52.37	****	-11.71		0.77 (0.10, 3.77)	0.8
SV       48       *****       *****       *****       90.09       *****       90.09       *****       -	Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
ARBs 48 **** **** **** **** 0 *****  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV 48 **** **** **** **** 48.19 *****  48.19 *****						****	90.09	****	00.00	****		
SV 48 **** **** **** 48.19 **** 48.19 ****	ARBs	48	****	****	****	****	0	****	90.09	4. 4. 4. 4.	-	-
3V 46.19 48.19 *****	Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.0 <u>5</u>						
40.19	SV	48	****	****	****	****	48.19	****	19 10	****		
· · · · · · · · · · · · · · · · · · ·	ARBs	48	****	****	****	****	0	****	48.19		-	-

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 148 of 247

<sup>&</sup>lt;sup>2</sup>Data presented by a dash are unable to be calculated. This table may not use all data representations.

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



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

			_	_		Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	<b>Person Years</b>	Users	Interval)	P-Value
No Angioedema (ever	r, -1)										
Site-Adjusted Analysis	S										
SV	43,178	****	****	****	****	0.52	****	-0.16	****	0.73 (0.36, 1.51)	0.401
ARBs	329,798	****	****	****	****	0.68	****	-0.10		0.73 (0.30, 1.31)	0.401
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	42,832	****	****	****	****	0.53	****	0	****	1.00 (0.30, 3.45)	1
ARBs	42,832	****	****	****	****	0.53	****	0		1.00 (0.29, 3.45)	1
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	per= 0.05						
SV	42,832	****	****	****	****	0.52	****	-0.01	****	0.97 (0.38, 2.47)	0.954
ARBs	42,832	****	****	****	****	0.54	****	-0.01		0.97 (0.38, 2.47)	0.954
Angioedema (ever, -1	)										
Site-Adjusted Analysis	s										
SV	599	****	****	****	****	4.46	****	-6.24	****	0.38 (0.05, 2.79)	0.344
ARBs	7,359	****	****	****	****	10.71	****	-0.24		0.36 (0.03, 2.73)	0.344
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	591	****	****	****	****	7.29	****	0	****	1.00 (0.00 15.00)	1
ARBs	591	****	****	****	****	7.29	****	0	ren ren ren ren	1.00 (0.06, 15.99)	1
Fixed Ratio 1:1 Prope	nsity Score Ma	tched Unco	onditional A	nalysis; Cali	per= 0.05						
SV	591	220.75	****	****	****	****	****	0.77	****	1 06 (0 07 17 02)	0.965
ARBs	591	266.21	****	****	****	****	****	0.77		1.06 (0.07, 17.03)	0.905

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 149 of 247

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



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

Number of Numb	Wald P-Value <sup>2</sup>
Number of New Users   Arisk   at Risk   at R	P-Value <sup>2</sup>
New Users   ARISK   At Risk   At Risk   At Risk   Events   Years   New Users   Person Years   Users   Interval   Years   New Users   Person Years   Vessel   Years   New Users   Person Years   New Users   Person Years   New Users   Person Years   New Ye	P-Value <sup>2</sup>
No Serious Allergies   Site-Adjusted Analysis	
Site-Adjusted Analysis         SV       37,847       *****       *****       *****       0.37       *****       -0.32       ******       0.50 (0.20, 1.23)         ARBs       282,725       *****       *****       *****       0.69       *****       -0.32       ******       0.50 (0.20, 1.23)         Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05         ARBs       37,637       *****       *****       *****       0.6       *****       -0.24       ******       0.60 (0.14, 2.51)         Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05         SV       37,637       ******       ******       ******       0.37       ******       -0.24       ******       0.58 (0.20, 1.71)         ARBs       37,637       ******       ******       ******       0.6       ******       -0.24       ******       0.58 (0.20, 1.71)	0.13
SV       37,847       *****       *****       *****       *****       0.37       *****       *****       0.50 (0.20, 1.23)         ARBs       282,725       *****       *****       *****       *****       0.69       *****       -0.32       *****       0.50 (0.20, 1.23)         Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05         ARBs       37,637       *****       *****       *****       *****       0.6       *****       -0.24       *****       0.60 (0.14, 2.51)         Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05         SV       37,637       *****       *****       *****       0.37       *****       -0.24       *****       0.58 (0.20, 1.71)         ARBs       37,637       *****       *****       *****       0.6       *****       -0.24       *****       0.58 (0.20, 1.71)	0.13
ARBs 282,725 **** **** **** **** 0.69 **** -0.32 ***** 0.50 (0.20, 1.23)  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV 37,637 **** **** **** **** 0.36 ****  -0.24 **** 0.60 (0.14, 2.51)  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV 37,637 **** **** **** 0.37 ***** -0.24 ***** 0.58 (0.20, 1.71)  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  ARBs 37,637 **** **** **** 0.37 ***** -0.24 ***** 0.58 (0.20, 1.71)	0.13
ARBs 282,725 **** **** **** **** 0.69 ***** **** ****  Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05  SV 37,637 **** **** **** **** 0.36 ***** **** 0.60 (0.14, 2.51)  ARBs 37,637 **** **** **** **** 0.37 *****  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV 37,637 **** **** **** **** 0.37 *****  ARBs 37,637 ***** **** **** 0.66 ***** 0.64 ***** 0.58 (0.20, 1.71)	0.15
SV       37,637       *****       *****       *****       *****       0.36       *****       -0.24       *****       0.60 (0.14, 2.51)         Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05         SV       37,637       *****       *****       *****       0.37       *****       -0.24       *****       0.58 (0.20, 1.71)         ARBs       37,637       *****       *****       *****       0.6       *****       -0.24       *****       0.58 (0.20, 1.71)	0.10
SV       37,637       *****       *****       *****       *****       0.36       *****       -0.24       *****       0.60 (0.14, 2.51)         Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05         SV       37,637       *****       *****       *****       0.37       *****       -0.24       *****       0.58 (0.20, 1.71)         ARBs       37,637       ******       *****       *****       0.6       *****       -0.24       *****       0.58 (0.20, 1.71)	
ARBs 37,637 **** **** **** **** 0.6 **** **** ****  Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05  SV 37,637 **** **** **** **** 0.37 *****  ARBs 37,637 **** **** **** 0.6 ***** -0.24 **** 0.58 (0.20, 1.71)	0.404
SV     37,637     *****     *****     *****     0.37     *****     -0.24     *****     0.58 (0.20, 1.71)       ARBs     37,637     *****     *****     *****     0.6     *****     -0.24     *****     0.58 (0.20, 1.71)	0.484
ARBS 37,637 ***** ***** ***** 0.58 (0.20, 1.71)	
ARBs 37,637 **** **** **** 0.6 **** 0.58 (0.20, 1.71)	0.325
Serious Allergies	0.323
out to work the to provide the top of the to	
Site-Adjusted Analysis	
SV 5,930 **** **** **** 2.05 **** -0.06 **** 0.93 (0.34, 2.59)	0.894
ARBs 54,432 **** **** **** 2.11 ****	0.654
Fixed Ratio 1:1 Propensity Score Matched Conditional Analysis; Caliper= 0.05 <sup>1</sup>	
SV 5.774 **** **** **** 1.77 ****	
ARBS 5,774 **** **** **** 0 **** 1.77 ***** -	-
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05	
SV 5,774 ***** ***** ***** 2.11 *****	
ARBS 5,774 ***** ***** ***** 0.87 ***** 1.24 ***** 2.55 (0.47, 13.98)	0.281

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 150 of 247

<sup>&</sup>lt;sup>2</sup>Data presented by a dash are unable to be calculated. This table may not use all data representations.

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



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

						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	New Users	<b>Person Years</b>	Users	Interval)	P-Value
Sex: Male											
<b>Site-Adjusted Analys</b>	sis										
SV	28,311	****	****	****	****	0.3	****	-0.6	****	0.31 (0.10, 1.00)	0.05
ARBs	149,252	****	****	****	****	0.9	****	-0.0		0.31 (0.10, 1.00)	0.03
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	27,999	****	****	****	****	0.33	****	0.33	****	0.50 (0.00, 3.73)	0.422
ARBs	27,999	****	****	****	****	0.66	****	-0.33		0.50 (0.09, 2.73)	0.423
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	27,999	****	****	****	****	0.3	****	-0.53	****	0.36 (0.10, 1.31)	0.12
ARBs	27,999	****	****	****	****	0.83	****	-0.55		0.30 (0.10, 1.31)	0.12
Sex: Female											
Site-Adjusted Analys	sis										
SV	15,466	****	****	****	****	1.09	****	0.2	****	1.15 (0.50, 2.64)	0.74
ARBs	187,905	****	****	****	****	0.89	****	0.2		1.13 (0.30, 2.04)	0.74
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	15,267	****	****	****	****	0.88	****	0.20	****	4.50/0.35 0.00\	0.657
ARBs	15,267	****	****	****	****	0.59	****	0.29	*** *** *** ***	1.50 (0.25, 8.98)	0.657
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	per= 0.05						
SV	15,267	****	****	****	****	1.1	****	0.8	****	2 56 (0.72, 17.70)	0.12
ARBs	15,267	****	****	****	****	0.3	****	0.8		3.56 (0.72, 17.70)	0.12

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 151 of 247

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



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

						Incidence		Incidence			
			Average	Average		Rate per		Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	<b>Hazard Ratio</b>	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	Events	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval)	P-Value
Age Group: 18-44 ye	ears										
<b>Site-Adjusted Analys</b>	sis										
SV	1,634	****	****	****	****	0	****	-2.74	****		_
ARBs	8,500	****	****	****	****	2.74	****	-2.74		-	
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	1,448	****	****	****	****	0	****	0	****		
ARBs	1,448	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV	1,448	****	****	****	****	0	****	-2.13	****		_
ARBs	1,448	****	****	****	****	2.13	****	-2.15		-	
Age Group: 45-54 ye	ears										
Site-Adjusted Analys	sis										
SV	3,068	****	****	****	****	0	****	-2.01	****	_	_
ARBs	18,297	****	****	****	****	2.01	****	-2.01			
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	2,938	****	****	****	****	0	****	0	****		
ARBs	2,938	****	****	****	****	0	****	U		-	-
Fixed Ratio 1:1 Prop	ensity Score Ma			nalysis; Cal	•						
SV	2,938	****	****	****	****	0	****	-0.93	****	_	_
ARBs	2,938	****	****	****	****	0.93	****	-0.55			_
Age Group: 55-64 ye											
Site-Adjusted Analys											
SV	6,120	****	****	****	****	1.41	****	-0.5	****	0.81 (0.25, 2.66)	0.732
ARBs	40,556	****	****	****	****	1.91	****	<u> </u>		0.01 (0.23, 2.00)	0.752
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	5,994	****	****	****	****	2.43	****	2.43	****		
ARBs	5,994	****	****	****	****	0	****	2.43		-	-

cder\_mpl2r\_wp016 Page 152 of 247



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

			Average	Average		Incidence Rate per		Incidence Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
<b>Medical Product</b>	<b>New Users</b>	at Risk	at Risk	at Risk	<b>Events</b>	Years	<b>New Users</b>	<b>Person Years</b>	Users	Interval)	P-Value
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	5,994	****	****	****	****	1.44	****	1.02	****	3.59 (0.37, 34.57)	0.269
ARBs	5,994	****	****	****	****	0.42	****	1.02		3.59 (0.37, 34.57)	0.269
Age Group: ≥65 year	rs										
Site-Adjusted Analys	sis										
SV	32,955	****	****	****	****	0.51	****	0.16	****	0.60/0.20 1.50	0.277
ARBs	269,804	****	****	****	****	0.66	****	-0.16		0.69 (0.30, 1.58)	0.377
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	r= 0.05 <sup>1</sup>						
SV	32,649	****	****	****	****	0.54	****	-0.27	****	0.67.(0.10, 3.36)	0.53
ARBs	32,649	****	****	****	****	0.81	****	-0.27		0.67 (0.19, 2.36)	0.53
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cali	iper= 0.05						
SV	32,649	****	****	****	****	0.43	****	-0.18	****	0.66 (0.22 1.06)	0.451
ARBs	32,649	****	****	****	****	0.61	****	-0.10		0.66 (0.22, 1.96)	0.431

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

cder\_mpl2r\_wp016 Page 153 of 247

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



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

			Average	Average		Incidence Rate per		Incidence Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	Hazard Ratio	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	•	Person Years	Users	· Interval) <sup>2</sup>	P-Value <sup>2</sup>
Race: Unknown	itell edele	ut mon	ut mon	ut mon	270	1 0 0 1 0	TICH COCIO	· ciseii reais	Cocio	e.rui,	
Site-Adjusted Analy	/sis										
SV	7,289	****	****	****	****	0	****	0.62	****		
ARBs	47,812	****	****	****	****	0.63	****	-0.63	***	-	-
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	7,159	****	****	****	****	0	****	0	****		
ARBs	7,159	****	****	****	****	0	****	0	4. 4. 4. 4. 4.	-	-
Fixed Ratio 1:1 Prop	pensity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV	7,159	****	****	****	****	0	****	0	****		
ARBs	7,159	****	****	****	****	0	****	U		-	
Race: American Ind	ian										
Site-Adjusted Analy	/sis										
SV	143	****	****	****	****	0	****	-1.36	****	_	_
ARBs	1,947	****	****	****	****	1.36	****	1.50			
Fixed Ratio 1:1 Prop	pensity Score Ma										
SV	138	****	****	****	****	0	****	0	****	_	_
ARBs	138	****	****	****	****	0	****				
Fixed Ratio 1:1 Prop	pensity Score Ma				•						
SV	138	****	****	****	****	0	****	0	****	_	_
ARBs	138	****	****	****	****	0	****				
Race: Asian											
Site-Adjusted Analy											
SV	511	****	****	****	****	0	****	-0.54	****	-	_
ARBs	7,817	****	****	****	****	0.54	****				
Fixed Ratio 1:1 Prop											
SV	484	****	****	****	****	0	****	0	****	-	_
ARBs	484	****	****	****	****	0	****	J			

cder\_mpl2r\_wp016 Page 154 of 247



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

			Average	Average		Incidence Rate per		Incidence Rate	Difference		
		Person	Person	Person	Number	1,000	Risk per	Difference	in Risk per	<b>Hazard Ratio</b>	
	Number of	Years	Days	Years	of	Person	1,000	per 1,000	1,000 New	(95% Confidence	Wald
Medical Product	New Users	at Risk	at Risk	at Risk	Events	Years	•	Person Years	Users	Interval) <sup>2</sup>	P-Value <sup>2</sup>
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05					·	
SV	484	****	****	****	****	0	****	0	****		
ARBs	484	****	****	****	****	0	****	0	4 4 4 4 4	-	-
Race: Black											
Site-Adjusted Analys	sis										
SV	5,853	****	****	****	****	2.86	****	0.07	****	0.94 (0.38, 2.34)	0.892
ARBs	55,815	****	****	****	****	2.79	****	0.07		0.94 (0.36, 2.34)	0.692
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	5,765	****	****	****	****	3.76	****	3.76	****		
ARBs	5,765	****	****	****	****	0	****	3.70		-	-
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Unco	onditional A	nalysis; Cal	iper= 0.05						
SV	5,765	****	****	****	****	2.9	****	1.98	****	3.08 (0.60, 15.94)	0.18
ARBs	5,765	****	****	****	****	0.92	****	1.96		3.08 (0.00, 13.94)	0.16
Race: Pacific Islande	r										
Site-Adjusted Analys	sis										
SV	46	****	****	****	****	0	****	0	****	_	_
ARBs	478	****	****	****	****	0	****				
Fixed Ratio 1:1 Prop	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	31	****	****	****	****	0	****	0	****	_	_
ARBs	31	****	****	****	****	0	****	0		_	
Fixed Ratio 1:1 Prop	ensity Score Ma				•						
SV	31	****	****	****	****	0	****	0	****	_	_
ARBs	31	****	****	****	****	0	****				
Race: White											
Site-Adjusted Analys											
SV	29,935	****	****	****	****	0.37	****	-0.2	****	0.60 (0.22, 1.64)	0.316
ARBs	223,288	****	****	****	****	0.57	****	0.2		0.00 (0.22, 1.04)	0.510

cder\_mpl2r\_wp016 Page 155 of 247



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

Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1,000 Person Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval) <sup>2</sup>	Wald P-Value <sup>2</sup>
Fixed Ratio 1:1 Prope	ensity Score Ma	tched Cond	ditional Ana	lysis; Calipe	er= 0.05 <sup>1</sup>						
SV	29,757	****	****	****	****	0.29	****	-0.44	****	0.40 (0.08, 2.06)	0.273
ARBs	29,757	****	****	****	****	0.74	****	-0.44	4. 4. 4. 4. 4.		
Fixed Ratio 1:1 Propensity Score Matched Unconditional Analysis; Caliper= 0.05											
SV	29,757	****	****	****	****	0.37	****	-0.37	****	0.47 (0.15, 1.51)	0.208
ARBs	29,757	****	****	****	****	0.74	****	-0.57			

<sup>&</sup>lt;sup>1</sup>Conditional analysis accounts for informative events and person-time.

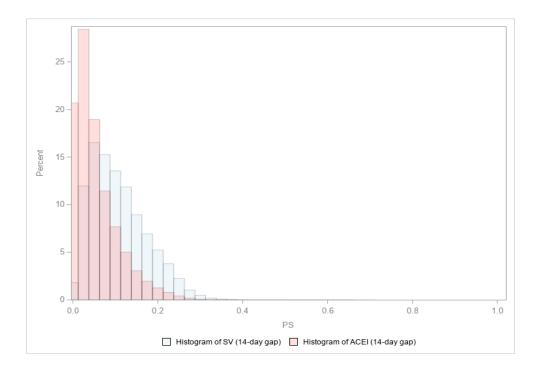
cder\_mpl2r\_wp016 Page 156 of 247

<sup>&</sup>lt;sup>2</sup>Data presented by a dash are unable to be calculated. This table may not use all data representations.

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



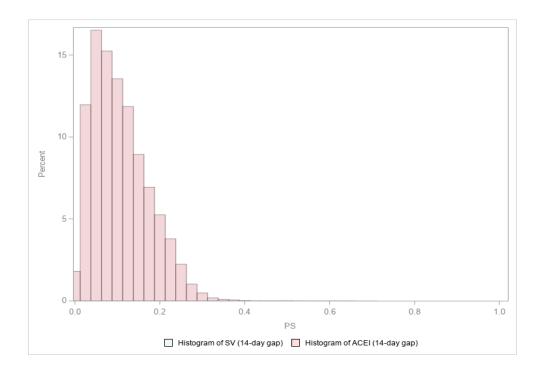
Figure 1a. Histograms of Propensity Score (PS) Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, Aggregated



cder\_mpl2r\_wp016 Page 157 of 247



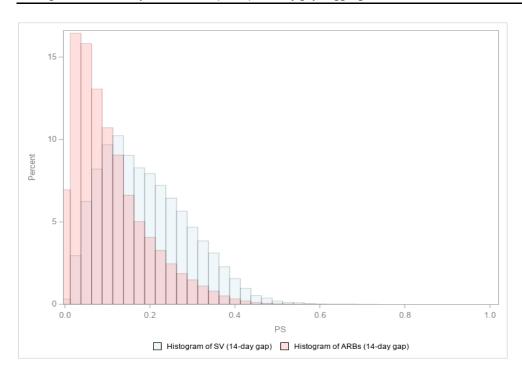
Figure 1b. Histograms of Propensity Score (PS) Fixed Ratio 1:1 Matched Cohort, Matched Caliper = 0.05 Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap



cder\_mpl2r\_wp016 Page 158 of 247



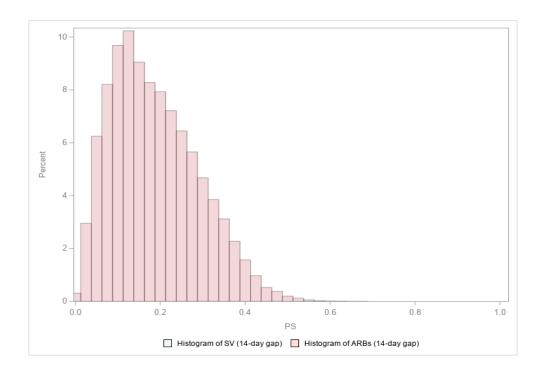
Figures 2a. Histograms of Propensity Score (PS) Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin II Receptor Blockers (ARBs), 14-day gap, Aggregated



cder\_mpl2r\_wp016 Page 159 of 247



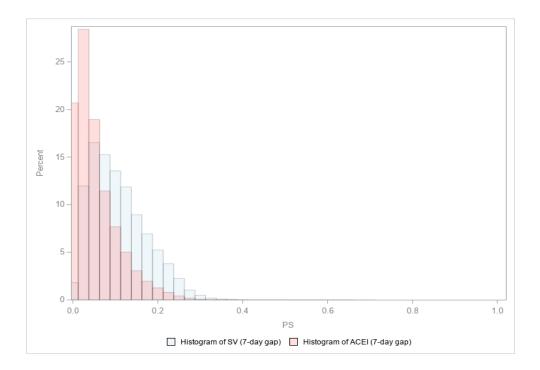
Figure 2b. Histograms of Propensity Score (PS) Fixed Ratio 1:1 Matched Cohort, Matched Caliper = 0.05 Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin II Receptor Blockers (ARBs), 14-Day Gap



cder\_mpl2r\_wp016 Page 160 of 247



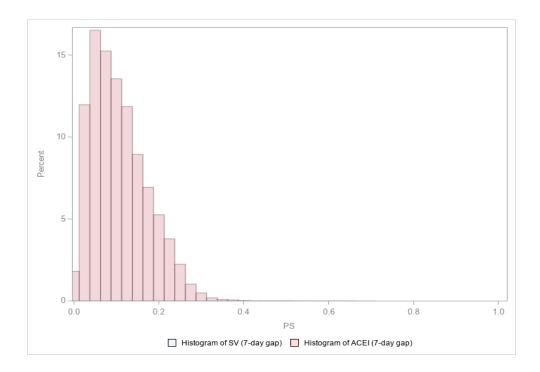
Figures 3a. Histograms of Propensity Score (PS) Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin-Converting Enzyme Inhibitors (ACEI), 7-Day Gap, Aggregated



cder\_mpl2r\_wp016 Page 161 of 247



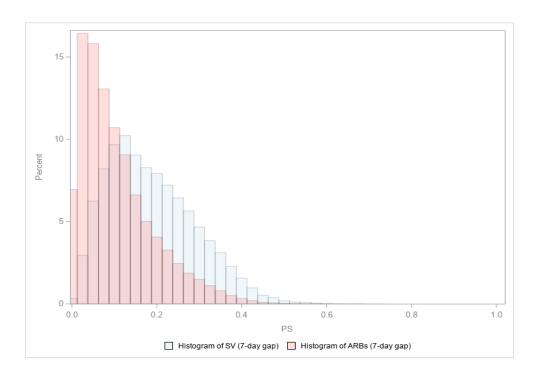
Figure 3b. Histograms of Propensity Score (PS) Fixed Ratio 1:1 Matched Cohort, Matched Caliper = 0.05 Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin-Converting Enzyme Inhibitors (ACEI), 7-Day Gap



cder\_mpl2r\_wp016 Page 162 of 247



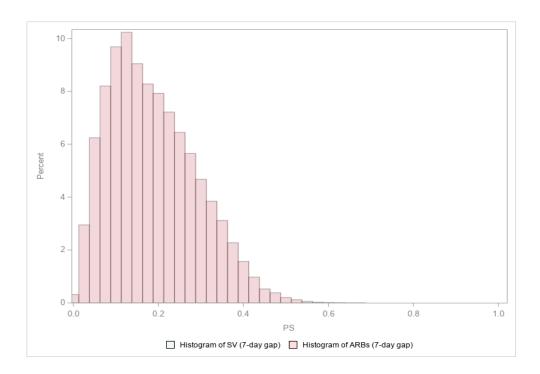
Figures 4a. Histograms of Propensity Score (PS) Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin II Receptor Blockers (ARBs), 7-day gap, Aggregated



cder\_mpl2r\_wp016 Page 163 of 247



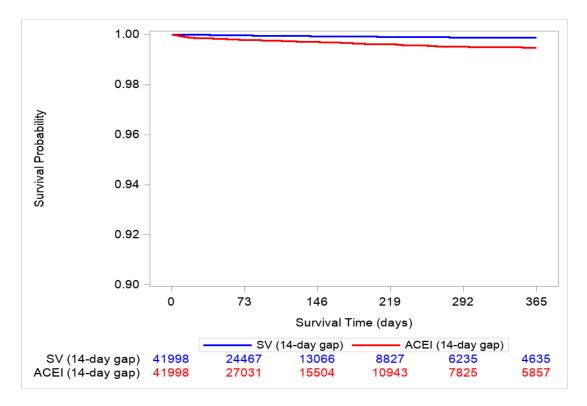
Figure 4b. Histograms of Propensity Score (PS) Fixed Ratio 1:1 Matched Cohort, Matched Caliper = 0.05 Distribution Comparing New Initiators of Sacubitril/Valsartan (SV) with use of Angiotensin II Receptor Blockers (ARBs), 7-Day Gap



cder\_mpl2r\_wp016 Page 164 of 247



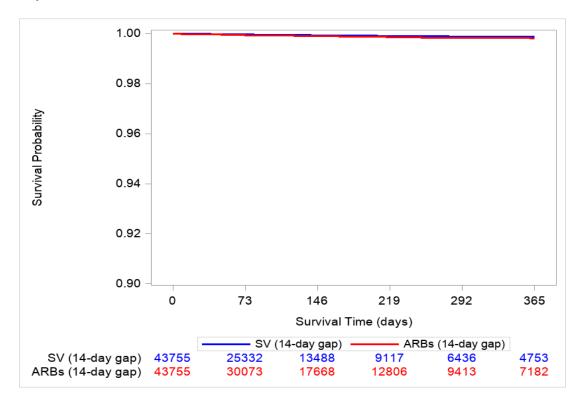
Figure 5. Kaplan Meier Survival Curves for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Angioedema



cder\_mpl2r\_wp016 Page 165 of 247



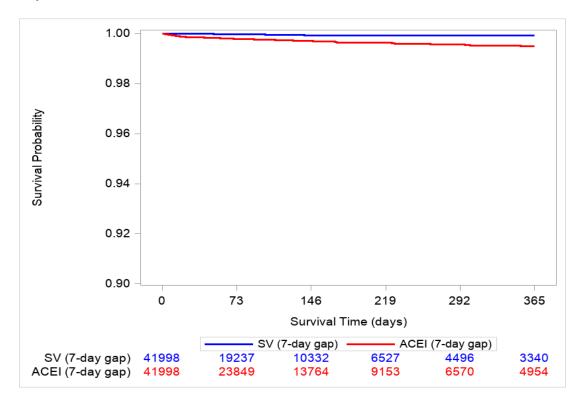
Figure 6. Kaplan Meier Survival Curves for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 14-Day Gap, and Risk of Angioedema



cder\_mpl2r\_wp016 Page 166 of 247



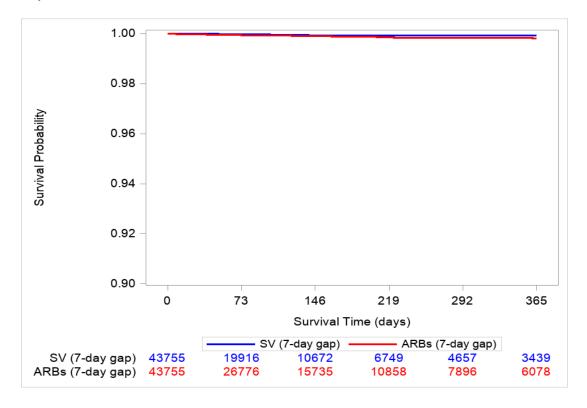
Figure 7. Kaplan Meier Survival Curves for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 7-Day Gap, and Risk of Angioedema



cder\_mpl2r\_wp016 Page 167 of 247



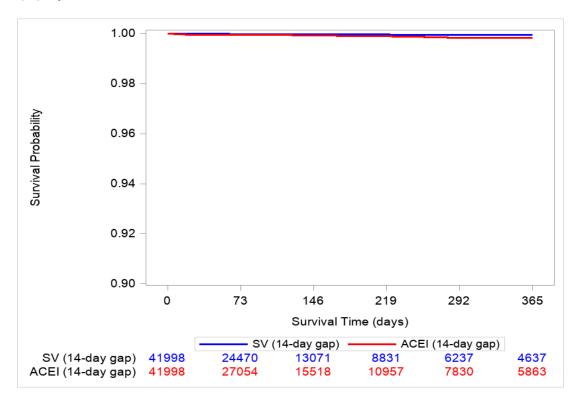
Figure 8. Kaplan Meier Survival Curves for Sacubitril/Valsartan (SV) and Angiotensin II Receptor Blockers (ARBs), 7-Day Gap, and Risk of Angioedema



cder\_mpl2r\_wp016 Page 168 of 247



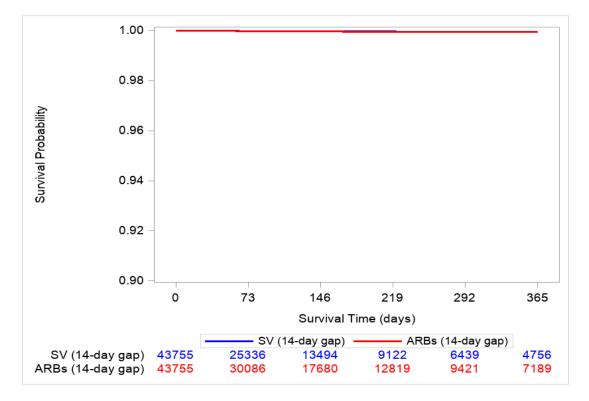
Figure 9. Kaplan Meier Survival Curves for Sacubitril/Valsartan (SV) and Angiotensin-Converting Enzyme Inhibitors (ACEI), 14-Day Gap, and Risk of Serious Angioedema



cder\_mpl2r\_wp016 Page 169 of 247



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

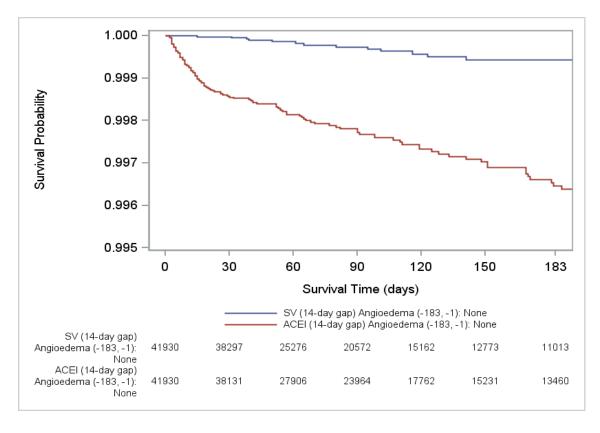


cder\_mpl2r\_wp016 Page 170 of 247



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

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

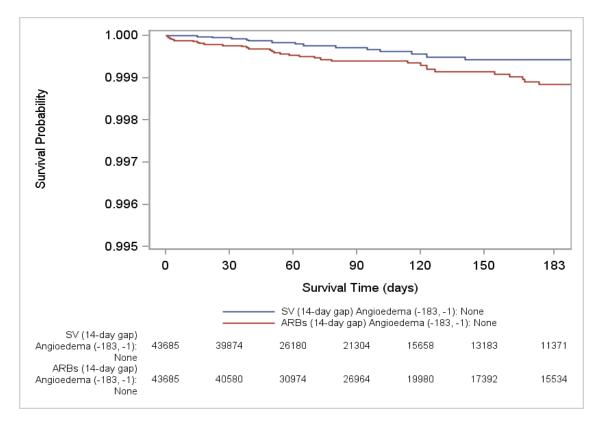


cder\_mpl2r\_wp016 Page 171 of 247



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

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



cder\_mpl2r\_wp016 Page 172 of 247



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

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

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

cder\_mpl2r\_wp016 Page 173 of 247



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

Generic Name Brand Name

**Angiotensin-Converting Enzyme Inhibitors (ACEI)** 

AMLODIPINE BESYLATE/BENAZEPRIL HCL Lotrel

AMLODIPINE BESYLATE/BENAZEPRIL HCL amlodipine-benazepril

BENAZEPRIL HCL Lotensin
BENAZEPRIL HCL
BENAZEPRIL 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 Lotensin
benazepril
enalapril maleate

lisinopril lisinopril

lisinopril/hydrochlorothiazide lisinopril-hydrochlorothiazide

quinapril HClquinaprilramiprilramipriltrandolapriltrandolapril

**Angiotensin II Receptor Blockers (ARB)** 

AMLODIPINE BESYLATE/OLMESARTAN MEDOXOMIL Azor

AMLODIPINE BESYLATE/OLMESARTAN MEDOXOMIL amlodipine-olmesartan

cder\_mpl2r\_wp016 Page 174 of 247



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

Appendix B. Generic and Brand Names of Medical Froducts Osed	to befine Exposures in this nequest
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	almospathon analysis is the thirty of
BESYLATE/HYDROCHLOROTHIAZIDE	olmesartan-amlodipin-hcthiazid
OLMESARTAN MEDOXOMIL/HYDROCHLOROTHIAZIDE	Benicar HCT
OLMESARTAN MEDOXOMIL/HYDROCHLOROTHIAZIDE	olmesartan-hydrochlorothiazide
TELMISARTAN TELMISARTAN	Micardis
TELMISARTAN TELMISARTAN/AMI ODIDINE RESVI ATE	telmisartan Twynsta
TELMISARTAN/AMLODIPINE BESYLATE	Twynsta telmicartan-amlodining
TELMISARTAN/AMLODIPINE BESYLATE	telmisartan-amlodipine
TELMISARTAN/HYDROCHLOROTHIAZIDE TELMISARTAN/HYDROCHLOROTHIAZIDE	Micardis HCT
TELMISARTAN/HYDROCHLOROTHIAZIDE	telmisartan-hydrochlorothiazid
VALSARTAN VALSARTAN	Diovan valsartan
VALSARTAN VALSARTAN/HYDROCHLOROTHIAZIDE	vaisartan Diovan HCT
VALSARTAN/HYDROCHLOROTHIAZIDE VALSARTAN/HYDROCHLOROTHIAZIDE	
amlodipine besylate/olmesartan medoxomil	valsartan-hydrochlorothiazide amlodipine-olmesartan
amiodipine besylate/olmesartan medoxomii amlodipine besylate/valsartan	amlodipine-oimesartan amlodipine-valsartan
amlodipine besylate/valsartan amlodipine besylate/valsartan/hydrochlorothiazide	amlodipine-valsartan amlodipine-valsartan-hcthiazid
candesartan cilexetil	Atacand
candesartan cilexetii	candesartan
candesartan cilexetii candesartan cilexetil/hydrochlorothiazide	Atacand HCT
candesartan cilexetii/hydrochlorothiazide	candesartan-hydrochlorothiazid
irbesartan	irbesartan
irbesartan/hydrochlorothiazide	irbesartan-hydrochlorothiazide
losartan potassium	losartan
losartan potassium/hydrochlorothiazide	losartan-hydrochlorothiazide
olmesartan medoxomil	Benicar

cder\_mpl2r\_wp016 Page 175 of 247



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

Generic Name	Brand Name			
olmesartan medoxomil	olmesartan			
olmesartan medoxomil/amlodipine besylate/hydrochlorothiazide	olmesartan-amlodipin-hcthiazid			
olmesartan medoxomil/hydrochlorothiazide	Benicar HCT			
telmisartan	telmisartan			
telmisartan/hydrochlorothiazide	telmisartan-hydrochlorothiazid			
valsartan	valsartan			
valsartan/hydrochlorothiazide	valsartan-hydrochlorothiazide			
Sacubitril/Valsartan				
SACUBITRIL/VALSARTAN	Entresto			

cder\_mpl2r\_wp016 Page 176 of 247



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

		Code	
Code	Description	Category	Code Type
	Intensive Care Unit Admission, Intubation, Tracheostomy, or Laryngoscopy		
09HN7BZ	Insertion of Airway into Nasopharynx, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
09HN8BZ	Insertion of Airway into Nasopharynx, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0B110F4	Bypass Trachea to Cutaneous with Tracheostomy Device, Open Approach	Procedure	ICD-10-PCS
0B110Z4	Bypass Trachea to Cutaneous, Open Approach	Procedure	ICD-10-PCS
0B113F4	Bypass Trachea to Cutaneous with Tracheostomy Device, Percutaneous Approach	Procedure	ICD-10-PCS
0B113Z4	Bypass Trachea to Cutaneous, Percutaneous Approach	Procedure	ICD-10-PCS
0B114F4	Bypass Trachea to Cutaneous with Tracheostomy Device, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
0B114Z4	Bypass Trachea to Cutaneous, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
0B710DZ	Dilation of Trachea with Intraluminal Device, Open Approach	Procedure	ICD-10-PCS
0B710ZZ	Dilation of Trachea, Open Approach	Procedure	ICD-10-PCS
0B713DZ	Dilation of Trachea with Intraluminal Device, Percutaneous Approach	Procedure	ICD-10-PCS
0B713ZZ	Dilation of Trachea, Percutaneous Approach	Procedure	ICD-10-PCS
0B714DZ	Dilation of Trachea with Intraluminal Device, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
0B714ZZ	Dilation of Trachea, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
0B717DZ	Dilation of Trachea with Intraluminal Device, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
0B717ZZ	Dilation of Trachea, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
0B718DZ	Dilation of Trachea with Intraluminal Device, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0B718ZZ	Dilation of Trachea, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0B720DZ	Dilation of Carina with Intraluminal Device, Open Approach	Procedure	ICD-10-PCS
0B720ZZ	Dilation of Carina, Open Approach	Procedure	ICD-10-PCS
0B723DZ	Dilation of Carina with Intraluminal Device, Percutaneous Approach	Procedure	ICD-10-PCS
0B723ZZ	Dilation of Carina, Percutaneous Approach	Procedure	ICD-10-PCS
0B724DZ	Dilation of Carina with Intraluminal Device, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
0B724ZZ	Dilation of Carina, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
0B727DZ	Dilation of Carina with Intraluminal Device, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
0B727ZZ	Dilation of Carina, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
0B728DZ	Dilation of Carina with Intraluminal Device, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0B728ZZ	Dilation of Carina, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0BH07DZ	Insertion of Intraluminal Device into Tracheobronchial Tree, Via Natural or Artificial Opening		ICD-10-PCS
OBH17EZ	Insertion of Endotracheal Airway into Trachea, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
OBH18EZ	Insertion of Endotracheal Airway into Trachea, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
OBJ14ZZ	Inspection of Trachea, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
OBJ18ZZ	Inspection of Trachea, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
OBQ10ZZ	Repair Trachea, Open Approach	Procedure	ICD-10-PCS
	Repair Trachea, Percutaneous Approach	Procedure	
OBQ14ZZ	Repair Trachea, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
OBQ17ZZ	Repair Trachea, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
OBQ18ZZ	Repair Trachea, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0BQ20ZZ		Procedure	ICD-10-PCS
OBQ23ZZ	Repair Carina, Percutaneous Approach	Procedure	ICD-10-PCS
0BQ24ZZ	Repair Carina, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
0BQ27ZZ	Repair Carina, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
0BQ28ZZ	Repair Carina, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0CHY7BZ	Insertion of Airway into Mouth and Throat, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
OCHY8BZ	Insertion of Airway into Mouth and Throat, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0CJS4ZZ	Inspection of Larynx, Percutaneous Endoscopic Approach	Procedure	ICD-10-PCS
0CJS8ZZ	Inspection of Larynx, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS

cder\_mpl2r\_wp016 Page 177 of 247



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

		Code	
Code	Description	Category	Code Type
0DH57BZ	Insertion of Airway into Esophagus, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
ODH58BZ	Insertion of Airway into Esophagus, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
0DL57DZ	Occlusion of Esophagus with Intraluminal Device, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
0DL58DZ	Occlusion of Esophagus with Intraluminal Device, Via Natural or Artificial Opening Endoscop	Procedure	ICD-10-PCS
0WHQ7YZ	Insertion of Other Device into Respiratory Tract, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
31.1	Tracheostomy	Procedure	ICD-9-CM
31.2	Tracheostomy	Procedure	ICD-9-CM
31.21	Tracheostomy	Procedure	ICD-9-CM
31.29	Tracheostomy	Procedure	ICD-9-CM
31.42	Laryngoscopy	Procedure	ICD-9-CM
31.99	Intubation	Procedure	ICD-9-CM
31231	Laryngoscopy	Procedure	CPT-4
31502	Intubation	Procedure	CPT-4
31505	Laryngoscopy	Procedure	CPT-4
31525	Laryngoscopy	Procedure	CPT-4
31526	Laryngoscopy	Procedure	CPT-4
31527	Laryngoscopy	Procedure	CPT-4
31528	Laryngoscopy	Procedure	CPT-4
31529	Laryngoscopy	Procedure	CPT-4
31560	Laryngoscopy	Procedure	CPT-4
31561	Laryngoscopy	Procedure	CPT-4
31603	Tracheostomy	Procedure	CPT-4
31605	Tracheostomy	Procedure	CPT-4
31610	Tracheostomy	Procedure	CPT-4
31612	Tracheostomy	Procedure	CPT-4
31615	Tracheostomy	Procedure	CPT-4
3E1F78Z	Irrigation of Respiratory Tract using Irrigating Substance, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
3E1F88Z	Irrigation of Respiratory Tract using Irrigating Substance, Via Natural or Artificial Opening En		ICD-10-PCS
5A1935Z	Respiratory Ventilation, Less than 24 Consecutive Hours	Procedure	ICD-10-PCS
5A1945Z	Respiratory Ventilation, 24-96 Consecutive Hours	Procedure	ICD-10-PCS
5A1955Z	Respiratory Ventilation, Greater than 96 Consecutive Hours	Procedure	ICD-10-PCS
91000	Intubation	Procedure	CPT-4
96	Intubation	Procedure	ICD-9-CM
96.0	Intubation	Procedure	ICD-9-CM
96.01	Intubation	Procedure	ICD-9-CM
96.02	Intubation	Procedure	ICD-9-CM
96.03	Intubation	Procedure	ICD-9-CM
96.04	Intubation	Procedure	ICD-9-CM
96.05	Intubation	Procedure	ICD-9-CM
96.06	Intubation	Procedure	ICD-9-CM
96.56	Intubation	Procedure	ICD-9-CM
96.7	Intubation	Procedure	ICD-9-CM
96.70 06.71	Intubation	Procedure	ICD-9-CM
96.71	Intubation	Procedure	ICD-9-CM
96.72	Intubation	Procedure	ICD-9-CM
99220	ICU Admission	Procedure	CPT-4
99221	ICU Admission	Procedure	CPT-4
99222	ICU Admission	Procedure	CPT-4

cder\_mpl2r\_wp016 Page 178 of 247



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

		Code			
Code	Description	Category	Code Type		
99223	ICU Admission	Procedure	CPT-4		
99224	ICU Admission	Procedure	CPT-4		
99225	ICU Admission	Procedure	CPT-4		
99226	ICU Admission	Procedure	CPT-4		
99291	ICU Admission	Procedure	CPT-4		
99292	ICU Admission	Procedure	CPT-4		
A0396	Intubation	Procedure	HCPCS		
V44.0	Tracheostomy	Diagnosis	ICD-9-CM		
V55.0	Tracheostomy	Diagnosis	ICD-9-CM		
Z43.0	Encounter for Attention to Tracheostomy	Diagnosis	ICD-10-CM		
Z93.0	Tracheostomy Status	Diagnosis	ICD-10-CM		
Angioedema					
995.1	Angioedema	Diagnosis	ICD-9-CM		
T783XXA	Angioedema	Diagnosis	ICD-10-CM		

cder\_mpl2r\_wp016 Page 179 of 247



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

Generic Name	Brand Name
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Angiotensin-Converting Enzyme Inhibitors (ACEI)

AMLODIPINE BESYLATE/BENAZEPRIL HCL Lotrel

AMLODIPINE BESYLATE/BENAZEPRIL HCL amlodipine-benazepril

BENAZEPRIL HCL Lotensin
BENAZEPRIL HCL
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 Lotensin
benazepril
enazepril
enazepril
enazepril
enazepril
enazepril
enazepril

Ustra and

lisinopril lisinopril

lisinopril/hydrochlorothiazidelisinopril-hydrochlorothiazidequinapril HClquinaprilramiprilramipriltrandolapriltrandolapril

Angiotensin II Receptor Blockers (ARB)

AMLODIPINE BESYLATE/OLMESARTAN MEDOXOMIL

Azor



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

Generic Name	Brand Name
AMLODIPINE BESYLATE/OLMESARTAN MEDOXOMIL	amlodipine-olmesartan
AMLODIPINE BESYLATE/VALSARTAN	Exforge
AMLODIPINE BESYLATE/VALSARTAN	amlodipine-valsartan
AMLODIPINE BESYLATE/VALSARTAN/HYDROCHLOROTHIAZIDE	Exforge HCT
AMLODIPINE BESYLATE/VALSARTAN/HYDROCHLOROTHIAZIDE	amlodipine-valsartan-hcthiazid
AZILSARTAN MEDOXOMIL	Edarbi
AZILSARTAN MEDOXOMIL/CHLORTHALIDONE	Edarbyclor
CANDESARTAN CILEXETIL	Atacand
CANDESARTAN CILEXETIL	candesartan
CANDESARTAN CILEXETIL/HYDROCHLOROTHIAZIDE	Atacand HCT
CANDESARTAN CILEXETIL/HYDROCHLOROTHIAZIDE	candesartan-hydrochlorothiazid
EPROSARTAN MESYLATE	Teveten
EPROSARTAN MESYLATE	eprosartan
EPROSARTAN MESYLATE/HYDROCHLOROTHIAZIDE	Teveten HCT
IRBESARTAN	Avapro
IRBESARTAN	irbesartan
IRBESARTAN/HYDROCHLOROTHIAZIDE	Avalide
IRBESARTAN/HYDROCHLOROTHIAZIDE	irbesartan-hydrochlorothiazide
LOSARTAN POTASSIUM	Cozaar
LOSARTAN POTASSIUM	losartan
LOSARTAN	
POTASSIUM/HYDROCHLOROTHIAZIDE	Hyzaar
LOSARTAN POTASSIUM/HYDROCHLOROTHIAZIDE	losartan-hydrochlorothiazide
NEBIVOLOL HCL/VALSARTAN	Byvalson
OLMESARTAN MEDOXOMIL	Benicar
OLMESARTAN MEDOXOMIL	olmesartan
OLMESARTAN MEDOXOMIL/AMLODIPINE	
BESYLATE/HYDROCHLOROTHIAZIDE OLMESARTAN MEDOXOMIL/AMLODIPINE	Tribenzor
BESYLATE/HYDROCHLOROTHIAZIDE	olmesartan-amlodipin-hcthiazid
OLMESARTAN MEDOXOMIL/HYDROCHLOROTHIAZIDE	Benicar HCT
OLMESARTAN MEDOXOMIL/HYDROCHLOROTHIAZIDE  OLMESARTAN MEDOXOMIL/HYDROCHLOROTHIAZIDE	olmesartan-hydrochlorothiazide
TELMISARTAN	Micardis
TELMISARTAN	telmisartan
TELMISARTAN/AMLODIPINE BESYLATE	Twynsta
TELMISARTAN/AMLODIPINE BESYLATE 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
ii besar tarij ii yar beriibi biriiaziae	in besti tuti riyat bembi bunazide

cder\_mpl2r\_wp016 Page 181 of 247



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

Generic Name	Brand Name
losartan potassium	losartan
losartan potassium/hydrochlorothiazide	losartan-hydrochlorothiazide
olmesartan medoxomil	Benicar
olmesartan medoxomil	olmesartan
olmesartan medoxomil/amlodipine besylate/hydrochlorothiazide	olmesartan-amlodipin-hcthiazid
olmesartan medoxomil/hydrochlorothiazide	Benicar HCT
telmisartan	telmisartan
telmisartan/hydrochlorothiazide	telmisartan-hydrochlorothiazid
valsartan	valsartan
valsartan/hydrochlorothiazide	valsartan-hydrochlorothiazide

cder\_mpl2r\_wp016 Page 182 of 247



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
	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with	Diagnosis	ICD-9-CM
404.01	chronic kidney disease stage I through stage IV, or unspecified		
	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with	Diagnosis	ICD-9-CM
404.03	chronic kidney disease stage V or end stage renal disease		
	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic	Diagnosis	ICD-9-CM
404.11	kidnev disease stage I through stage IV, or unspecified		
	Hypertensive heart and chronic kidney disease, benign, with heart failure and chronic	Diagnosis	ICD-9-CM
404.13	kidney disease stage V or end stage renal disease		
	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and with	Diagnosis	ICD-9-CM
404.91	chronic kidney disease stage I through stage IV, or unspecified		
	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic	Diagnosis	ICD-9-CM
404.93	kidnev disease stage V or end stage renal disease		
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
111.0	Hypertensive heart disease with heart failure	Diagnosis	ICD-10-CM
	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage	Diagnosis	ICD-10-CM
113.0	4 chronic kidney disease, or unspecified chronic kidney disease Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic	Diagnosis	ICD-10-CM
113.2	kidney disease, or end stage renal disease		
150	Heart failure	Diagnosis	ICD-10-CM
150.1	Left ventricular failure, unspecified	Diagnosis	ICD-10-CM
150.2	Systolic (congestive) heart failure	Diagnosis	ICD-10-CM
150.20	Unspecified systolic (congestive) heart failure	Diagnosis	ICD-10-CM
150.21	Acute systolic (congestive) heart failure	Diagnosis	ICD-10-CM
150.22	Chronic systolic (congestive) heart failure	Diagnosis	ICD-10-CM
150.23	Acute on chronic systolic (congestive) heart failure	Diagnosis	ICD-10-CM
150.3	Diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
150.30	Unspecified diastolic (congestive) heart failure	Diagnosis	ICD-10-CM

cder\_mpl2r\_wp016 Page 183 of 247



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	
Code	Description	Category	Code Type
150.31	Acute diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
150.32	Chronic diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
150.33	Acute on chronic diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
150.4	Combined systolic (congestive) and diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
150.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
150.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
150.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
150.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure	Diagnosis	ICD-10-CM
150.810	Right heart failure, unspecified	Diagnosis	ICD-10-CM
150.811	Acute right heart failure	Diagnosis	ICD-10-CM
150.812	Chronic right heart failure	Diagnosis	ICD-10-CM
150.813	Acute on chronic right heart failure	Diagnosis	ICD-10-CM
150.814	Right heart failure due to left heart failure	Diagnosis	ICD-10-CM
150.82	Biventricular heart failure	Diagnosis	ICD-10-CM
150.83	High output heart failure	Diagnosis	ICD-10-CM
150.84	End stage heart failure	Diagnosis	ICD-10-CM
150.89	Other heart failure	Diagnosis	ICD-10-CM
150.9	Heart failure, unspecified	Diagnosis	ICD-10-CM

cder\_mpl2r\_wp016 Page 184 of 247



Code	Description	Code Category	Code Type
Code	Allergies	Category	code Type
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

cder\_mpl2r\_wp016 Page 185 of 247



		Code	
Code	Description	Category	Code Type
J30.0	Vasomotor rhinitis	Diagnosis	ICD-10-CM
J30.1	Allergic rhinitis due to pollen	Diagnosis	ICD-10-CM
J30.2	Other seasonal allergic rhinitis	Diagnosis	ICD-10-CM
J30.5	Allergic rhinitis due to food	Diagnosis	ICD-10-CM
J30.81	Allergic rhinitis due to animal (cat) (dog) hair and dander	Diagnosis	ICD-10-CM
J30.89	Other allergic rhinitis	Diagnosis	ICD-10-CM
J30.9	Allergic rhinitis, unspecified	Diagnosis	ICD-10-CM
J31.0	Chronic rhinitis	Diagnosis	ICD-10-CM
J39.3	Upper respiratory tract hypersensitivity reaction, site unspecified	Diagnosis	ICD-10-CM
K52.21	Food protein-induced enterocolitis syndrome	Diagnosis	ICD-10-CM
K52.22	Food protein-induced enteropathy	Diagnosis	ICD-10-CM
K52.29	Other allergic and dietetic gastroenteritis and colitis	Diagnosis	ICD-10-CM
L20.0	Besnier's prurigo	Diagnosis	ICD-10-CM
L20.81	Atopic neurodermatitis	Diagnosis	ICD-10-CM
L20.82	Flexural eczema	Diagnosis	ICD-10-CM
L20.84	Intrinsic (allergic) eczema	Diagnosis	ICD-10-CM
L20.89	Other atopic dermatitis	Diagnosis	ICD-10-CM
L20.9	Atopic dermatitis, unspecified	Diagnosis	ICD-10-CM
L22	Diaper dermatitis	Diagnosis	ICD-10-CM
L23.0	Allergic contact dermatitis due to metals	Diagnosis	ICD-10-CM
L23.1	Allergic contact dermatitis due to adhesives	Diagnosis	ICD-10-CM
L23.2	Allergic contact dermatitis due to cosmetics	Diagnosis	ICD-10-CM
L23.3	Allergic contact dermatitis due to drugs in contact with skin	Diagnosis	ICD-10-CM
L23.4	Allergic contact dermatitis due to dyes	Diagnosis	ICD-10-CM
L23.5	Allergic contact dermatitis due to other chemical products	Diagnosis	ICD-10-CM
L23.6	Allergic contact dermatitis due to food in contact with the skin	Diagnosis	ICD-10-CM
L23.7	Allergic contact dermatitis due to plants, except food	Diagnosis	ICD-10-CM
L23.81	Allergic contact dermatitis due to animal (cat) (dog) dander	Diagnosis	ICD-10-CM
L23.89	Allergic contact dermatitis due to other agents	Diagnosis	ICD-10-CM
L23.9	Allergic contact dermatitis, unspecified cause	Diagnosis	ICD-10-CM
L24.0	Irritant contact dermatitis due to detergents	Diagnosis	ICD-10-CM
L24.1	Irritant contact dermatitis due to oils and greases	Diagnosis	ICD-10-CM
L24.2	Irritant contact dermatitis due to solvents	Diagnosis	ICD-10-CM
L24.3	Irritant contact dermatitis due to cosmetics	Diagnosis	ICD-10-CM
L24.4	Irritant contact dermatitis due to drugs in contact with skin	Diagnosis	ICD-10-CM
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

cder\_mpl2r\_wp016 Page 186 of 247



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

cder\_mpl2r\_wp016 Page 187 of 247



		Code	
Code	Description	Category	Code Type
T78.03XA	Anaphylactic reaction due to other fish, initial encounter	Diagnosis	ICD-10-CM
	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
	Anaphylactic reaction due to fruits and vegetables, initial encounter	Diagnosis	ICD-10-CM
	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
	Anaphylactic reaction due to tree nuts and seeds, initial encounter	Diagnosis	ICD-10-CM
	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
	Anaphylactic reaction due to food additives, initial encounter	Diagnosis	ICD-10-CM
	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
	Anaphylactic reaction due to milk and dairy products, initial encounter	Diagnosis	ICD-10-CM
	Anaphylactic reaction due to milk and dairy products, subsequent encounter	Diagnosis	ICD-10-CM
T78.07XS	Anaphylactic reaction due to milk and dairy products, subsequent encounter  Anaphylactic reaction due to milk and dairy products, sequela	Diagnosis	ICD-10-CM
T78.07		_	ICD-10-CM
	Anaphylactic reaction due to eggs	Diagnosis	
	Anaphylactic reaction due to eggs, initial encounter	Diagnosis	ICD-10-CM
	Anaphylactic reaction due to eggs, subsequent encounter	Diagnosis	ICD-10-CM
T78.08XS		Diagnosis	ICD-10-CM
T78.09	Anaphylactic reaction due to other food products	Diagnosis	ICD-10-CM
	Anaphylactic reaction due to other food products, initial encounter	Diagnosis	ICD-10-CM
T78.09XD		Diagnosis	ICD-10-CM
T78.09XS		Diagnosis	ICD-10-CM
T78.1XXA		Diagnosis	ICD-10-CM
T78.2	Anaphylactic shock, unspecified	Diagnosis	ICD-10-CM
T78.2XXA		Diagnosis	ICD-10-CM
T78.2XXD		Diagnosis	ICD-10-CM
T78.2XXS	Anaphylactic shock, unspecified, sequela	Diagnosis	ICD-10-CM
T78.40	Allergy, unspecified	Diagnosis	ICD-10-CM
	Allergy, unspecified, initial encounter	Diagnosis	ICD-10-CM
T78.40XD		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
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cder\_mpl2r\_wp016 Page 188 of 247



		Code	
Code	Description	Category	Code Type
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	Diagnosis	ICD-10-CM
	administered		
T88.6XXA	Anaphylactic reaction due to adverse effect of correct drug or medicament properly	Diagnosis	ICD-10-CM
	administered, initial encounter		
T88.6XXD	Anaphylactic reaction due to adverse effect of correct drug or medicament properly	Diagnosis	ICD-10-CM
	administered, subsequent		
	encounter		
T88.6XXS	Anaphylactic reaction due to adverse effect of correct drug or medicament properly	Diagnosis	ICD-10-CM
	administered, sequela		
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 Z87.892	Encounter for desensitization to allergens	Diagnosis	ICD-10-CM
Z88.0	Personal history of anaphylaxis	Diagnosis	ICD-10-CM
	Allergy status to penicillin Allergy status to other antibiotic agents status	Diagnosis	ICD-10-CM ICD-10-CM
Z88.1	<del></del>	Diagnosis	
Z88.2 Z88.3	Allergy status to sulfonamides status Allergy status to other anti-infective agents status	Diagnosis	ICD-10-CM
Z88.4	Allergy status to other anti-infective agents status  Allergy status to anesthetic agent status	Diagnosis Diagnosis	ICD-10-CM ICD-10-CM
Z88.5	Allergy status to narcotic agent status	Diagnosis	ICD-10-CM
Z88.6	Allergy status to analgesic agent status	Diagnosis	ICD-10-CM
Z88.7	Allergy status to serum and vaccine status	Diagnosis	ICD-10-CM
Z88.8	Allergy status to other drugs, medicaments and biological substances status	Diagnosis	ICD-10-CM
Z88.9	Allergy status to unspecified drugs, medicaments and biological substances status	Diagnosis	ICD-10-CM
Z91.0	Allergy status, other than to drugs and biological substances	Diagnosis	ICD-10-CM
Z91.01	Food allergy status	Diagnosis	ICD-10-CM
Z91.010	Allergy to peanuts	Diagnosis	ICD-10-CM
Z91.010	Allergy to milk products	Diagnosis	ICD-10-CM
Z91.011	Allergy to eggs	Diagnosis	ICD-10-CM
Z91.012	Allergy to seafood	Diagnosis	ICD-10-CM
Z91.013	Allergy to other foods	Diagnosis	ICD-10-CM
Z91.018	Food additives allergy status	Diagnosis	ICD-10-CM
Z91.03	Insect allergy status	Diagnosis	ICD-10-CM
_51.05	model and by states	Diagnosis	ICD TO CIVI

cder\_mpl2r\_wp016 Page 189 of 247



		Code	
Code	Description	Category	Code Type
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

cder\_mpl2r\_wp016 Page 190 of 247



		Code	
Code	Description	Category	Code Type
	Angioedema		
995.1	Angioedema	Diagnosis	ICD-9-CM
T783XXA	Angioedema	Diagnosis	ICD-10-CM
T783XXD	Angioneurotic edema, sequela	Diagnosis	ICD-10-CM
T783XXS	Angioneurotic edema, subsequent encounter	Diagnosis	ICD-10-CM
	Diabetes		
250	Diabetes mellitus	Diagnosis	ICD-9-CM
250.0	Diabetes mellitus without mention of complication	Diagnosis	ICD-9-CM
250.00	Diabetes mellitus without mention of complication, type II or unspecified type, not stated	Diagnosis	ICD-9-CM
	as uncontrolled		
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,	Diagnosis	ICD-9-CM
250.02	uncontrolled	Diagnosis	ICD 5 CIVI
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
250.10	Diabetes with ketoacidosis, type I for unspecimed type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.11	Diabetes with ketoacidosis, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.12	Diabetes with ketoacidosis, type I for unspecimed type, uncontrolled	Diagnosis	ICD-9-CM
250.13	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
250.20	Diabetes with hyperosmolarity, type if of unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.21	Diabetes with hyperosmolarity, type I governie type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.22	Diabetes with hyperosmolarity, type if of unspectified type, uncontrolled	Diagnosis	ICD-9-CM
250.25	Diabetes with hyperosmolarity, type i [juverille type], uncontrolled		ICD-9-CM
250.3 250.30		Diagnosis	ICD-9-CM
	Diabetes with other coma, type II or unspecified type, not stated as uncontrolled	Diagnosis	
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	Diagnosis	ICD-9-CM
	uncontrolled		
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	Diagnosis	ICD-9-CM
	uncontrolled	-	
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

cder\_mpl2r\_wp016 Page 191 of 247



		Code	
Code	Description	Category	Code Type
250.63	Diabetes with neurological manifestations, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
250.7	Diabetes with peripheral circulatory disorders	Diagnosis	ICD-9-CM
250.70	Diabetes with peripheral circulatory disorders, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.71	Diabetes with peripheral circulatory disorders, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.72	Diabetes with peripheral circulatory disorders, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.73	Diabetes with peripheral circulatory disorders, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
250.8	Diabetes with other specified manifestations	Diagnosis	ICD-9-CM
250.80	Diabetes with other specified manifestations, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.81	Diabetes with other specified manifestations, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.82	Diabetes with other specified manifestations, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.83	Diabetes with other specified manifestations, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
250.9	Diabetes with unspecified complication	Diagnosis	ICD-9-CM
250.90	Diabetes with unspecified complication, type II or unspecified type, not stated as	Diagnosis	ICD-9-CM
	uncontrolled		
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-	Procedure	HCPCS
	shelf depth-inlay shoe manufactured to accommodate multidensity insert(s), per shoe		
A5501	For diabetics only, fitting (including follow-up), custom preparation and supply of shoe	Procedure	HCPCS
A5503	molded from cast(s) of patient's foot (custom molded shoe), per shoe For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or	Procedure	HCPCS
A3303	custom molded shoe with roller or rigid rocker bottom, per shoe	riocedule	TICECS
A5504	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or	Procedure	HCPCS
713304	custom molded shoe with wedge(s), per shoe	rroccaare	1101 05
A5505	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or	Procedure	HCPCS
7.5505	custom molded shoe with metatarsal bar, per shoe	rioccaare	
A5506	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or	Procedure	HCPCS
	custom molded shoe with off-set heel(s), per shoe		
A5507	For diabetics only, not otherwise specified modification (including fitting) of off-the-shelf	Procedure	HCPCS
	depth-inlay shoe or custom molded shoe, per shoe		
A5508	For diabetics only, deluxe feature of off-the-shelf depth-inlay shoe or custom molded shoe,	Procedure	HCPCS
	per shoe		
A5510	For diabetics only, direct formed, compression molded to patient's foot without external	Procedure	HCPCS
	heat source, multiple-density insert(s) prefabricated, per shoe		
A5512	For diabetics only, multiple density insert, direct formed, molded to foot after external	Procedure	HCPCS
	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		

cder\_mpl2r\_wp016 Page 192 of 247



		Code	
Code	Description	Category	Code Type
A5513	For diabetics only, multiple density insert, custom molded from model of patient's foot,	Procedure	HCPCS
	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,		
E10.10	Type 1 diabetes mellitus with ketoacidosis without coma	Diagnosis	ICD-10-CM
E10.11	Type 1 diabetes mellitus with ketoacidosis with coma	Diagnosis	ICD-10-CM
E10.21	Type 1 diabetes mellitus with diabetic nephropathy	Diagnosis	ICD-10-CM
E10.22	Type 1 diabetes mellitus with diabetic chronic kidney disease	Diagnosis	ICD-10-CM
E10.29	Type 1 diabetes mellitus with other diabetic kidney complication	Diagnosis	ICD-10-CM
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema	Diagnosis	ICD-10-CM
E10.319	Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema	Diagnosis	ICD-10-CM
E10.3211	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
E10.3212	edema. right eve Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
	edema, left eye		
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 eve	Diagnosis	ICD-10-CM
E10.3291	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular	Diagnosis	ICD-10-CM
E10.3292	edema, right eve Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular	Diagnosis	ICD-10-CM
E10.3293	edema, left eve Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular	Diagnosis	ICD-10-CM
E10.3299	edema. bilateral Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular	Diagnosis	ICD-10-CM
E10.3311	edema. unspecified eve Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
E10.3312	edema. right eve Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
E10.3313	edema. left eve Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
E10.3319	edema. bilateral Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
E10.3391	edema, unspecified eve Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without	Diagnosis	ICD-10-CM
E10.3392	macular edema, right eye Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without	Diagnosis	ICD-10-CM
E10.3393	macular edema. left eve Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without	Diagnosis	ICD-10-CM
E10.3399	macular edema, bilateral Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without	Diagnosis	ICD-10-CM
E10.3411	macular edema, unspecified eve Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
E10.3412	edema, right eve Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
E10.3413	edema, left eve Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM

cder\_mpl2r\_wp016 Page 193 of 247



Code	Description	Code Category	Code Type
E10.3419	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
E10.3491	edema, unspecified eve Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular		ICD-10-CM
E10.3492	edema, right eve Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular	Diagnosis	ICD-10-CM
E10.3493	edema, left eve 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 eve	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 eve	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 eve	Diagnosis	ICD-10-CM
E10.3521	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula,	Diagnosis	ICD-10-CM
E10.3522	right eve Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula,	Diagnosis	ICD-10-CM
E10.3523	left eve Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula,	Diagnosis	ICD-10-CM
E10.3529	hilateral Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula,	Diagnosis	ICD-10-CM
E10.3531	unspecified eve Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the	Diagnosis	ICD-10-CM
E10.3532	macula, right eve Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the	Diagnosis	ICD-10-CM
E10.3533	macula. left eve	Diagnosis	ICD-10-CM
E10.3539	macula, hilateral Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the	Diagnosis	ICD-10-CM
E10.3541	macula, unspecified eve Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and	Diagnosis	ICD-10-CM
E10.3542	rhegmatogenous retinal detachment, right eve Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eve	Diagnosis	ICD-10-CM

cder\_mpl2r\_wp016 Page 194 of 247



		Code	
Code	Description	Category	Code Type
E10.3543	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction	Diagnosis	ICD-10-CM
	retinal detachment and	J	
	rhegmatogenous retinal detachment hilateral		
E10.3549	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction	Diagnosis	ICD-10-CM
	retinal detachment and		
	rhegmatogenous retinal detachment unspecified eve		
E10.3551	• • • • • • • • • • • • • • • • • • • •	Diagnosis	ICD-10-CM
	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, left eye	Diagnosis	ICD-10-CM
	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		Diagnosis	ICD-10-CM
540 2502	right eye	D: :	100 40 604
E10.3592	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema,	Diagnosis	ICD-10-CM
E10 2E02	left eve	Diamaria	ICD 10 CM
E10.3593	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema,	Diagnosis	ICD-10-CM
F10 2F00	bilateral Type 1 diabetes mellitus with preliferative diabetic retinanethy without masular adams	Diagnasis	ICD 10 CM
E10.3599	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema,	Diagnosis	ICD-10-CM
E10.36	unspecified eve Type 1 diabetes mellitus with diabetic cataract	Diagnosis	ICD-10-CM
E10.37X1	Type 1 diabetes mellitus with diabetic catalact  Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, right	Diagnosis	ICD-10-CM
LIU.S/AI		Diagnosis	ICD-10-CIVI
E10.37X2	eve Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, left	Diagnosis	ICD-10-CM
L10.57 NZ	eve	Diagnosis	TED TO CIVI
E10.37X3	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment,	Diagnosis	ICD-10-CM
	bilateral		
E10.37X9	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment,	Diagnosis	ICD-10-CM
	unspecified eve	J	
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

cder\_mpl2r\_wp016 Page 195 of 247



		Code	
Code	Description	Category	Code Type
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-	Diagnosis	ICD-10-CM
	hyperosmolar coma (NKHHC)		
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	Diagnosis	ICD-10-CM
	edema, right eye		
E11.3212	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
	edema, left eve		
E11.3213	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
	edema, bilateral		
E11.3219	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
	edema, unspecified eve		
E11.3291	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular	Diagnosis	ICD-10-CM
	edema, right eve		
E11.3292	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular	Diagnosis	ICD-10-CM
	edema, left eve		
E11.3293	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular	Diagnosis	ICD-10-CM
	edema, bilateral		
E11.3299	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular	Diagnosis	ICD-10-CM
	edema, unspecified eve		
E11.3311	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
	edema, right eve		
E11.3312	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
	edema, left eve		
E11.3313	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
	edema, bilateral		
E11.3319	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
	edema, unspecified eye		
E11.3391	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without	Diagnosis	ICD-10-CM
	macular edema, right eve		
E11.3392	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without	Diagnosis	ICD-10-CM
	macular edema, left eve		
E11.3393	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without	Diagnosis	ICD-10-CM
	macular edema, bilateral		
E11.3399	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without	Diagnosis	ICD-10-CM
	macular edema, unspecified eve		
E11.3411	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
	edema, right eve		
E11.3412	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
<b>=44 = **</b> *	edema, left eve		105 45 55
E11.3413	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
	edema, bilateral		

cder\_mpl2r\_wp016 Page 196 of 247



		Code	
Code	Description	Category	Code Type
E11.3419	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
E11.3491	edema, unspecified eve Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular	Diagnosis	ICD-10-CM
E11.3492	edema. right eve Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular	Diagnosis	ICD-10-CM
E11.3493	edema. left eve 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 eve	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 eve	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 eve	Diagnosis	ICD-10-CM
E11.3521		Diagnosis	ICD-10-CM
E11.3522	right eve Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula,	Diagnosis	ICD-10-CM
E11.3523	left eve Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula,	Diagnosis	ICD-10-CM
E11.3529	hilateral Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula,	Diagnosis	ICD-10-CM
E11.3531	unspecified eve Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the	Diagnosis	ICD-10-CM
E11.3532	macula. right eve Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal	Diagnosis	ICD-10-CM
544 2522	detachment not involving the  macula, left eve	5	100 40 614
E11.3533	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the	Diagnosis	ICD-10-CM
E11.3539	macula. hilateral Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the	Diagnosis	ICD-10-CM
E11.3541	macula, unspecified eve	Diagnosis	ICD-10-CM
E11.3542	rhegmatogenous retinal detachment, right eve Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eve	Diagnosis	ICD-10-CM

cder\_mpl2r\_wp016 Page 197 of 247



		Code	
Code	Description	Category	Code Type
E11.3543	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction	Diagnosis	ICD-10-CM
	retinal detachment and	J	
	rhegmatogenous retinal detachment hilateral		
E11.3549	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction	Diagnosis	ICD-10-CM
	retinal detachment and		
	rhegmatogenous retinal detachment unspecified eve		
	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, right eye	Diagnosis	ICD-10-CM
	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, left eye	Diagnosis	ICD-10-CM
	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		Diagnosis	ICD-10-CM
544.0500	right eye		100 40 014
E11.3592	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema,	Diagnosis	ICD-10-CM
E44 2E02	left eve	Diamania	ICD 40 CM
E11.3593	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema,	Diagnosis	ICD-10-CM
E11 2E00	bilateral  Type 2 diabetes mellitus with preliferative diabetic retipenathy without masular adams	Diagnasis	ICD 10 CM
E11.3599	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema,	Diagnosis	ICD-10-CM
E11.36	unspecified eve Type 2 diabetes mellitus with diabetic cataract	Diagnosis	ICD-10-CM
E11.37X1	Type 2 diabetes mellitus with diabetic catalact  Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, right	Diagnosis	ICD-10-CM
LII.J/AI		Diagnosis	ICD-10-CIVI
E11.37X2	eve Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, left	Diagnosis	ICD-10-CM
LII.J/NZ	eve	Diagnosis	TED TO CIVI
E11.37X3	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment,	Diagnosis	ICD-10-CM
	bilateral		
E11.37X9	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment,	Diagnosis	ICD-10-CM
	unspecified eve	J	
E11.39	Type 2 diabetes mellitus with other diabetic ophthalmic complication	Diagnosis	ICD-10-CM
E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified	Diagnosis	ICD-10-CM
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy	Diagnosis	ICD-10-CM
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy	Diagnosis	ICD-10-CM
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy	Diagnosis	ICD-10-CM
E11.44	Type 2 diabetes mellitus with diabetic amyotrophy	Diagnosis	ICD-10-CM
E11.49	Type 2 diabetes mellitus with other diabetic neurological complication	Diagnosis	ICD-10-CM
E11.51	Type 2 diabetes mellitus with diabetic peripheral angiopathy without gangrene	Diagnosis	ICD-10-CM
E11.52	Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene	Diagnosis	ICD-10-CM
E11.59	Type 2 diabetes mellitus with other circulatory complications	Diagnosis	ICD-10-CM
E11.610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy	Diagnosis	ICD-10-CM
E11.618	Type 2 diabetes mellitus with other diabetic arthropathy	Diagnosis	ICD-10-CM
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

cder\_mpl2r\_wp016 Page 198 of 247



		Code	
Code	Description	Category	Code Type
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-	Diagnosis	ICD-10-CM
	hyperosmolar coma (NKHHC)		
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	Diagnosis	ICD-10-CM
E13.319	edema Other specified diabetes mellitus with unspecified diabetic retinopathy without macular	Diagnosis	ICD-10-CM
	edema	Ü	
E13.3211	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eve	Diagnosis	ICD-10-CM
E13.3212	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with	Diagnosis	ICD-10-CM
E13.3213	macular edema, left eve Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with	Diagnosis	ICD-10-CM
E13.3219	macular edema, bilateral Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with	Diagnosis	ICD-10-CM
E13.3291	macular edema, unspecified eve Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without	Diagnosis	ICD-10-CM
E13.3292	macular edema, right eve Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without	Diagnosis	ICD-10-CM
	macular edema, left eve	_	
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	Diagnosis	ICD-10-CM
	eve		
E13.3311	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with	Diagnosis	ICD-10-CM
E13.3312	macular edema, right eye Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with	Diagnosis	ICD-10-CM
E13.3313	macular edema. left eve Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with	Diagnosis	ICD-10-CM
E13.3319	macular edema. bilateral Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with	Diagnosis	ICD-10-CM
	macular edema, unspecified		
E13.3391	eve Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy	Diagnosis	ICD-10-CM
	without macular edema, right eve		
E13.3392	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy	Diagnosis	ICD-10-CM
E13.3393	without macular edema. left eve Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy	Diagnosis	ICD-10-CM
	without macular edema. bilateral	-	

cder\_mpl2r\_wp016 Page 199 of 247



Code	Description	Code Category	Code Type
E13.3399	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy	Diagnosis	ICD-10-CM
	without macular edema,		
E13.3411	unspecified eve Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with	Diagnosis	ICD-10-CM
E13.3412	macular edema, right eve Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with	Diagnosis	ICD-10-CM
E13.3413	macular edema. left eve Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with	Diagnosis	ICD-10-CM
E13.3419	macular edema, bilateral Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with	Diagnosis	ICD-10-CM
E13.3491	macular edema, unspecified eve Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without	Diagnosis	ICD-10-CM
E13.3492	macular edema, right eve Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without	Diagnosis	ICD-10-CM
E13.3493	macular edema, left eye Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without	Diagnosis	ICD-10-CM
E13.3499	macular edema, bilateral Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without	Diagnosis	ICD-10-CM
E13.3511	macular edema, unspecified eve Other specified diabetes mellitus with proliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
E13.3512	edema, right eve Other specified diabetes mellitus with proliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
E13.3513	edema, left eve Other specified diabetes mellitus with proliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
E13.3519	edema, bilateral Other specified diabetes mellitus with proliferative diabetic retinopathy with macular	Diagnosis	ICD-10-CM
E13.3521	edema, unspecified eve Other specified diabetes mellitus with proliferative diabetic retinopathy with traction	Diagnosis	ICD-10-CM
E13.3522	retinal detachment involving the macula, right eve Other specified diabetes mellitus with proliferative diabetic retinopathy with traction	Diagnosis	ICD-10-CM
E13.3523	retinal detachment involving the macula, left eve Other specified diabetes mellitus with proliferative diabetic retinopathy with traction	Diagnosis	ICD-10-CM
E13.3529	retinal detachment involving the macula, bilateral Other specified diabetes mellitus with proliferative diabetic retinopathy with traction	Diagnosis	ICD-10-CM
E13.3531	retinal detachment involving the macula, unspecified eve Other specified diabetes mellitus with proliferative diabetic retinopathy with traction	Diagnosis	ICD-10-CM
E13.3532	retinal detachment not involving the macula, right eye Other specified diabetes mellitus with proliferative diabetic retinopathy with traction	Diagnosis	ICD-10-CM
E13.3533	retinal detachment not involving the macula, left eve Other specified diabetes mellitus with proliferative diabetic retinopathy with traction	Diagnosis	ICD-10-CM
E13.3539	retinal detachment not involving the macula, bilateral Other specified diabetes mellitus with proliferative diabetic retinopathy with traction	Diagnosis	ICD-10-CM
E13.3541	retinal detachment not involving the macula, unspecified eve Other specified diabetes mellitus with proliferative diabetic retinopathy with combined	Diagnosis	ICD-10-CM
E13.3542	traction retinal detachment and rhegmatogenous retinal detachment, right eye Other specified diabetes mellitus with proliferative diabetic retinopathy with combined	Diagnosis	ICD-10-CM
	traction retinal detachment and rhegmatogenous retinal detachment, left eye		

cder\_mpl2r\_wp016 Page 200 of 247



		Code	
Code	Description	Category	Code Type
E13.3543	Other specified diabetes mellitus with proliferative diabetic retinopathy with combined	Diagnosis	ICD-10-CM
	traction retinal detachment and rhegmatogenous retinal detachment, bilateral	.0	
E13.3549	Other specified diabetes mellitus with proliferative diabetic retinopathy with combined	Diagnosis	ICD-10-CM
213.33 13	traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye	Diagnosis	102 10 0141
E13.3551	Other specified diabetes mellitus with stable proliferative diabetic retinopathy, right eye	Diagnosis	ICD-10-CM
E13.3551		_	ICD-10-CM
	Other specified diabetes mellitus with stable proliferative diabetic retinopathy, left eye	Diagnosis	
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	Diagnosis	ICD-10-CM
E13.3591	eve Other specified diabetes mellitus with proliferative diabetic retinopathy without macular	Diagnosis	ICD-10-CM
E13.3592	edema, right eve Other specified diabetes mellitus with proliferative diabetic retinopathy without macular	Diagnosis	ICD-10-CM
E13.3593	edema. left eve Other specified diabetes mellitus with proliferative diabetic retinopathy without macular	Diagnosis	ICD-10-CM
E13.3599	edema. bilateral Other specified diabetes mellitus with proliferative diabetic retinopathy without macular	Diagnosis	ICD-10-CM
E13.36	edema. unspecified eve Other specified diabetes mellitus with diabetic cataract	Diagnosis	ICD-10-CM
E13.37X1	Other specified diabetes mellitus with diabetic dataract	Diagnosis	ICD-10-CIVI
L13.37X1	treatment, right eve	Diagnosis	ICD-10-CIVI
E13.37X2		Diagnosis	ICD-10-CM
E13.37X3	Other specified diabetes mellitus with diabetic macular edema, resolved following	Diagnosis	ICD-10-CM
E13.37X9	treatment, bilateral Other specified diabetes mellitus with diabetic macular edema, resolved following	Diagnosis	ICD-10-CM
E13.39	treatment, unspecified eve Other specified diabetes mellitus with other diabetic ophthalmic complication	Diagnosis	ICD-10-CM
E13.39 E13.40	Other specified diabetes mellitus with diabetic neuropathy, unspecified	Diagnosis Diagnosis	ICD-10-CM
E13.40	Other specified diabetes mellitus with diabetic mononeuropathy	Diagnosis	ICD-10-CIVI
E13.42	Other specified diabetes mellitus with diabetic mononeuropathy	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
	5	- 10.01.00.0	
E13.52	Other specified diabetes mellitus with diabetic peripheral angiopathy with gangrene	Diagnosis	ICD-10-CM
E13.59	Other specified diabetes mellitus with other circulatory complications	Diagnosis	ICD-10-CM
E13.610	Other specified diabetes mellitus with diabetic neuropathic arthropathy	Diagnosis	ICD-10-CM
E13.618	Other specified diabetes mellitus with other diabetic arthropathy	Diagnosis	ICD-10-CM
E13.620	Other specified diabetes mellitus with diabetic dermatitis	Diagnosis	ICD-10-CM
E13.621	Other specified diabetes mellitus with foot ulcer	Diagnosis	ICD-10-CM
E13.622	Other specified diabetes mellitus with other skin ulcer	Diagnosis	ICD-10-CM
E13.628	Other specified diabetes mellitus with other skin complications	Diagnosis	ICD-10-CM
E13.630	Other specified diabetes mellitus with periodontal disease	Diagnosis	ICD-10-CM
E13.638	Other specified diabetes mellitus with other oral complications	Diagnosis	ICD-10-CM
E13.641	Other specified diabetes mellitus with hypoglycemia with coma	Diagnosis	ICD-10-CM
E13.649	Other specified diabetes mellitus with hypoglycemia without coma	Diagnosis	ICD-10-CM
E13.65	Other specified diabetes mellitus with hyperglycemia	Diagnosis	ICD-10-CM

cder\_mpl2r\_wp016 Page 201 of 247



		Code	
Code	Description	Category	Code Type
E13.69	Other specified diabetes mellitus with other specified complication	Diagnosis	ICD-10-CM
E13.8	Other specified diabetes mellitus with unspecified complications	Diagnosis	ICD-10-CM
E13.9	Other specified diabetes mellitus without complications	Diagnosis	ICD-10-CM
G0108	Diabetes outpatient self-management training services, individual, per 30 minutes	Procedure	HCPCS
G0109	Diabetes outpatient self-management training services, group session (2 or more), per 30	Procedure	HCPCS
	minutes		

cder\_mpl2r\_wp016 Page 202 of 247



Cada	Description	Code	Cada Tura
Code	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 Procedure	HCPCS
	Follow-up physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include at least the following: (1) a patient history, (2) a physical examination that includes: (a) visual inspection of the forefoot, hindfoot, and toe web spaces, (b) evaluation of protective sensation, (c) evaluation of foot structure and biomechanics, (d) evaluation of vascular status and skin integrity, and (e) evaluation and recommendation of footwear, and (3)	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	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)	Procedure	HCPCS
G8017	documented as less than or equal to 9% Clinician documented that diabetic patient was not eligible candidate for hemoglobin A1c	Procedure	HCPCS
G8018	measure Clinician has not provided care for the diabetic patient for the required time for	Procedure	HCPCS
G8019	hemoglobin A1c measure (6 months) Diabetic patient with most recent low-density lipoprotein (within the last 12 months)	Procedure	HCPCS
G8020	documented as greater than or equal to 100 mg/dl Diabetic patient with most recent low-density lipoprotein (within the last 12 months)	Procedure	HCPCS
G8021	documented as less than 100 mg/dl Clinician documented that diabetic patient was not eligible candidate for low-density	Procedure	HCPCS
G8022	lipoprotein measure Clinician has not provided care for the diabetic patient for the required time for low-	Procedure	HCPCS
G8023	density lipoprotein measure (12 months) 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	Procedure	HCPCS
G8025	as less than 140 systolic and less than 80 diastolic Clinician documented that the diabetic patient was not eligible candidate for blood	Procedure	HCPCS
G8026	pressure measure Clinician has not provided care for the diabetic patient for the required time for blood	Procedure	HCPCS
G8332	pressure measure (within the last 6 months) Clinician has not provided care for the diabetic retinopathy patient for the required time	Procedure	HCPCS
G8333	for macular edema and retinopathy measurement Patient documented to have had findings of macular or fundus exam communicated to the physician managing the diabetes care	Procedure	HCPCS

cder\_mpl2r\_wp016 Page 203 of 247



		Code	
Code	Description	Category	Code Type
G8334	Documentation of findings of macular or fundus exam not communicated to the physician	Procedure	HCPCS
G8335	managing the patient's ongoing diabetes care Clinician documentation that patient was not an eligible candidate for the findings of their	Procedure	HCPCS
	macular or fundus exam being communicated to the physician managing their diabetes		
G8336	care during the reporting year Clinician has not provided care for the diabetic retinopathy patient for the required time	Procedure	HCPCS
	for physician communication measurement		
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	Procedure	HCPCS
	12 months)  Ischemic Heart Disease		
	issuicinia ricare piscasc		
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 native coronary aftery	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-CIVI
414.05	Coronary atherosclerosis of unspecified type of bypass graft	Diagnosis	ICD-9-CM
414.06	Coronary atherosclerosis, of native coronary artery of transplanted heart	Diagnosis	ICD-9-CM
414.07	Coronary atherosclerosis, of bypass graft (artery) (vein) of transplanted heart	Diagnosis	ICD-9-CM
414.1	Aneurysm and dissection of heart	Diagnosis	ICD-9-CM
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

cder\_mpl2r\_wp016 Page 204 of 247



		Code	
Code	Description	Category	Code Type
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-	Procedure	HCPCS
	blocker therapy		
G8034	Prior myocardial infarction, coronary artery disease patient not documented to be on beta-	Procedure	HCPCS
G8035	blocker therapy	Dragodura	HCDCS
G8035	Clinician documented that prior myocardial infarction, coronary artery disease patient was not eligible candidate for	Procedure	HCPCS
	heta-blocker therapy measure		
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	Procedure	HCPCS
00000	antiplatelet therapy measure		
G8039	Coronary artery disease patient with low-density lipoprotein documented to be greater	Procedure	HCPCS
	than 100 mg/dl		
G8040	Coronary artery disease patient with low-density lipoprotein documented to be less than	Procedure	HCPCS
	or equal to 100 mg/dl		
G8041	Clinician documented that coronary artery disease patient was not eligible candidate for	Procedure	HCPCS
	low-density lipoprotein measure		
120.0	Unstable angina	Diagnosis	ICD-10-CM
120.1	Angina pectoris with documented spasm	Diagnosis	ICD-10-CM
120.8	Other forms of angina pectoris	Diagnosis	ICD-10-CM
120.9	Angina pectoris, unspecified	Diagnosis	ICD-10-CM
123.0	Hemopericardium as current complication following acute myocardial infarction	Diagnosis	ICD-10-CM
123.1	Atrial septal defect as current complication following acute myocardial infarction	Diagnosis	ICD-10-CM
123.2	Ventricular septal defect as current complication following acute myocardial infarction	Diagnosis	ICD-10-CM
123.3	Rupture of cardiac wall without hemopericardium as current complication following acute	Diagnosis	ICD-10-CM
123.3	myocardial infarction	Diagnosis	ICD-10-CIVI
123.4	Rupture of chordae tendineae as current complication following acute myocardial	Diagnosis	ICD-10-CM
123.4	infarction	Diagnosis	ICD 10 CIVI
123.5	Rupture of papillary muscle as current complication following acute myocardial infarction	Diagnosis	ICD-10-CM
123.6	Thrombosis of atrium, auricular appendage, and ventricle as current complications	Diagnosis	ICD-10-CM
	following acute myocardial		
122.7	infarction  Partief action angles	Diamasia	ICD 10 CM
123.7	Postinfarction angina	Diagnosis	ICD-10-CM
123.8	Other current complications following acute myocardial infarction	Diagnosis	ICD-10-CM
124.0	Acute coronary thrombosis not resulting in myocardial infarction	Diagnosis	ICD-10-CM
124.1	Dressler's syndrome	Diagnosis	ICD-10-CM
124.8	Other forms of acute ischemic heart disease	Diagnosis	ICD-10-CM
124.9	Acute ischemic heart disease, unspecified	Diagnosis	ICD-10-CM
125.10	Atherosclerotic heart disease of native coronary artery without angina pectoris	Diagnosis	ICD-10-CM
125.110	Atherosclerotic heart disease of native coronary artery with unstable angina pectoris	Diagnosis	ICD-10-CM
125.111	Atherosclerotic heart disease of native coronary artery with angina pectoris with	Diagnosis	ICD-10-CM
	documented spasm		

cder\_mpl2r\_wp016 Page 205 of 247



		Code	
Code	Description	Category	Code Type
125.118	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
125.3	Aneurysm of heart	Diagnosis	ICD-10-CM
125.41	Coronary artery aneurysm	Diagnosis	ICD-10-CM
125.42	Coronary artery dissection	Diagnosis	ICD-10-CM
125.5	Ischemic cardiomyopathy	Diagnosis	ICD-10-CM
125.6	Silent myocardial ischemia	Diagnosis	ICD-10-CM
125.700	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unstable angina	Diagnosis	ICD-10-CM
125.701	pectoris Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris with	Diagnosis	ICD-10-CM
125.708	documented spasm Atherosclerosis of coronary artery bypass graft(s), unspecified, with other forms of angina	Diagnosis	ICD-10-CM
125.709	pectoris Atherosclerosis of coronary artery bypass graft(s), unspecified, with unspecified angina	Diagnosis	ICD-10-CM
125.710	pectoris Atherosclerosis of autologous vein coronary artery bypass graft(s) with unstable angina	Diagnosis	ICD-10-CM
125.711	pectoris Atherosclerosis of autologous vein coronary artery bypass graft(s) with angina pectoris	Diagnosis	ICD-10-CM
125.718	with documented spasm Atherosclerosis of autologous vein coronary artery bypass graft(s) with other forms of	Diagnosis	ICD-10-CM
125.719	angina pectoris Atherosclerosis of autologous vein coronary artery bypass graft(s) with unspecified angina	Diagnosis	ICD-10-CM
125.720	pectoris Atherosclerosis of autologous artery coronary artery bypass graft(s) with unstable angina	Diagnosis	ICD-10-CM
125.721	pectoris Atherosclerosis of autologous artery coronary artery bypass graft(s) with angina pectoris	Diagnosis	ICD-10-CM
125.728	with documented spasm Atherosclerosis of autologous artery coronary artery bypass graft(s) with other forms of	Diagnosis	ICD-10-CM
125.729	angina pectoris Atherosclerosis of autologous artery coronary artery bypass graft(s) with unspecified	Diagnosis	ICD-10-CM
125.730	angina pectoris Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unstable	Diagnosis	ICD-10-CM
125.731	angina pectoris Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with angina pectoris with documented	Diagnosis	ICD-10-CM
125.738	snasm Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with other	Diagnosis	ICD-10-CM
125.739	forms of angina pectoris Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with	Diagnosis	ICD-10-CM
125 750	unspecified angina pectoris  Atheres learning of pative corporary artery of transplanted heart with unstable angina	Diagnosis	ICD 10 CN4
125.750	Atherosclerosis of native coronary artery of transplanted heart with unstable angina	Diagnosis	ICD-10-CM
125.751	Atherosclerosis of native coronary artery of transplanted heart with angina pectoris with documented spasm	Diagnosis	ICD-10-CM
125.758	Atherosclerosis of native coronary artery of transplanted heart with other forms of angina	Diagnosis	ICD-10-CM
125.759	pectoris Atherosclerosis of native coronary artery of transplanted heart with unspecified angina pectoris	Diagnosis	ICD-10-CM

cder\_mpl2r\_wp016 Page 206 of 247



		Code	
Code	Description	Category	Code Type
125.760	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unstable	Diagnosis	ICD-10-CM
	angina		
125.761	Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina	Diagnosis	ICD-10-CM
	pectoris with documented spasm		
125.768	Atherosclerosis of bypass graft of coronary artery of transplanted heart with other forms of	Diagnosis	ICD-10-CM
	angina pectoris		
125.769	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unspecified	Diagnosis	ICD-10-CM
	angina pectoris		
125.790	Atherosclerosis of other coronary artery bypass graft(s) with unstable angina pectoris	Diagnosis	ICD-10-CM
125.791	Atherosclerosis of other coronary artery bypass graft(s) with angina pectoris with	Diagnosis	ICD-10-CM
	documented spasm		
125.798	Atherosclerosis of other coronary artery bypass graft(s) with other forms of angina pectoris	Diagnosis	ICD-10-CM
125.799	Atherosclerosis of other coronary artery bypass graft(s) with unspecified angina pectoris	Diagnosis	ICD-10-CM
125.810	Atherosclerosis of coronary artery bypass graft(s) without angina pectoris	Diagnosis	ICD-10-CM
125.811	Atherosclerosis of native coronary artery of transplanted heart without angina pectoris	Diagnosis	ICD-10-CM
125 042		<b>5</b>	100 40 614
125.812	Atherosclerosis of bypass graft of coronary artery of transplanted heart without angina	Diagnosis	ICD-10-CM
125.02	pectoris  Characia total population of parameter automa	Diamania	ICD 10 CM
125.82	Chronic total occlusion of coronary artery  Coronary atherosclerosis due to lipid rich plague	Diagnosis	ICD-10-CM
125.83		Diagnosis	ICD-10-CM
125.84 125.89	Coronary atherosclerosis due to calcified coronary lesion Other forms of chronic ischemic heart disease	Diagnosis	ICD-10-CM ICD-10-CM
125.89	Chronic ischemic heart disease  Chronic ischemic heart disease, unspecified	Diagnosis Diagnosis	ICD-10-CM
125.9 151.0	Cardiac septal defect, acquired	Diagnosis	ICD-10-CM
151.0	Rupture of chordae tendineae, not elsewhere classified	Diagnosis	ICD-10-CM
151.1	Rupture of papillary muscle, not elsewhere classified	Diagnosis	ICD-10-CM
I51.2 I51.9	Heart disease, unspecified	Diagnosis	ICD-10-CM
151.9	Other heart disorders in diseases classified elsewhere	Diagnosis	ICD-10-CM
132	Renal Disorders	Diagnosis	ICD-10-CIVI
584	Acute kidney failure	Diagnosis	ICD-9-CM
584.5	Acute kidney failure with lesion of tubular necrosis	Diagnosis	ICD-9-CM
584.6	Acute kidney failure with lesion of renal cortical necrosis	Diagnosis	ICD-9-CM
584.7	Acute kidney failure with lesion of medullary [papillary] necrosis	Diagnosis	ICD-9-CM
584.8	Acute kidney failure with other specified pathological lesion in kidney	Diagnosis	ICD-9-CM
584.9	Acute kidney failure, unspecified	Diagnosis	ICD-9-CM
585	Chronic kidney disease (CKD)	Diagnosis	ICD-9-CM
585.1	Chronic kidney disease, Stage I	Diagnosis	ICD-9-CM
585.2	Chronic kidney disease, Stage II (mild)	Diagnosis	ICD-9-CM
585.3	Chronic kidney disease, Stage III (moderate)	Diagnosis	ICD-9-CM
585.4	Chronic kidney disease, Stage IV (severe)	Diagnosis	ICD-9-CM
585.5	Chronic kidney disease, Stage V	Diagnosis	ICD-9-CM
585.6	End stage renal disease	Diagnosis	ICD-9-CM
585.9	Chronic kidney disease, unspecified	Diagnosis	ICD-9-CM
586	Unspecified renal failure	Diagnosis	ICD-9-CM
587	Unspecified renal sclerosis	Diagnosis	ICD-9-CM
N17.0	Acute kidney failure with tubular necrosis	Diagnosis	ICD-10-CM
N17.1	Acute kidney failure with acute cortical necrosis	Diagnosis	ICD-10-CM

cder\_mpl2r\_wp016 Page 207 of 247



		Code	
Code	Description	Category	Code Type
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

cder\_mpl2r\_wp016 Page 208 of 247



**Generic Name Brand Name Allergy Treatments** Chlorpheniramine Maleate/Codeine Cotabflu Phosphate/Acetaminophen 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) Brovana arformoterol tartrate azelastine HCl Astelin azelastine HCl Astepro azelastine HCl Optivar azelastine HCl azelastine azelastine HCI/fluticasone propionate Dymista azelastine/fluticasone/sodium chloride/sodium **Ticalast** bicarbonate Beconase AQ beclomethasone dipropionate beclomethasone dipropionate QNASL beclomethasone dipropionate Qvar beclomethasone dipropionate Qvar RediHaler Fasenra benralizumab bepotastine besilate **Bepreve** betamethasone acetate and sodium phos in sterile betameth ac, sodphos(PF)-water water/PF betamethasone acetate and sodium **Betaloan SUIK** phosph/norflurane/HFC 245fa Pod-Care 100CG betamethasone acetate and sodium phosph/norflurane/HFC 245fa betamethasone acetate/betamethasone sodium Beta-1 phosphate betamethasone acetate/betamethasone sodium Celestone Soluspan phosphate Pod-Care 100C betamethasone acetate/betamethasone sodium phosphate betamethasone acetate/betamethasone sodium ReadySharp Betamethasone phosphate betamethasone acetate/betamethasone sodium betamethasone acet, sod phos phosphate betamethasone acetate/betamethasone sodium betamethasone ace, sodphos-wtr phosphate/water betamethasone sodium phosph in sterile water for betamethasone sodphosph-water iniection

cder\_mpl2r\_wp016 Page 209 of 247

brompheniramine maleate brompheniramine maleate

J-TAN PD

brompheniramine maleate(bulk)



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	Trexbrom
HCI/chlophedianol HCI	TEASTOTII
brompheniramine maleate/phenylephrine	M-END PE
HCI/codeine phosphate	, -
brompheniramine maleate/phenylephrine	Poly-Tussin AC
HCI/codeine phosphate	
brompheniramine maleate/phenylephrine	AP-Hist DM
HCI/dextromethorphan	
brompheniramine maleate/phenylephrine	Ala-Hist DM
HCI/dextromethorphan	
brompheniramine maleate/phenylephrine	Altipres-B
HCI/dextromethorphan	
brompheniramine maleate/phenylephrine	Bio T Pres-B
HCI/dextromethorphan	510
brompheniramine maleate/phenylephrine	BroveX PEB DM
HCI/dextromethorphan	
brompheniramine maleate/phenylephrine	Children's Cold and Cough(PE)
HCI/dextromethorphan	
brompheniramine maleate/phenylephrine	Children's Cold and CoughDM
HCI/dextromethorphan	· ·
brompheniramine maleate/phenylephrine	Children's Dibromm DMCold-Cou
HCI/dextromethorphan	
brompheniramine maleate/phenylephrine	Cold and Cough DM
HCI/dextromethorphan	C
brompheniramine maleate/phenylephrine	Cold and Cough Elixir
HCI/dextromethorphan	
brompheniramine maleate/phenylephrine	Dimaphen DM
HCI/dextromethorphan	
brompheniramine maleate/phenylephrine	Dimetapp DM Cold-Cough(PE)
HCI/dextromethorphan	
brompheniramine maleate/phenylephrine	EndaCof - DM
HCI/dextromethorphan	
brompheniramine maleate/phenylephrine	Glenmax PEB DM
HCI/dextromethorphan	
brompheniramine maleate/phenylephrine	Glenmax PEB DM Forte
HCI/dextromethorphan	
brompheniramine maleate/phenylephrine	LoHist PEB DM
HCI/dextromethorphan	
brompheniramine maleate/phenylephrine	LoHist-DM
HCI/dextromethorphan	
brompheniramine maleate/phenylephrine	M-Hist DM
HCI/dextromethorphan	
brompheniramine maleate/phenylephrine	Niva-Hist DM
HCI/dextromethorphan	
brompheniramine maleate/phenylephrine	Presgen B
HCI/dextromethorphan	
brompheniramine maleate/phenylephrine	RelCof DM
HCI/dextromethorphan	

cder\_mpl2r\_wp016 Page 210 of 247



Generic Name	Brand Name
brompheniramine maleate/phenylephrine	Rynex DM
HCI/dextromethorphan	Ny hex 2 m
brompheniramine maleate/phenylephrine	Tussi Pres-B
HCI/dextromethorphan	
brompheniramine maleate/phenylephrine	Wal-tap DM
HCI/dextromethorphan	
brompheniramine maleate/phenylephrine	brompheniramin-phenylephrin-DM
HCI/dextromethorphan	. , , ,
brompheniramine maleate/pseudoephedrine	Atuss DA
HCl/chlophedianol	
brompheniramine maleate/pseudoephedrine	brompheniramine-pseudoeph-DM
HCI/dextromethorphan	·
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

cder\_mpl2r\_wp016 Page 211 of 247



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	Biclora-D
HCI/chlophedianol HCI chlorcyclizine HCI/pseudoephedrine HCI/codeine	Poly-Tussin D
phosphate	,
chlorcyclizine hydrochloride/chlophedianol	Biclora
hydrochloride	
chlorpheniram/phenyleph/dextromethorphn	Cold-Flu M-SymptomDay-Night
/acetaminophen/guaifn	
chlorpheniram/phenyleph/dextromethorphn	Tylenol Cold-Flu SevereDay-Nt
/acetaminophen/guaifn	
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	Carbaphen CH
HCI/chlophedianol HCI	-3.04p 5
chlorpheniramine maleate/phenylephrine	Carbaphen Ped CH
HCl/chlophedianol HCl	
Tiel, emopriedianoi fiei	

cder\_mpl2r\_wp016 Page 212 of 247



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

Generic Name	Brand Name
chlorpheniramine maleate/phenylephrine	ExaPhen CH
HCI/chlophedianol HCI	Exameli on
chlorpheniramine maleate/phenylephrine	Phenagil CH
HCI/chlophedianol HCI	
chlorpheniramine maleate/phenylephrine	CapCof
HCI/codeine phosphate chlorpheniramine maleate/phenylephrine	Maxi-Tuss CD
HCI/codeine phosphate chlorpheniramine maleate/phenylephrine	Bio-Rytuss
HCI/dextromethorphan	210 11,14433
chlorpheniramine maleate/phenylephrine	Maxichlor PEH DM
HCI/dextromethorphan chlorpheniramine maleate/phenylephrine	Advil Allergy-Congestion RIf
HCI/ibuprofen	
chlorpheniramine maleate/phenylephrine bitartrate/aspirin	Cold Relief
chlorpheniramine maleate/phenylephrine	Cold Relief Plus
bitartrate/aspirin chlorpheniramine maleate/pseudoephedrine	Tricode AR
HCI/codeine	7-1-1-04-035
chlorpheniramine maleate/pseudoephedrine HCl/codeine	Zodryl DAC 25
chlorpheniramine maleate/pseudoephedrine	Zodryl DAC 30
HCI/codeine chlorpheniramine maleate/pseudoephedrine	Zodryl DAC 35
HCI/codeine chlorpheniramine maleate/pseudoephedrine	Zodryl DAC 40
HCI/codeine	Zodi yi DAC 40
chlorpheniramine maleate/pseudoephedrine	Zodryl DAC 50
HCI/codeine chlorpheniramine maleate/pseudoephedrine	Zodryl DAC 60
HCI/codeine	
chlorpheniramine maleate/pseudoephedrine	Zodryl DAC 80
HCI/codeine	
chlorpheniramine maleate/pseudoephedrine	Advil Allergy Sinus
HCI/ibuprofen ciclesonide	Alverse
	Alvesco
ciclesonide ciclesonide	Omnaris 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

cder\_mpl2r\_wp016 Page 213 of 247



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	dexamethasone ac, sodph-water
sterile water	
dexamethasone acetate in sodium chloride,	dexamethasoneace-NaCl,iso-osm
iso-osmotic	
dexamethasone acetate, micronized	dexamethasone ac, micro(bulk)
dexamethasone sodium phosphate	Dexonto
dexamethasone sodium phosphate	dexamethasone sod phos(bulk)
dexamethasone sodium phosphate in 0.9 %	dexamethasone-0.9 % sod.chlor
sodium chloride	Antico Injection (III D /DE)
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-l
dexamethasone, micronized	dexamethasone,micronized(bulk) DMT SUIK
dexamethasone/PF/norflurane/pentafluoropropane	DIVIT SUIK
(HFC 245fa) dexbromphen-pseudoephedrine	M-End DMX
-dextromethorphan	IVI-LIIU DIVIX
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	Acticon (dexbromph-pse)
HCl	
dexbrompheniramine maleate/pseudoephedrine	M-End Max D
HCI/codeine phos	
rici, coucine prios	

cder\_mpl2r\_wp016 Page 214 of 247



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	Pro-Red AC (w/dexchlorphenir)
HCI/codeine	
dexchlorpheniramine	Polytussin DM
maleate/phenylephrine/dextromethorphan dextromethorphan	Child Plus Cough and Runny Nose
HBr/acetaminophen/chlorpheniramine maleate dextromethorphan	Child's TylenolplusCough,RNos
HBr/acetaminophen/chlorpheniramine maleate dextromethorphan	Coricidin HBP Flu
HBr/acetaminophen/chlorpheniramine maleate dextromethorphan	Flu BP
HBr/acetaminophen/chlorpheniramine maleate	
dextromethorphan HBr/acetaminophen/chlorpheniramine maleate	Flu HBP
dextromethorphan	Maximum Strength Flu
HBr/acetaminophen/chlorpheniramine maleate dextromethorphan	Vicks NyQuil Cold/Flu (cpm)
HBr/acetaminophen/chlorpheniramine maleate dextromethorphan	Diabetic Tussin Night Time
HBr/acetaminophen/diphenhvdramine HCl dextromethorphan	All-Nite Cold-Flu
HBr/acetaminophen/doxylamine dextromethorphan	Cold-Flu Relief
HBr/acetaminophen/doxylamine dextromethorphan	Contac Cold-Flu Night
HBr/acetaminophen/doxylamine dextromethorphan	Coricidin HBP Cold-MultiSympt
HBr/acetaminophen/doxylamine dextromethorphan	Cough-Sore Throat Night
HBr/acetaminophen/doxylamine	
dextromethorphan HBr/acetaminophen/doxylamine	Night Time
dextromethorphan HBr/acetaminophen/doxylamine	Night Time Cold
dextromethorphan	Night Time Cold and FluRelief
HBr/acetaminophen/doxylamine dextromethorphan	Night Time Cold-Flu
HBr/acetaminophen/doxylamine dextromethorphan	Night Time Cold-Flu Relief
HBr/acetaminophen/doxylamine dextromethorphan	Nighttime Cold-Flu
HBr/acetaminophen/doxylamine dextromethorphan	Nighttime Cold-Flu Relief
HBr/acetaminophen/doxylamine dextromethorphan	Nite Time Cold-Flu
HBr/acetaminophen/doxylamine	Aite fille cold fid
dextromethorphan HBr/acetaminophen/doxylamine	Nite Time Cold-Flu Relief
ribi/acetaiiiiiopiieii/uoxylaiiiiile	

cder\_mpl2r\_wp016 Page 215 of 247



Canadia Nama	Durand Name
Generic Name	Brand Name  Nite-Time Cold-Flu
dextromethorphan	Nite-Time Cold-Flu
HBr/acetaminophen/doxylamine dextromethorphan	Nitetime Multi-Symptom
HBr/acetaminophen/doxvlamine dextromethorphan	Robitussin Cold-Flu Night
HBr/acetaminophen/doxylamine dextromethorphan	Vicks Nature Fusion Cold-Flu
HBr/acetaminophen/doxvlamine dextromethorphan	Vicks NyQuil Cold/FluLiquicap
HBr/acetaminophen/doxvlamine dextromethorphan	Vicks Nyquil Nighttime Relief
HBr/acetaminophen/doxylamine	
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	Cold Head CongestionDaytime
HCl/acetaminophen dextromethorphan HBr/phenylephrine	Cold Multi-Symptom
HCI/acetaminophen	cold Mater Symptom
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Cold-Flu Relief
dextromethorphan HBr/phenylephrine	Day Multi-Symp Flu-SevereCold
HCl/acetaminophen dextromethorphan HBr/phenylephrine	Day Time PE
HCI/acetaminophen	DayTimo
dextromethorphan HBr/phenylephrine HCl/acetaminophen	DayTime
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Daytime Cold
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Daytime Cold-Flu
dextromethorphan HBr/phenylephrine	Daytime Cold-Flu Relief (PE)
HCl/acetaminophen dextromethorphan HBr/phenylephrine	Flu Relief Therapy Daytime
HCl/acetaminophen dextromethorphan HBr/phenylephrine	Flu-Severe Cold-CoughDaytime
HCI/acetaminophen dextromethorphan HBr/phenylephrine	HerbioMed Body Aches-SinusM-S
HCl/acetaminophen dextromethorphan HBr/phenylephrine	Mapap Cold Formula
HCI/acetaminophen	
dextromethorphan HBr/phenylephrine HCl/acetaminophen	Mucinex Fast-MaxCongest-Head
non acctaninophen	

cder\_mpl2r\_wp016 Page 216 of 247



Generic Name	Brand Name
dextromethorphan HBr/phenylephrine	Mucinex Fast-MaxSevCold-Sinus
HCl/acetaminophen dextromethorphan HBr/phenylephrine	Robitussin Cold-Flu Day
HCI/acetaminophen dextromethorphan HBr/phenylephrine	Sudafed PEPressure-Pain-Cough
HCl/acetaminophen dextromethorphan HBr/phenylephrine	Theraflu ExpressMax ColdDay
HCI/acetaminophen dextromethorphan HBr/phenylephrine	Theraflu Multi-Symptom Cold
HCl/acetaminophen dextromethorphan HBr/phenylephrine	Tylenol Cold Max Day
HCl/acetaminophen dextromethorphan HBr/phenylephrine	Tylenol Cold Multi-SymptomDay
HCl/acetaminophen dextromethorphan HBr/phenylephrine	Vicks DayQuil Cold-Flu Relief
HCl/acetaminophen dextromethorphan HBr/phenylephrine	Vicks Nature Fusion
HCl/acetaminophen dextromethorphan HBr/phenylephrine	Wal-Flu Severe Cold-Cough
HCl/acetaminophen dextromethorphan HBr/phenylephrine	Alahist CF
HCl/dexbrompheniramine dextromethorphan HBr/phenylephrine	Alahist DM
HCI/dexbrompheniramine dextromethorphan HBr/phenylephrine	Bionatuss DXP
HCl/dexbrompheniramine dextromethorphan HBr/phenylephrine	G-P-Tuss DXP
HCl/dexbrompheniramine dextromethorphan HBr/phenylephrine	Supress A
HCl/dexbrompheniramine dextromethorphan	Alka-Seltzer PlusSin-Allg-Cgh
HBr/phenylephrine/acetaminophen/doxylamine dextromethorphan	Cold Multi-SymptomNightTime
HBr/phenylephrine/acetaminophen/doxylamine dextromethorphan	Cold and Flu Relief Plus (D/N)
HBr/phenylephrine/acetaminophen/doxylamine dextromethorphan	Cold-Flu Relief, Day/Night
HBr/phenvlephrine/acetaminophen/doxvlamine dextromethorphan	Daytime-Nighttime
HBr/phenylephrine/acetaminophen/doxylamine dextromethorphan	Daytime-Nighttime Cold-Flu
HBr/phenylephrine/acetaminophen/doxylamine dextromethorphan	Mucinex Fast-Max Nite (doxyl)
HBr/phenylephrine/acetaminophen/doxylamine dextromethorphan	Nite Time Cold-Flu Relief (PE)
HBr/phenylephrine/acetaminophen/doxylamine dextromethorphan	Severe Cold and FluNighttime
HBr/phenylephrine/acetaminophen/doxylamine dextromethorphan	Severe Sinus CongestAlrgy-Cgh
HBr/phenylephrine/acetaminophen/doxylamine dextromethorphan HBr/phenylephrine/acetaminophen/doxylamine	Tylenol Cold Max Night

cder\_mpl2r\_wp016 Page 217 of 247



Generic Name	Brand Name
dextromethorphan	Tylenol Cold Multi-SymptNight
HBr/phenvlephrine/acetaminophen/doxvlamine dextromethorphan	Vicks NyQuil Severe Cold-Flu
HBr/phenylephrine/acetaminophen/doxylamine dextromethorphan HBr/pseudoephedrine	DAY-TIME
HCI/acetaminophen dextromethorphan HBr/pseudoephedrine	Daytime Cold and Flu Relief
HCl/acetaminophen dextromethorphan/phenylephrine/acetaminophen	HerbioMed Deep Cold-FluNight
/diphenhvdramine dextromethorphan/phenylephrine/acetaminophen	Multi-Symptom SevereCold-Nt
/diphenhvdramine dextromethorphan/pseudoephrine	Alka-Seltzer Plus Cold+Flu
HCl/acetaminophen/doxylamine dextromethorphan/pseudoephrine	Night Time Cold Medicine
HCI/acetaminophen/doxylamine	
dextromethorphan/pseudoephrine HCl/acetaminophen/doxylamine	Night Time Cold-Flu
dextromethorphan/pseudoephrine	Night Time Cold-Flu Relief
HCl/acetaminophen/doxvlamine dextromethorphan/pseudoephrine	Nite Time
HCl/acetaminophen/doxylamine 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

cder\_mpl2r\_wp016 Page 218 of 247



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	Adult Robitussin Night M-SCld
HCl/acetaminophen	
diphenhydramine HCl/phenylephrine	Allergy M-S Nighttime
HCl/acetaminophen	
diphenhydramine HCl/phenylephrine	Allergy Plus Severe Sinus HA
HCl/acetaminophen	
diphenhydramine HCl/phenylephrine	Allergy Sinus Headache (PE)
HCI/acetaminophen	
diphenhydramine HCl/phenylephrine	Allergy and Cold PE
HCI/acetaminophen	
diphenhydramine HCl/phenylephrine	Child Delsym Cough+Cold
HCI/acetaminophen	
diphenhydramine HCl/phenylephrine	Children Dimetapp M-SCold-Flu
HCI/acetaminophen	
diphenhydramine HCl/phenylephrine	Children's Mucinex NightTime
HCI/acetaminophen	
diphenhydramine HCl/phenylephrine	Cold and FluRelief(diphen-pe)
HCI/acetaminophen	
diphenhydramine HCl/phenylephrine	Cough and Severe Cold
HCI/acetaminophen	
diphenhydramine HCl/phenylephrine	Delsym Cough-ColdNightTime
HCI/acetaminophen	

cder\_mpl2r\_wp016 Page 219 of 247



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

cder\_mpl2r\_wp016 Page 220 of 247



Generic Name	Brand Name	
doxylamine/phenylephrine/dextromethorphan	Mucinex Fast-MaxDay-Nt(doxyl)	
/acetaminophen/GG		
doxylamine/phenylephrine/dextromethorphan	Mucinex Sinus-Max Dy-Nt(dxyl)	
/acetaminophen/GG		
doxylamine/phenylephrine/dextromethorphan	Severe Cold andFlu(Day/Night)	
/acetaminophen/GG		
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	Еру	
epinephrine	Primatene Mist	
epinephrine	Symjepi	
epinephrine	epinephrine	
epinephrine HCI/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 HCI/pseudoephedrine HCI	Allegra-D 24 Hour	
fexofenadine HCl/pseudoephedrine HCl	Allergy Relief D	
fexofenadine HCI/pseudoephedrine HCI	Allergy Relief-D(fexofenadine)	
fexofenadine HCI/pseudoephedrine HCI	Allergy-CongestRelief-D(fexo)	
fexofenadine HCl/pseudoephedrine HCl	Wal-Fex D 12 Hour	

cder\_mpl2r\_wp016 Page 221 of 247



Generic Name	Brand Name
fexofenadine HCI/pseudoephedrine HCI	Wal-Fex D 24 Hour
fexofenadine HCI/pseudoephedrine HCI	fexofenadine-pseudoephedrine
fludrocortisone acetate	fludrocortisone
flunisolide	Aerospan
flunisolide	flunisolide
fluocinolone acetonide/emollient combination	Synalar Cream Kit
no.65	
fluocinolone acetonide/emollient combination	Synalar Ointment Kit
no.65	
fluocinolone acetonide/skin cleanser comb no.28	Synalar TS
fluocinolone acetonide/skin cleanser	Xilapak
no.10/silicone, tape	
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	Trelegy Ellipta
trifenat	
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 RIf
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	Beser Kit
no.65	
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	Ticanase
bicarbonate	Tianana
fluticasone propionate/sodium chloride/sodium	Ticaspray
bicarbonate formatate	Foradil Aprolizor
formateral fumerate	Foradil Aerolizer
formateral fumarate	Perforomist
formateral fumarate dihudrate micronized	formoterol fumarate (bulk)
formoterol fumarate dihydrate, micronized	formoterol fum dihyd,mic(bulk)
glycopyrrolate	Seebri Neohaler

cder\_mpl2r\_wp016 Page 222 of 247



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

cder\_mpl2r\_wp016 Page 223 of 247



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

cder\_mpl2r\_wp016 Page 224 of 247



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 and Cough Max
guaifenesin/dextromethorphan HBr/phenylephrine	
guaifenesin/dextromethorphan HBr/phenylephrine	Supress DX 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

cder\_mpl2r\_wp016 Page 225 of 247



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	Sorbutuss
	Sorbutuss
citrate guaifenesin/dextromethorphan	Actinel
HBr/pseudoephedrine HCl	Actifici
guaifenesin/dextromethorphan	Actinel Pediatric
HBr/pseudoephedrine HCl	Actifici i calatric
guaifenesin/dextromethorphan	Ambi 40PSE-400GFN-20DM
HBr/pseudoephedrine HCl	Allibi 401 SE-40001 N-20DIVI
guaifenesin/dextromethorphan	Bionel
	מוטווכו
HBr/pseudoephedrine HCl guaifenesin/dextromethorphan	Bionel Pediatric
HBr/pseudoephedrine HCl	bioliei rediatric
guaifenesin/dextromethorphan	Capmist DM
· · · · · · · · · · · · · · · · · · ·	Capitiist Divi
HBr/pseudoephedrine HCl guaifenesin/dextromethorphan	Desgen DM(pseudoephedrine)
	Desgen Divi(pseudoephedrine)
HBr/pseudoephedrine HCl guaifenesin/dextromethorphan	Despec-DM(pseudoeph-DM-guaif)
•	Despec-Divi(pseudoepii-Divi-guaii)
HBr/pseudoephedrine HCl guaifenesin/dextromethorphan	Entex PAC
- ·	LITTER PAC
HBr/pseudoephedrine HCl guaifenesin/dextromethorphan	Entre-Cough
HBr/pseudoephedrine HCl	Lifti e-cough
guaifenesin/dextromethorphan	ExeFen DMX
HBr/pseudoephedrine HCl	LACI CII DIVIA
guaifenesin/dextromethorphan	Pecgen PSE
HBr/pseudoephedrine HCl	i ecgen i Je
guaifenesin/dextromethorphan	Poly-Vent DM
HBr/pseudoephedrine HCl	1 diy-vent bivi
guaifenesin/dextromethorphan	Robafen CF
HBr/pseudoephedrine HCl	Nobulcii di
guaifenesin/dextromethorphan	TRISPEC PSE
HBr/pseudoephedrine HCl	
guaifenesin/dextromethorphan	Tusnel DMPediatric(pseudoeph)
HBr/pseudoephedrine HCl	, , , , , , , , , , , , , , , , , , , ,
guaifenesin/dextromethorphan	Tusnel New Formula
HBr/pseudoephedrine HCl	
guaifenesin/dextromethorphan	Tusnel Pediatric
HBr/pseudoephedrine HCl	
guaifenesin/dextromethorphan	Tussin CF
HBr/pseudoephedrine HCl	
guaifenesin/dextromethorphan	Z-Cof 12 DM
HBr/pseudoephedrine HCl	
guaifenesin/dyphylline	Difil-G 400
guaifenesin/ephedrine HCl	Primatene Asthma
guaifenesin/hydrocodone bitartrate	Flowtuss
guaifenesin/hydrocodone bitartrate	Obredon

cder\_mpl2r\_wp016 Page 226 of 247



guaifenesin/hydrocodone bitartrate guaifenesin/phenylephrine HCI g	Generic Name	Brand Name
guaifenesin/phenylephrine HCl acetaminophen guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/ph		
guaifenesin/phenylephrine HCl guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/phenylep		· · · · · · · · · · · · · · · · · · ·
guaifenesin/phenylephrine HCI guaifenesin/phenylephrine HCI/acetaminophen guaifenesin/ph	_	
guaifenesin/phenylephrine HCl guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/phenylephrine HCl/acetam		
guaifenesin/phenylephrine HCl guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/phenylephrin	_	
guaifenesin/phenylephrine HCI guaifenesin/phenylephrine HCI/acetaminophen guaifene		
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guaifenesin/phenylephrine HCl guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/phenylephrine HC		
guaifenesin/phenylephrine HCl guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/ph		=
guaifenesin/phenylephrine HCl guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/phenylephrine HCl/acetaminophe		·
guaifenesin/phenylephrine HCI guaifenesin/phenylephrine HCI/acetaminophen gu		
guaifenesin/phenylephrine HCl guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/phenylephrine HCl/acet		
guaifenesin/phenylephrine HCI guaifenesin/phenylephrine HCI/acetaminophen guai		•
guaifenesin/phenylephrine HCl acetaminophen guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/phenylephrine HCl/acetam		
guaifenesin/phenylephrine HCl guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/phenylephrine HCl/acetam		
guaifenesin/phenylephrine HCl guaifenesin/phenylephrine HCl/acetaminophen guaifenesi		·
guaifenesin/phenylephrine HCl guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/phenylephrine HCl/acetaminop		
guaifenesin/phenylephrine HCl guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/pseudoephedrine HCl Congest-Eze guaifenesin/pseudoephedrin		•
guaifenesin/phenylephrine HCl guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/		•
guaifenesin/phenylephrine HCl guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/phenylephrine HCl/acetaminophe		•
guaifenesin/phenylephrine HCl guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/ph		
guaifenesin/phenylephrine HCI guaifenesin/phenylephrine HCI/acetaminophen		
guaifenesin/phenylephrine HCI guaifenesin/phenylephrine HCI/acetaminophen guaifenesin/pseudoephedrine HCI Ambi 60PSE-400GFN Congestac guaifenesin/pseudoephedrine HCI Congestac guaifenesin/pseudoephedrine HCI Congestac guaifenesin/pseudoephedrine HCI Congestac guaifenesin/pseudoephedrine HCI Despec-Tab		
guaifenesin/phenylephrine HCl guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/pseudoephedrine HCl Ambi 60PSE-400GFN Chest Congestion Relief D Guaifenesin/pseudoephedrine HCl Congest-Eze guaifenesin/pseudoephedrine HCl Despec-Tab		
guaifenesin/phenylephrine HCl guaifenesin/phenylephrine HCl guaifenesin/phenylephrine HCl guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/pseudoephedrine HCl Ambi 60PSE-400GFN Chest Congestion Relief D guaifenesin/pseudoephedrine HCl Congest-Eze guaifenesin/pseudoephedrine HCl Despec-Tab		
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guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/pseudoephedrine HCl Ambi 60PSE-400GFN  guaifenesin/pseudoephedrine HCl Congest-Eze guaifenesin/pseudoephedrine HCl Congest-Eze guaifenesin/pseudoephedrine HCl Despec-Tab		
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guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/pseudoephedrine HCl		Mucinex Sinus-MaxPressur-Pain
guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/pseudoephedrine HCl Despec-Tab		<del>-</del>
guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/pseudoephedrine HCl Despec-Tab		
guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/pseudoephedrine HCl guaifenesin/pseudoephedrine HCl guaifenesin/pseudoephedrine HCl guaifenesin/pseudoephedrine HCl guaifenesin/pseudoephedrine HCl guaifenesin/pseudoephedrine HCl Gongest-Eze guaifenesin/pseudoephedrine HCl Despec-Tab	guaifenesin/phenylephrine HCl/acetaminophen	Mucus ReliefSinusPressur-Pain
guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/pseudoephedrine HCl Despec-Tab	guaifenesin/phenylephrine HCl/acetaminophen	Mucus RIf Severe SinusCongest
guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/pseudoephedrine HCl Despec-Tab	guaifenesin/phenylephrine HCl/acetaminophen	
guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/pseudoephedrine HCl Despec-Tab	guaifenesin/phenylephrine HCl/acetaminophen	Severe Congestion Relief
guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/pseudoephedrine HCl Despec-Tab	guaifenesin/phenylephrine HCl/acetaminophen	Severe Sinus
guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/pseudoephedrine HCl Despec-Tab	guaifenesin/phenylephrine HCl/acetaminophen	Sinus Congestion-Pain(guaif)
guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/pseudoephedrine HCl Despec-Tab	guaifenesin/phenylephrine HCl/acetaminophen	Sinus Relief Pressure andPain
guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/pseudoephedrine HCl Despec-Tab	guaifenesin/phenylephrine HCl/acetaminophen	Sinus Relief SevereCongestion
guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/pseudoephedrine HCl Despec-Tab	guaifenesin/phenylephrine HCl/acetaminophen	Sudafed PEPressure-Pain-Mucus
guaifenesin/phenylephrine HCl/acetaminophen guaifenesin/pseudoephedrine HCl Despec-Tab	guaifenesin/phenylephrine HCl/acetaminophen	Tylenol Cold Head CongestSevr
guaifenesin/pseudoephedrine HCl Despec-Tab	guaifenesin/phenylephrine HCl/acetaminophen	Tylenol Sinus CongestionPain
guaifenesin/pseudoephedrine HCl Despec-Tab	guaifenesin/phenylephrine HCl/acetaminophen	Tylenol Sinus Severe
guaifenesin/pseudoephedrine HCl Chest Congestion Relief D guaifenesin/pseudoephedrine HCl Congest-Eze guaifenesin/pseudoephedrine HCl Congestac guaifenesin/pseudoephedrine HCl Despec-Tab		Ambi 60PSE-400GFN
guaifenesin/pseudoephedrine HCl Congest-Eze guaifenesin/pseudoephedrine HCl Congestac guaifenesin/pseudoephedrine HCl Despec-Tab		Chest Congestion Relief D
guaifenesin/pseudoephedrine HCl Congestac guaifenesin/pseudoephedrine HCl Despec-Tab		
guaifenesin/pseudoephedrine HCl Despec-Tab		
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		Entex T

cder\_mpl2r\_wp016 Page 227 of 247



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	Hydrocodone Compound
methylbromide	,
hydrocodone bitartrate/homatropine	Hydromet
methylbromide	•
hydrocodone bitartrate/homatropine	Tussigon
methylbromide	Ü
hydrocodone bitartrate/homatropine	hydrocodone-homatropine
methylbromide	7
hydrocodone bitartrate/pseudoephedrine	Hycofenix
HCl/guaifenesin	,
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	Novacort (with aloe)
polysaccharide	
hydrocortisone acetate/pramoxine HCI/emollient	Pramosone E
base	
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
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cder\_mpl2r\_wp016 Page 228 of 247



Generic Name	Brand Name
hydrocortisone/aloe vera	hydrocortisone-aloe vera
hydrocortisone/aloe vera/vitamin E	Anti-Itch (HC) with Aloe-Vit E
acetate/vitamins A and D	( -,
hydrocortisone/aloe vera/vitamin E	Anti-Itch Plus
acetate/vitamins A and D	
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 ipratropium bromide/albuterol sulfate	Combivent Respimat 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

cder\_mpl2r\_wp016 Page 229 of 247



	<u>.</u>
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, Nasal Decongest
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  Madral
methylprednisolone	Medral (Pak)
methylprednisolone	Methylared DR
methylprednisolone	Methylpred DP
methylprednisolone	methylprednisolone
methylprednisolone acetate	Depo-Medrol  P. Caro D40
methylprednisolone acetate	P-Care D40
methylprednisolone acetate	P-Care D80  Poody/SharpMothylprodpicologo
methylprednisolone acetate	ReadySharpMethylprednisolone
methylprednisolone acetate	methylprednisolone acetate

cder\_mpl2r\_wp016 Page 230 of 247



Generic Name	Brand Name
methylprednisolone acetate in sodium	methylpredac(PF)-NaCl,iso-osm
chloride.iso-osmotic/PF	,, , , , ,
methylprednisolone acetate in sterile water for	methylprednisoloneacet-water
injection	
methylprednisolone acetate/bupivacaine HCl	Physicians EZ Use M-Pred
methylprednisolone acetate/bupivacaine HCl in	methylprednisolac-bupivac-wat
sterile water	
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 HCI/acetaminophen	AcetaminophenCongestion-Pain
phenylephrine HCI/acetaminophen	Contac Cold-Flu Day
phenylephrine HCl/acetaminophen	DayTime Sinus
phenylephrine HCl/acetaminophen	Daytime Sinus-Congestion
phenylephrine HCI/acetaminophen	Mapap Sinus Max Strength(PE)
phenylephrine HCI/acetaminophen	Non-Aspirin Sinus
phenylephrine HCl/acetaminophen	Pain Relief Sinus PE
phenylephrine HCI/acetaminophen	Pyrroxate Cold andCongestion

cder\_mpl2r\_wp016 Page 231 of 247



Generic Name	Brand Name
phenylephrine HCI/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	Allergy Multi-Symptom
HCI/acetaminophen/chlorpheniramine	
phenylephrine	Allergy Relief Multi-Symptom
HCI/acetaminophen/chlorpheniramine	
phenylephrine	Allergy Relief(chlorphen-acet)
HCI/acetaminophen/chlorpheniramine	
phenylephrine	Allergy Sinus PE
HCI/acetaminophen/chlorpheniramine	
phenylephrine	Contac Cold-Flu Day andNight
HCI/acetaminophen/chlorpheniramine	
phenylephrine	Contac Cold-Flu Max Strength
HCI/acetaminophen/chlorpheniramine	
phenylephrine	Dristan Cold
HCI/acetaminophen/chlorpheniramine	
phenylephrine	Effervescent Cold Relief Plus
HCI/acetaminophen/chlorpheniramine	
phenylephrine	Medicidin-D
HCI/acetaminophen/chlorpheniramine	
phenylephrine	Norel AD
HCI/acetaminophen/chlorpheniramine	
phenylephrine	Sinus Congest-PainDay-Night
HCI/acetaminophen/chlorpheniramine	
phenylephrine	SinusCongestion-Pain(chlorph)
HCI/acetaminophen/chlorpheniramine	
phenylephrine	Sinutrol PE
HCI/acetaminophen/chlorpheniramine	
phenylephrine HCI/acetaminophen/doxylamine	DayTime and NiteTime Sinus
succinate	
phenylephrine HCI/acetaminophen/doxylamine	NightTime Sinus
succinate	
phenylephrine HCI/acetaminophen/doxylamine	Nighttime Sinus-Congestion
succinate	
phenylephrine HCI/acetaminophen/doxylamine	Sinus Daytime-Nightime
succinate	Art I at the
phenylephrine HCI/acetaminophen/doxylamine	Vicks Nyquil Sinex
succinate	Will of a day by a
phenylephrine HCI/acetaminophen/doxylamine	Vicks QlearQuil NightimeSinus
succinate	Departments Deplicable
phenylephrine HCl/chlophedianol HCl/guaifenesin	Donatussin Pediatric
phenylephrine HCI/chlophedianol HCI/guaifenesin	Vanacof GPE

cder\_mpl2r\_wp016 Page 232 of 247



Generic Name	Brand Name
phenylephrine HCl/chlophedianol HCl/guaifenesin	phenylephrine-chlophedianol-GG
phenylephrine HCl/codeine	Phenflu CD
phosphate/acetaminophen/guaifen	pl (I opy
phenylephrine HCI/codeine	Phenflu CDX
phosphate/acetaminophen/guaifen	Children's Cold Cough Core
phenylephrine HCl/dextromethorphan	Children's Cold-Cough-Sore
HBr/acetaminophen/guaifen ohenylephrine HCl/dextromethorphan	Children's MucinexCold-Fever
HBr/acetaminophen/guaifen	Cilidren 3 Muchiexcolu-i evel
phenylephrine HCI/dextromethorphan	Cold Head Congestion SeverDay
HBr/acetaminophen/guaifen	cold fredd colligesdoll severbay
phenylephrine HCl/dextromethorphan	Cold Severe Congestion
HBr/acetaminophen/guaifen	ŭ
phenylephrine HCI/dextromethorphan	Cold and Flu Severe
HBr/acetaminophen/guaifen	
phenylephrine HCl/dextromethorphan	Cold-Cough Sinus Relief PE
HBr/acetaminophen/guaifen	
phenylephrine HCI/dextromethorphan	Decorel Forte Plus
HBr/acetaminophen/guaifen	
phenylephrine HCI/dextromethorphan	Delsym Cough-Cold Daytime
HBr/acetaminophen/guaifen	
phenylephrine HCl/dextromethorphan	Dometuss G
HBr/acetaminophen/guaifen	Fast Mucus Relief SevereCold
phenylephrine HCl/dextromethorphan	rast iviucus keilei severecolu
HBr/acetaminophen/guaifen bhenylephrine HCl/dextromethorphan	Head Congestion Cold Relief
HBr/acetaminophen/guaifen	ricua congestion cola nellei
phenylephrine HCl/dextromethorphan	Herbiomed Severe Cold-FluM-S
HBr/acetaminophen/guaifen	
phenylephrine HCl/dextromethorphan	Mucinex Cold,Flu,Sore Throat
HBr/acetaminophen/guaifen	
phenylephrine HCl/dextromethorphan	Mucinex Fast-MaxCold-Flu-Thrt
HBr/acetaminophen/guaifen	
phenylephrine HCI/dextromethorphan	Mucinex Fast-Max SevereCold
HBr/acetaminophen/guaifen	
phenylephrine HCI/dextromethorphan	Mucinex Sinus-MaxPressure-Cgh
HBr/acetaminophen/guaifen	Advairant Circus Adam Can Canad DAA
phenylephrine HCI/dextromethorphan	Mucinex Sinus-Max SevCong(DM)
HBr/acetaminophen/guaifen phenylephrine HCl/dextromethorphan	Mucus Relief Cold-Flu-SoreThr
HBr/acetaminophen/guaifen	Mucus Nellel Colu-Hu-Sole IIII
phenylephrine HCI/dextromethorphan	Mucus Relief Plus
HBr/acetaminophen/guaifen	Madas Nellet Flas
phenylephrine HCI/dextromethorphan	Mucus Relief SevCongest-Cold
HBr/acetaminophen/guaifen	ŭ
phenylephrine HCl/dextromethorphan	Mucus Relief Severe Cold
HBr/acetaminophen/guaifen	
phenylephrine HCI/dextromethorphan	Multi-Symptom Cold (PE)
HBr/acetaminophen/guaifen	
phenylephrine HCl/dextromethorphan	Non-Pseudo Cold Relief
HBr/acetaminophen/guaifen	

cder\_mpl2r\_wp016 Page 233 of 247



Generic Name	Brand Name
phenylephrine HCl/dextromethorphan	Pain Relief Cold
HBr/acetaminophen/guaifen phenylephrine HCl/dextromethorphan	Pressure-Pain PE Plus Cold
HBr/acetaminophen/guaifen phenylephrine HCl/dextromethorphan	Pressure-Pain-Cold
HBr/acetaminophen/guaifen phenylephrine HCl/dextromethorphan	Rompe Pecho Max MultiSymptoms
HBr/acetaminophen/guaifen phenylephrine HCl/dextromethorphan	Severe Cold
HBr/acetaminophen/guaifen phenylephrine HCl/dextromethorphan	Severe Cold Multi-Symptom
HBr/acetaminophen/guaifen phenylephrine HCl/dextromethorphan	Severe Cold and Flu (PE)
HBr/acetaminophen/guaifen phenylephrine HCl/dextromethorphan	Sudafed PEPressure-Pain-Cold
HBr/acetaminophen/guaifen phenylephrine HCI/dextromethorphan	Tussin CF Max Severe M-SCold
HBr/acetaminophen/guaifen phenylephrine HCl/dextromethorphan	Tylenol Cold and Flu Severe
HBr/acetaminophen/guaifen phenylephrine HCl/dextromethorphan	Vicks DayQuil SevereCold-Flu
HBr/acetaminophen/guaifen phenylephrine HCl/dextromethorphan	Wal-Phed PE Cold-Cough
HBr/acetaminophen/guaifen phenylephrine HCl/dextromethorphan	Wal-Phed PEPressure+Pain+Cold
HBr/acetaminophen/guaifen	
phenylephrine HCl/diphenhydramine HCl	Allews and Giron Bellinf
phenylephrine HCl/diphenhydramine HCl	Allergy and Sinus Relief
phenylephrine HCl/diphenhydramine HCl phenylephrine HCl/diphenhydramine HCl	Child Allergy Plus Congestion 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 HCI/diphenhydramine HCI	Dimetapp Cold-Congestion
phenylephrine HCI/diphenhydramine HCI	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 HCI/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 HCI/pyrilamine maleate	pyrilamine-phenylephrine
phenylephrine HCI/triprolidine HCI	Histex PE
phenylephrine HCI/triprolidine HCI	Sinus Nighttime
prednisolone	Millipred
prednisolone	Millipred DP
prednisolone	Prelone
prednisolone	prednisolone

cder\_mpl2r\_wp016 Page 234 of 247



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 HCI/codeine	promethazine-codeine
promethazine HCI/dextromethorphan HBr	promethazine-DM
promethazine/phenylephrine HCI/codeine	Promethazine VC-Codeine
promethazine/phenylephrine HCl/codeine	promethazine-phenyleph-codeine
pseudoephedrine HCI/acetaminophen	Nexafed Sinus Pressure-Pain
pseudoephedrine HCI/acetaminophen	Sinus HeadacheDegongestant
pseudoephedrine	Allergy Sinus-D
HCI/acetaminophen/chlorpheniramine	-
pseudoephedrine	Non-Aspirin Allergy Sinus
HCI/acetaminophen/chlorpheniramine	
pseudoephedrine	Non-Aspirin Child's Cold
HCI/acetaminophen/chlorpheniramine	Daire Dalisa on Allegary Circus
pseudoephedrine	Pain Reliever Allergy Sinus
HCl/acetaminophen/chlorpheniramine	Community D
pseudoephedrine HCl/acrivastine	Semprex-D
pseudoephedrine HCl/chlophedianol HCl	Rondec-D Certuss-D
pseudoephedrine HCl/chlophedianol	Certuss-D
HCl/guaifenesin	Vanacof DX
pseudoephedrine HCl/chlophedianol	Valiacoi DX
HCI/guaifenesin	Vanatab DX
pseudoephedrine HCl/chlophedianol	valiatad DV
HCl/guaifenesin pseudoephedrine HCl/chlorpheniramine	Respa-AR
maleate/bellad alk	·
pseudoephedrine HCI/codeine phosphate	Codar D
pseudoephedrine HCl/codeine	Maxiflu CD
phosphate/acetaminophen/guaifen	
pseudoephedrine HCl/codeine	Maxiflu CDX
phosphate/acetaminophen/guaifen	
pseudoephedrine HCI/codeine	Cheratussin DAC
phosphate/guaifenesin	
pseudoephedrine HCI/codeine	Coditussin DAC
phosphate/guaifenesin	
pseudoephedrine HCI/codeine	Guaifenesin DAC
phosphate/guaifenesin	
pseudoephedrine HCI/codeine	Lortuss EX
phosphate/guaifenesin	

cder\_mpl2r\_wp016 Page 235 of 247



Generic Name	Brand Name
pseudoephedrine HCI/codeine	Phenylhistine
phosphate/guaifenesin	. nenymoune
pseudoephedrine HCl/codeine	Tricode GF
phosphate/guaifenesin	
pseudoephedrine HCl/codeine	Tusnel C
phosphate/guaifenesin	
pseudoephedrine HCI/codeine	Virtussin DAC
phosphate/guaifenesin	
pseudoephedrine HCI/codeine	Zodryl DEC 25
phosphate/guaifenesin	7
pseudoephedrine HCl/codeine	Zodryl DEC 30
phosphate/guaifenesin pseudoephedrine HCl/codeine	Zodryl DEC 35
phosphate/guaifenesin	Zodi yi DEC 33
pseudoephedrine HCl/codeine	Zodryl DEC 40
phosphate/guaifenesin	2001)1 220 10
pseudoephedrine HCI/codeine	Zodryl DEC 50
phosphate/guaifenesin	•
pseudoephedrine HCl/codeine	Zodryl DEC 60
phosphate/guaifenesin	
pseudoephedrine HCI/codeine	Zodryl DEC 80
phosphate/guaifenesin	
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 VanaCof AC
pyrilamine maleate/chlophedianol HCl pyrilamine maleate/chlophedianol HCl	VanaTab AC
pyrilamine maleate/chlophedianol HCl	Vanacof-8
pyrilamine maleate/chlophedianol	Ninjacof-A
HCI/acetaminophen	Timpacot / C
pyrilamine maleate/dextromethorphan HBr	Capron DM
pyrilamine maleate/dextromethorphan HBr	Capron DMT
pyrilamine maleate/phenylephrine	Pro-Chlo
HCI/chlophedianol HCI	
pyrilamine maleate/phenylephrine	Codituss DM
HCI/dextromethorphan HBr	
pyrilamine maleate/pseudoephedrine	Ninjacof-D
HCI/chlophedianol HCI	A 11 6 : D 6!!
racepinephrine HCl	Asthmanefrin Refill
racepinephrine HCl	Asthmanefrin Starter Kit
racepinephrine HCI	S2 Racepinephrine
racepinephrine HCl racepinephrine HCl	racepinephrine racepinephrine (bulk)
reslizumab	Cingair
revefenacin	Yupelri
roflumilast	Daliresp
salmeterol xinafoate	Serevent Diskus
terbutaline sulfate	terbutaline
theophylline anhydrous	Elixophyllin
theophylline anhydrous	Theo-24

cder\_mpl2r\_wp016 Page 236 of 247



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	Vanacof APE
HCI/chlophedianol HCI	Valiacol Al L
thonzylamine HCl/phenylephrine	Poly-Hist DM (thonzylamine)
HCI/dextromethorphan HBr	
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	Elizia Pak
triamcinolone acetonide/dimethicone/silicone,	DermaSilkRx SDS
adhesive	Der madmin obd
triamcinolone acetonide/dimethicone/silicone,	DermaWerx SDS
adhesive	
triamcinolone acetonide/dimethicone/silicone,	DermacinRx SilaPak
adhesive	
triamcinolone acetonide/dimethicone/silicone,	NuTriaRx
adhesive triamcinolone acetonide/dimethicone/silicone,	SanaDermRx
adhesive	Saliabellilix
triamcinolone acetonide/dimethicone/silicone,	Sure Result Tac Pak
adhesive	
triamcinolone acetonide/dimethicone/silicone,	Tri-Sila
adhesive	
triamcinolone acetonide/dimethicone/silicone,	Whytederm TDPak
adhesive	
triamcinolone acetonide/dimethicone/silicone,	Whytederm Trilasil Pak
adhesive	
triamcinolone acetonide/emollient combination	Pediaderm TA
no.45	

cder\_mpl2r\_wp016 Page 237 of 247



Generic Name	Brand Name
triamcinolone acetonide/emollient combination	Dermasorb TA Complete Kit
no.86	·
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	triamcinolonedia(PF)-0.9%NaCl
chloride/PF	• •
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	P-Care K40G
(HFC 245fa)	
triamcinolone/norflurane and pentafluoropropane	P-Care K80G
(HFC 245fa)	
triamcinolone/norflurane and pentafluoropropane	Pod-Care 100KG
(HFC 245fa)	
triamcinolone/norflurane and pentafluoropropane	Triloan II SUIK
(HFC 245fa)	
triamcinolone/norflurane and pentafluoropropane	Triloan SUIK
(HFC 245fa)	
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	Histex-AC
phosphate	
triprolidine HCl/phenylephrine	Histex DM
HCI/dextromethorphan HBr	
triprolidine HCI/pseudoephedrine HCI	Aprodine
triprolidine HCI/pseudoephedrine	Trymine CD
HCI/chlophedianol HCI	
umeclidinium bromide	Incruse Ellipta
umeclidinium bromide/vilanterol trifenatate	Anoro Ellipta
zafirlukast	Accolate
zafirlukast	zafirlukast
zileuton	Zyflo
zileuton	Zyflo CR
zileuton	zileuton
Nonsteroidal Anti-Inf	Jammatory Drugs

#### Nonsteroidal Anti-Inflammatory Drugs

CHLORPHENIRAMINE Advil Allergy-Congestion Rlf

MALEATE/PHENYLEPHRINE HCL/IBUPROFEN

CHLORPHENIRAMINE

MALEATE/PSEUDOEPHEDRINE

HCI /IBUPROFFN

**Advil Allergy Sinus** 

cder\_mpl2r\_wp016 Page 238 of 247



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	Aleve Cold and Sinus
HCL	Aleve Cold and Sinds
NAPROXEN SODIUM/PSEUDOEPHEDRINE	Aleve Sinus and Headache
HCL NAPROXEN SODIUM/PSEUDOEPHEDRINE	Aleve-D Sinus and Cold
HCL NAPROXEN SODIUM/PSEUDOEPHEDRINE	Aleve-D Sinus and Headache
HCL	, 10.00 2 0.1100 0.1100 0.1100
NAPROXEN SODIUM/PSEUDOEPHEDRINE	All Day Pain Relief Sinus,Cold
HCL	
NAPROXEN SODIUM/PSEUDOEPHEDRINE	Sinus and Cold-D
HCL	
OXAPROZIN	oxaprozin
PIROXICAM	piroxicam
SUMATRIPTAN SUCCINATE/NAPROXEN	Treximet
SODIUM	
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

cder\_mpl2r\_wp016 Page 239 of 247



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

Generic NameBrand NameflurbiprofenAnsaidibuprofenAdvilibuprofenAdvil Liqui-GelibuprofenAdvil MigraineibuprofenChild IbuprofenibuprofenChildren's AdvilibuprofenChildren's Medi-ProfenibuprofenChildren's MotrinibuprofenChildren's Profen IBibuprofenI-PrinibuprofenIBUibuprofenIBU-200ibuprofenIbu-DropsibuprofenInfant's AdvilibuprofenInfant's Medi-ProfenibuprofenInfant's Medi-ProfenibuprofenInfant's MotrinibuprofenInfant's MotrinibuprofenInfants ProfenIBibuprofenInfants ProfenIB
ibuprofen
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ibuprofen
ibuprofen
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 IBU ibuprofen IBU-200 ibuprofen Ibu-Drops ibuprofen Infant's Advil ibuprofen Infant's Medi-Profen ibuprofen Infant's Motrin ibuprofen Infants ProfenIB
ibuprofen IBU-200 ibuprofen Ibu-Drops ibuprofen Infant's Advil ibuprofen Infant's Medi-Profen ibuprofen Infant's Motrin ibuprofen Infants ProfenIB
ibuprofen Ibu-Drops ibuprofen Infant's Advil ibuprofen Infant's Medi-Profen ibuprofen Infant's Motrin ibuprofen Infants ProfenIB
ibuprofenInfant's AdvilibuprofenInfant's Medi-ProfenibuprofenInfant's MotrinibuprofenInfants ProfenIB
ibuprofen Infant's Medi-Profen ibuprofen Infant's Motrin ibuprofen Infants ProfenIB
ibuprofen Infant's Motrin Infants ProfenIB
ibuprofen Infants ProfenIB
·
ibuprofen Motrin iB
The second secon
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)

cder\_mpl2r\_wp016 Page 240 of 247



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

cder\_mpl2r\_wp016 Page 241 of 247



#### **Appendix H. Specifications Defining Parameters for this Request**

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

Query Period: July 7, 2015 - Februrary 29, 2020

**Coverage Requirement:** Medical and drug coverage

**Enrollment Requirement:** 183 days **Enrollment Gap:** 45 days

Age Groups: 18-44, 45-54, 55-64, 65+ years

Output Requested: Attrition table, Kaplan-Meier curves

	No prior comparator use; angioedema			No prior comparator use; angioedema Gap sensitivity analysis				No prior comparator use; serious angioedema					
	Comparison 1		Comparison 2		Comparison 3		Comparison 4		Comparison 5		Comparison 6		
Drug/Exposure					•								
Exposure/ Comparator	Sacubitril/ Valsartan (SV)	Angiotensin- converting enzyme inhibitors	SV	Angiotensin II receptor blockers (ARBs)	SV	ACEI	SV	ARBs	SV	ACEI	SV	ARBs	
Incident with Respect to:	ACEI, ARBs, SV		ACEI, ARBs, SV		ACEI, ARBs, SV		ACEI, ARBs, SV		ACEI, ARBs, SV		ACEI, ARBs, SV		
Incidence Assessment	Dispensing date or days supply		Dispensing date or days supply		Dispensing date or days supply		Dispensing date or days supply		Dispensing date or days supply		Dispensing date or days supply		
Washout (days)	183		183		183		183		183				
Cohort Definition	First valid incident exposure episode			dent exposure sode	First valid incident exposure episode		First valid incident exposure episode		First valid incident exposure episode		First valid incident exposure episode		
Stockpiling overlapping claims	Default		Def	ault	Default		Default		Default		Default		
Episode Gap (days)	14		14		7		7	14		14			
Episode Extension Period (days)	14		1	14		7		7		14		14	
Maximum Episode Duration (days)	36	55	3	65	365		365		365		365		

cder\_mpl2r\_wp016 Page 242 of 247



Appendix H. Specifications Defining Parameters for this Request

	No prior comparator use; angioedema			No prior comparator use; angioedema Gap sensitivity analysis				No prior comparator use; serious angioedema				
	Compa	rison 1	Compa	rison 2	Compa	rison 3	Compa	arison 4	Compa	rison 5	Compa	rison 6
Censor Criteria	ACEI	SV	ARBs	SV	ACEI	SV	ARBs	SV	ACEI	SV	ARBs	SV
	ARBs, end o	f treatment,	ACEI, end of	f treatment,	ARBs, end o	f treatment,	ACEI, end o	f treatment,	ARBs, end o	f treatment,	ACEI, end o	f treatment,
		ccurrence,		ccurrence,		ccurrence,		occurrence,	outcome c	•	outcome c	•
		nt, recorded	disenrollme	•		nt, recorded		nt, recorded		nt, recorded		nt, recorded
	death, dat	a end date	death, dat	a end date	death, dat	a end date	death, dat	a end date	death, dat	a end date	death, dat	a end date
Inclusion/Exclusion												
Pre-Existing Condition	Heart	failure	Heart	failure	Heart	failure	Heart	failure	Heart	failure	Heart	failure
Include/Exclude	Incl	ude	Incl	ude	Incl	ude	Incl	ude	Incl	ude	Incl	ude
Lookback Period (days)	-18	3, 0	-18	3, 0	-18	3, 0	-18	3, 0	-18	3, 0	-18	3, 0
Pre-Existing Condition	ACEI, ARBs	SV, ARBs	ACEI, ARBs	SV, ACEI	ACEI, ARBs	SV, ARBs	ACEI, ARBs	SV, ACEI	ACEI, ARBs	SV, ARBs	ACEI, ARBs	SV, ACEI
Include/Exclude	Exclude	Exclude	Exclude	Exclude	Exclude	Exclude	Exclude	Exclude	Exclude	Exclude	Exclude	Exclude
Care Setting/ Primary Diagnosis	Any	Any	Any	Any	Any	Any	Any	Any	Any	Any	Any	Any
Lookback Period (dyas)	0	0	0	0	0	0	0	0	0	0	0	0
Inclusion Assessment	Dispensing date	Dispensing date	Dispensing date	Dispensing date	Dispensing date	Dispensing date	Dispensing date	Dispensing date	Dispensing date	Dispensing date	Dispensing date	Dispensing date

cder\_mpl2r\_wp016 Page 243 of 247



Appendix H. Specifications Defining Parameters for this Request

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

cder\_mpl2r\_wp016 Page 244 of 247



Appendix H. Specifications Defining Parameters for this Request

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

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

cder\_mpl2r\_wp016 Page 245 of 247



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

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

cder\_mpl2r\_wp016 Page 246 of 247



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

CovariateCovariate Evaluation WindowNumber of unique drug classes dispensed-183 to 0

cder\_mpl2r\_wp016 Page 247 of 247

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