

Disclaimer

The following report(s) provides findings from an FDA-initiated query using its Mini-Sentinel pilot. While Mini-Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Mini-Sentinel, and seeking to better understand the capabilities of the Mini-Sentinel pilot.

Data obtained through Mini-Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, post market 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 the Mini-Sentinel pilot in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Mini-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 to16_cap_mpl1r_wp034_nsdp_v01, Report 1 of 1

<u>Request Description</u>	This report contains the estimated rates of bradycardia and/or pacemaker insertion following use of sofosbuvir and amiodarone.
<u>Request ID</u>	to16_cap_mpl1r_wp034_nsdp_v01 Report 1 of 1
<u>Data Source</u>	Data from December 6, 2013 to July 15, 2015 from 15 health plans contributing to the Mini-Sentinel Distributed Database (MSDD) were included in this report. This request was distributed to Data Partners on July 29, 2015.
<u>Study Design</u>	This request was designed to identify exposures and follow-up time. The exposure of interest and the occurrence of the health outcome of interest during exposed time were identified. The number of exposure episodes, number of individuals, number of events, and days at-risk in the MSDD were calculated overall and were stratified by age group, sex, and year.
<u>Mini-Sentinel Modular Program</u>	Cohort Identification and Descriptive Analysis (CIDA) tool, version 2.0.8
<u>Tool Used</u>	
<u>Exposure of Interest</u>	The exposures of interest were sofosbuvir and amiodarone.
<u>Cohort Eligibility Criteria</u>	<p>There were three cohorts of interest:</p> <ol style="list-style-type: none"> 1. New sofosbuvir users with evidence of amiodarone use in the three months (ninety days) prior to or on the day of the exposure of interest. Individuals were also required to have no evidence of the drug of interest in the six months (one hundred and eighty-three days) prior to the dispensing of the drug of interest. Only the first valid incident treatment episode during the query period was included. 2. New amiodarone users with evidence of sofosbuvir use in the first month (thirty days) prior to or on the day of the exposure of interest. Individuals were also required to have no evidence of the drug of interest in the six months (one hundred and eighty-three days) prior to the dispensing of the drug of interest. Only the first valid incident treatment episode during the query period was included. 3. Prevalent amiodarone users. All valid treatment episodes during the query period were included. <p>Those included in each cohort were required to be continuously enrolled in plans with both medical and drug coverage for at least six months (one hundred and eighty-three days) before their dispensing date, during which gaps in coverage of up to forty-five days were allowed. Members were excluded if they had the outcome of interest in either the inpatient or emergency department care setting in the three months (ninety days) prior to the exposure of interest. Members were also excluded if they had a pacemaker or implantable cardioverter defibrillator in the six months (one hundred and eighty-three days) prior to the exposure of interest or if they had a diagnosis or treatment from hyperthyroidism or hypothyroidism in the six months (one hundred and eighty-three days) prior to or on the day of the exposure of interest. Exclusions were defined using National Drug Codes (NDCs), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis, ICD-9-CM Procedure, Current Procedural Terminology, Fourth Edition (CPT-4), and Healthcare Common Procedure Coding System (HCPCS) codes. When grouping by age/year some patients may have been double counted.</p>
<u>Follow-Up Time</u>	Follow-up began on the day the first prescription for the exposure of interest was dispensed, and continued until the first occurrence of any of the following: 1) the outcome of interest; 2) disenrollment; 3) the end of the query period (July 15, 2015); 4) the end of the data range provided by each Data Partner (see Appendix F); or 4) the end of the exposure episode. Sensitivity analyses were run to evaluate three different exposure episode lengths: 7 days, 14 days, and 30 days.
<u>Outcomes of Interest</u>	There were four outcome definitions of interest: 1) bradycardia; 2) a restricted definition of bradycardia; 3) pacemaker insertion; and 4) bradycardia or pacemaker insertion. The restricted definition of bradycardia outcome was assessed for the 14-day exposure episode only. Each outcome of interest was restricted to occurrences in either the inpatient or emergency department care setting and were defined by ICD-9-CM diagnosis codes, ICD-9-CM procedure codes, and CPT-4 codes. Please see Appendix B for specific codes used in each outcome definition.
<u>Limitations</u>	Algorithms to define exposures, exclusion criteria, and outcomes are imperfect and, therefore, may be misclassified.
<u>Notes</u>	Please contact the Sentinel Operations Center Query Fulfillment Team (qf@sentinelssystem.org) for questions and to provide comments/suggestions for future enhancements to this document.

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

- Amount Supplied** - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing. This is equivalent to the "RxAmt"
- Blackout Period** - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the
- Care Setting** - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or Missing (U). Along with the Principal Diagnosis Indicator, forms the Care Setting/PDX parameter.
- Cohort Definition (drug/exposure)**- indicates how the cohort will be defined: (1) 01: Cohort includes only the first valid incident treatment episode during the query period; (2) 02: Cohort includes all valid incident treatment episodes during the query period; (3) 03: Cohort includes all valid incident treatment episodes during the query period until an event occurs.
- Days Supplied** - number of days supplied for all dispensings in qualifying treatment episodes.
- Episodes** - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by
- Enrollment Gap** - number of days allowed between two consecutive enrollment periods without breaking a "continuously enrolled"
- Episode Gap** - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same
- Event Deduplication** - specifies how events are counted by the MP algorithm: (0) 0: Counts all occurrences of an HOI during an exposure episode; (1) 1: de-duplicates occurrences of the same HOI code and code type on the same day; (2) 2: de-duplicates occurrences of the
- Exposure Extension Period** - number of days post treatment period in which the outcomes/events are counted for a treatment episode.
- Exposure Episode Length** - number of days after exposure initiation that is considered "exposed time."
- Lookback Period (pre-existing condition)** - number of days wherein a member is required to have evidence of pre-existing condition
- 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.
- Principal Diagnosis (PDX)** - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the
- Query Period** - period in which the modular program looks for exposures and outcomes of interest.
- Treatment Episode Truncation Indicator** - indicates whether observation of the incident query code during follow-up requires truncation of valid treatment episodes. A value of Y indicates that the treatment episodes should be truncated at the first occurrence of an incident query code. A value of N indicates that the treatment episodes should not be truncated at the occurrence of the incident query code.
- Users** - number of members with exposure during the query period. Member must have no evidence of exposure(s) of interest (defined by incidence criteria) in the prior washout period. A user may only be counted once in a query period.
- Washout Period (drug/exposure)**** - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.
- Washout Period (event/outcome)**** - number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.
- Years at Risk** - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

*all terms may not be used in this report

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

Table 1: Sofosbuvir and Amiodarone Use and Bradycardia or Pacemaker Insertion Outcomes in the Mini-Sentinel Distributed Database (MSDD) Between December 6, 2013 and July 15, 2015, by Exposure, Outcome, and Episode Length

	New Users	New Episodes	Days Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member- Years	New Users / 100K Eligible Members	Days Supplied / User	Days Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 1K Years at Risk
Incident Sofosbuvir with Amiodarone in the Previous 90 Days														
<i>Bradycardia Events</i>														
7-Day Episode	4	4	4	28	28	0.1	0	51,698	18,140.7	7.74	7.00	1.00	7.00	0.00
14-Day Episode	4	4	4	56	56	0.2	0	51,698	18,140.7	7.74	14.00	1.00	14.00	0.00
30-Day Episode	4	4	4	92	92	0.3	0	51,698	18,140.7	7.74	23.00	1.00	23.00	0.00
<i>Restricted Bradycardia Definition Events</i>														
14-Day Episode	4	4	4	56	56	0.2	0	52,191	18,432.5	7.66	14.00	1.00	14.00	0.00
<i>Pacemaker Insertion Events</i>														
7-Day Episode	4	4	4	28	28	0.1	0	53,729	19,423.7	7.44	7.00	1.00	7.00	0.00
14-Day Episode	4	4	4	56	56	0.2	0	53,729	19,423.7	7.44	14.00	1.00	14.00	0.00
30-Day Episode	4	4	4	92	92	0.3	0	53,729	19,423.7	7.44	23.00	1.00	23.00	0.00
<i>Bradycardia or Pacemaker Insertion Events</i>														
7-Day Episode	4	4	4	28	28	0.1	0	51,698	18,140.7	7.74	7.00	1.00	7.00	0.00
14-Day Episode	4	4	4	56	56	0.2	0	51,698	18,140.7	7.74	14.00	1.00	14.00	0.00
30-Day Episode	4	4	4	92	92	0.3	0	51,698	18,140.7	7.74	23.00	1.00	23.00	0.00
Incident Amiodarone with Sofosbuvir in the Previous 30 Days														
<i>Bradycardia Events</i>														
7-Day Episode	3	3	3	21	70	0.1	0	6,726	1,341.2	44.60	7.00	1.00	7.00	0.00
14-Day Episode	3	3	3	42	140	0.1	0	6,726	1,341.2	44.60	14.00	1.00	14.00	0.00
30-Day Episode	3	3	3	90	300	0.2	0	6,726	1,341.2	44.60	30.00	1.00	30.00	0.00
<i>Restricted Bradycardia Definition Events</i>														
14-Day Episode	3	3	3	42	140	0.1	0	6,727	1,343.6	44.60	14.00	1.00	14.00	0.00
<i>Pacemaker Insertion Events</i>														
7-Day Episode	5	5	5	35	91	0.1	0	6,733	1,349.6	74.26	7.00	1.00	7.00	0.00
14-Day Episode	5	5	5	70	182	0.2	0	6,733	1,349.6	74.26	14.00	1.00	14.00	0.00
30-Day Episode	5	5	5	143	376	0.4	0	6,733	1,349.6	74.26	28.60	1.00	28.60	0.00
<i>Bradycardia or Pacemaker Insertion Events</i>														
7-Day Episode	3	3	3	21	70	0.1	0	6,726	1,341.2	44.60	7.00	1.00	7.00	0.00
14-Day Episode	3	3	3	42	140	0.1	0	6,726	1,341.2	44.60	14.00	1.00	14.00	0.00
30-Day Episode	3	3	3	90	300	0.2	0	6,726	1,341.2	44.60	30.00	1.00	30.00	0.00

Prevalent Amiodarone														
<i>Bradycardia Events</i>														
7-Day Episode	41,186	114,282	114,282	786,821	985,629	2,156.2	465	38,778,617	21,999,791.6	106.21	19.10	2.77	6.88	215.66
14-Day Episode	41,157	113,499	113,499	1,531,607	1,906,150	4,208.4	835	38,778,617	21,997,757.3	106.13	37.21	2.76	13.49	198.41
30-Day Episode	37,526	74,816	74,816	2,048,861	2,590,848	5,714.9	1,132	38,778,617	21,996,191.9	96.77	54.60	1.99	27.39	198.08
<i>Restricted Bradycardia Definition Events</i>														
14-Day Episode	41,895	115,497	115,497	1,558,544	1,948,291	4,285.6	713	38,780,597	22,006,493.5	108.03	37.20	2.76	13.49	166.37
<i>Pacemaker Insertion Events</i>														
7-Day Episode	44,373	123,425	123,425	849,823	1,084,667	2,332.9	53	38,788,675	22,040,328.1	114.40	19.15	2.78	6.89	22.72
14-Day Episode	44,341	122,524	122,524	1,652,849	2,095,799	4,559.0	109	38,788,675	22,038,123.2	114.31	37.28	2.76	13.49	23.91
30-Day Episode	40,880	81,224	81,224	2,217,414	2,861,305	6,249.5	145	38,788,675	22,036,376.5	105.39	54.24	1.99	27.30	23.20
<i>Bradycardia or Pacemaker Insertion Events</i>														
7-Day Episode	41,186	114,282	114,282	786,821	985,629	2,156.2	467	38,778,617	21,999,791.6	106.21	19.10	2.77	6.88	216.59
14-Day Episode	41,157	113,499	113,499	1,531,607	1,906,150	4,208.3	846	38,778,617	21,997,757.3	106.13	37.21	2.76	13.49	201.03
30-Day Episode	37,526	74,816	74,816	2,048,861	2,590,848	5,714.4	1,150	38,778,617	21,996,191.9	96.77	54.60	1.99	27.39	201.24

Table 2: Sofosbuvir and Amiodarone Use and Bradycardia or Pacemaker Insertion Outcomes in the Mini-Sentinel Distributed Database (MSDD) Between December 6, 2013 and July 15, 2015, by Exposure, Outcome, Episode Length, and Age Group

	New Users	New Episodes	Days Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 100K Eligible Members	Days Supplied/ User	Days Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 1K Years at Risk
Incident Sofosbuvir with Amiodarone in the Previous 90 Days														
<i>Bradycardia Events</i>														
7-Day Episode														
0-17 Years	0	0	0	0	0	0.0	0	56	17.8	0.00	---	---	---	---
18-44 Years	0	0	0	0	0	0.0	0	819	218.9	0.00	---	---	---	---
45-64 Years	4	4	4	28	28	0.1	0	13,568	4,153.9	29.48	7.00	1.00	7.00	0.00
65+ Years	0	0	0	0	0	0.0	0	37,662	13,750.1	0.00	---	---	---	---
14-Day Episode														
0-17 Years	0	0	0	0	0	0.0	0	56	17.8	0.00	---	---	---	---
18-44 Years	0	0	0	0	0	0.0	0	819	218.9	0.00	---	---	---	---
45-64 Years	4	4	4	56	56	0.2	0	13,568	4,153.9	29.48	14.00	1.00	14.00	0.00
65+ Years	0	0	0	0	0	0.0	0	37,662	13,750.1	0.00	---	---	---	---
30-Day Episode														
0-17 Years	0	0	0	0	0	0.0	0	56	17.8	0.00	---	---	---	---
18-44 Years	0	0	0	0	0	0.0	0	819	218.9	0.00	---	---	---	---
45-64 Years	4	4	4	92	92	0.3	0	13,568	4,153.9	29.48	23.00	1.00	23.00	0.00
65+ Years	0	0	0	0	0	0.0	0	37,662	13,750.1	0.00	---	---	---	---
<i>Restricted Bradycardia Definition Events</i>														
14-Day Episode														
0-17 Years	0	0	0	0	0	0.0	0	56	17.9	0.00	---	---	---	---
18-44 Years	0	0	0	0	0	0.0	0	828	223.9	0.00	---	---	---	---
45-64 Years	4	4	4	56	56	0.2	0	13,678	4,218.2	29.24	14.00	1.00	14.00	0.00
65+ Years	0	0	0	0	0	0.0	0	38,039	13,972.6	0.00	---	---	---	---
<i>Pacemaker Insertion Events</i>														
7-Day Episode														
0-17 Years	0	0	0	0	0	0.0	0	59	20.8	0.00	---	---	---	---
18-44 Years	0	0	0	0	0	0.0	0	861	237.8	0.00	---	---	---	---
45-64 Years	4	4	4	28	28	0.1	0	14,077	4,430.6	28.42	7.00	1.00	7.00	0.00
65+ Years	0	0	0	0	0	0.0	0	39,159	14,734.5	0.00	---	---	---	---
14-Day Episode														
0-17 Years	0	0	0	0	0	0.0	0	59	20.8	0.00	---	---	---	---
18-44 Years	0	0	0	0	0	0.0	0	861	237.8	0.00	---	---	---	---
45-64 Years	4	4	4	56	56	0.2	0	14,077	4,430.6	28.42	14.00	1.00	14.00	0.00
65+ Years	0	0	0	0	0	0.0	0	39,159	14,734.5	0.00	---	---	---	---
30-Day Episode														
0-17 Years	0	0	0	0	0	0.0	0	59	20.8	0.00	---	---	---	---
18-44 Years	0	0	0	0	0	0.0	0	861	237.8	0.00	---	---	---	---
45-64 Years	4	4	4	92	92	0.3	0	14,077	4,430.6	28.42	23.00	1.00	23.00	0.00
65+ Years	0	0	0	0	0	0.0	0	39,159	14,734.5	0.00	---	---	---	---

Bradycardia or Pacemaker Insertion Events														
7-Day Episode														
0-17 Years	0	0	0	0	0	0.0	0	56	17.8	0.00	---	---	---	---
18-44 Years	0	0	0	0	0	0.0	0	819	218.9	0.00	---	---	---	---
45-64 Years	4	4	4	28	28	0.1	0	13,568	4,153.9	29.48	7.00	1.00	7.00	0.00
65+ Years	0	0	0	0	0	0.0	0	37,662	13,750.1	0.00	---	---	---	---
14-Day Episode														
0-17 Years	0	0	0	0	0	0.0	0	56	17.8	0.00	---	---	---	---
18-44 Years	0	0	0	0	0	0.0	0	819	218.9	0.00	---	---	---	---
45-64 Years	4	4	4	56	56	0.2	0	13,568	4,153.9	29.48	14.00	1.00	14.00	0.00
65+ Years	0	0	0	0	0	0.0	0	37,662	13,750.1	0.00	---	---	---	---
30-Day Episode														
0-17 Years	0	0	0	0	0	0.0	0	56	17.8	0.00	---	---	---	---
18-44 Years	0	0	0	0	0	0.0	0	819	218.9	0.00	---	---	---	---
45-64 Years	4	4	4	92	92	0.3	0	13,568	4,153.9	29.48	23.00	1.00	23.00	0.00
65+ Years	0	0	0	0	0	0.0	0	37,662	13,750.1	0.00	---	---	---	---
Incident Amiodarone with Sofosbuvir in the Previous 30 Days														
Bradycardia Events														
7-Day Episode														
0-17 Years	0	0	0	0	0	0.0	0	1	0.1	0.00	---	---	---	---
18-44 Years	0	0	0	0	0	0.0	0	619	121.8	0.00	---	---	---	---
45-64 Years	2	2	2	14	42	0.0	0	5,108	1,022.9	39.15	7.00	1.00	7.00	0.00
65+ Years	1	1	1	7	28	0.0	0	1,063	196.4	94.07	7.00	1.00	7.00	0.00
14-Day Episode														
0-17 Years	0	0	0	0	0	0.0	0	1	0.1	0.00	---	---	---	---
18-44 Years	0	0	0	0	0	0.0	0	619	121.8	0.00	---	---	---	---
45-64 Years	2	2	2	28	84	0.1	0	5,108	1,022.9	39.15	14.00	1.00	14.00	0.00
65+ Years	1	1	1	14	56	0.0	0	1,063	196.4	94.07	14.00	1.00	14.00	0.00
30-Day Episode														
0-17 Years	0	0	0	0	0	0.0	0	1	0.1	0.00	---	---	---	---
18-44 Years	0	0	0	0	0	0.0	0	619	121.8	0.00	---	---	---	---
45-64 Years	2	2	2	60	180	0.2	0	5,108	1,022.9	39.15	30.00	1.00	30.00	0.00
65+ Years	1	1	1	30	120	0.1	0	1,063	196.4	94.07	30.00	1.00	30.00	0.00
Restricted Bradycardia Definition Events														
14-Day Episode														
0-17 Years	0	0	0	0	0	0.0	0	1	0.1	0.00	---	---	---	---
18-44 Years	0	0	0	0	0	0.0	0	619	121.8	0.00	---	---	---	---
45-64 Years	2	2	2	28	84	0.1	0	5,109	1,024.8	39.15	14.00	1.00	14.00	0.00
65+ Years	1	1	1	14	56	0.0	0	1,063	196.9	94.07	14.00	1.00	14.00	0.00

Pacemaker Insertion Events														
7-Day Episode														
0-17 Years	0	0	0	0	0	0.0	0	1	0.1	0.00	---	---	---	---
18-44 Years	0	0	0	0	0	0.0	0	620	122.3	0.00	---	---	---	---
45-64 Years	4	4	4	28	63	0.1	0	5,114	1,029.0	78.22	7.00	1.00	7.00	0.00
65+ Years	1	1	1	7	28	0.0	0	1,063	198.2	94.07	7.00	1.00	7.00	0.00
14-Day Episode														
0-17 Years	0	0	0	0	0	0.0	0	1	0.1	0.00	---	---	---	---
18-44 Years	0	0	0	0	0	0.0	0	620	122.3	0.00	---	---	---	---
45-64 Years	4	4	4	56	126	0.2	0	5,114	1,029.0	78.22	14.00	1.00	14.00	0.00
65+ Years	1	1	1	14	56	0.0	0	1,063	198.2	94.07	14.00	1.00	14.00	0.00
30-Day Episode														
0-17 Years	0	0	0	0	0	0.0	0	1	0.1	0.00	---	---	---	---
18-44 Years	0	0	0	0	0	0.0	0	620	122.3	0.00	---	---	---	---
45-64 Years	4	4	4	113	256	0.3	0	5,114	1,029.0	78.22	28.25	1.00	28.25	0.00
65+ Years	1	1	1	30	120	0.1	0	1,063	198.2	94.07	30.00	1.00	30.00	0.00
Bradycardia or Pacemaker Insertion Events														
7-Day Episode														
0-17 Years	0	0	0	0	0	0.0	0	1	0.1	0.00	---	---	---	---
18-44 Years	0	0	0	0	0	0.0	0	619	121.8	0.00	---	---	---	---
45-64 Years	2	2	2	14	42	0.0	0	5,108	1,022.9	39.15	7.00	1.00	7.00	0.00
65+ Years	1	1	1	7	28	0.0	0	1,063	196.4	94.07	7.00	1.00	7.00	0.00
14-Day Episode														
0-17 Years	0	0	0	0	0	0.0	0	1	0.1	0.00	---	---	---	---
18-44 Years	0	0	0	0	0	0.0	0	619	121.8	0.00	---	---	---	---
45-64 Years	2	2	2	28	84	0.1	0	5,108	1,022.9	39.15	14.00	1.00	14.00	0.00
65+ Years	1	1	1	14	56	0.0	0	1,063	196.4	94.07	14.00	1.00	14.00	0.00
30-Day Episode														
0-17 Years	0	0	0	0	0	0.0	0	1	0.1	0.00	---	---	---	---
18-44 Years	0	0	0	0	0	0.0	0	619	121.8	0.00	---	---	---	---
45-64 Years	2	2	2	60	180	0.2	0	5,108	1,022.9	39.15	30.00	1.00	30.00	0.00
65+ Years	1	1	1	30	120	0.1	0	1,063	196.4	94.07	30.00	1.00	30.00	0.00
Prevalent Amiodarone														
Bradycardia Events														
7-Day Episode														
0-17 Years	48	163	163	1,122	5,819	3.1	2	8,125,911	4,563,823.8	0.59	23.38	3.40	6.88	651.07
18-44 Years	619	1,494	1,494	10,218	15,576	28.1	6	15,483,977	8,274,420.0	4.00	16.51	2.41	6.84	213.41
45-64 Years	10,416	28,302	28,302	194,238	265,561	532.9	89	11,338,749	6,257,124.9	91.86	18.65	2.72	6.86	167.01
65+ Years	30,324	84,323	84,323	581,243	698,673	1,592.1	368	4,633,869	2,904,422.9	654.40	19.17	2.78	6.89	231.14
14-Day Episode														
0-17 Years	48	151	151	2,021	10,782	5.5	3	8,125,911	4,563,821.3	0.59	42.10	3.15	13.38	545.15
18-44 Years	619	1,481	1,481	19,699	29,286	54.7	10	15,483,977	8,274,393.9	4.00	31.82	2.39	13.30	182.72
45-64 Years	10,412	28,184	28,184	377,741	513,127	1,040.3	147	11,338,749	6,256,622.7	91.83	36.28	2.71	13.40	141.30
65+ Years	30,299	83,683	83,683	1,132,146	1,352,955	3,107.9	675	4,633,865	2,902,919.5	653.86	37.37	2.76	13.53	217.19
30-Day Episode														
0-17 Years	34	54	54	1,461	6,890	4.1	1	8,125,911	4,563,822.5	0.42	42.97	1.59	27.06	246.79
18-44 Years	560	962	962	25,502	39,736	73.2	14	15,483,977	8,274,375.1	3.62	45.54	1.72	26.51	191.16
45-64 Years	9,313	17,686	17,686	475,506	672,840	1,340.1	193	11,338,747	6,256,307.4	82.13	51.06	1.90	26.89	144.02
65+ Years	27,782	56,114	56,114	1,546,392	1,871,382	4,297.5	924	4,633,860	2,901,686.9	599.54	55.66	2.02	27.56	215.01

Restricted Bradycardia Definition Events														
14-Day Episode														
0-17 Years	48	153	153	2,049	11,118	5.6	3	8,125,948	4,563,931.4	0.59	42.69	3.19	13.39	537.66
18-44 Years	635	1,514	1,514	20,127	30,059	56.0	9	15,484,187	8,275,127.7	4.10	31.70	2.38	13.29	160.80
45-64 Years	10,612	28,644	28,644	383,850	523,398	1,058.2	112	11,339,370	6,258,795.9	93.59	36.17	2.70	13.40	105.84
65+ Years	30,823	85,186	85,186	1,152,518	1,383,716	3,165.9	589	4,635,072	2,908,638.5	665.00	37.39	2.76	13.53	186.05
Pacemaker Insertion Events														
7-Day Episode														
0-17 Years	51	191	191	1,316	8,157	3.6	0	8,126,208	4,564,764.7	0.63	25.80	3.75	6.89	0.00
18-44 Years	687	1,635	1,635	11,183	17,091	30.8	0	15,485,950	8,280,439.3	4.44	16.28	2.38	6.84	0.00
45-64 Years	11,247	30,364	30,364	208,404	289,382	572.6	12	11,342,137	6,268,510.7	99.16	18.53	2.70	6.86	20.96
65+ Years	32,617	91,235	91,235	628,920	770,037	1,725.9	41	4,638,758	2,926,613.4	703.14	19.28	2.80	6.89	23.76
14-Day Episode														
0-17 Years	51	179	179	2,392	15,355	6.6	0	8,126,208	4,564,761.7	0.63	46.90	3.51	13.36	0.00
18-44 Years	687	1,622	1,622	21,557	32,175	60.1	2	15,485,950	8,280,410.6	4.44	31.38	2.36	13.29	33.29
45-64 Years	11,244	30,224	30,224	404,968	558,738	1,118.8	19	11,342,137	6,267,970.5	99.13	36.02	2.69	13.40	16.98
65+ Years	32,588	90,499	90,499	1,223,932	1,489,531	3,373.5	88	4,638,754	2,924,980.4	702.52	37.56	2.78	13.52	26.09
30-Day Episode														
0-17 Years	38	69	69	1,855	13,999	5.3	0	8,126,208	4,564,762.7	0.47	48.82	1.82	26.88	0.00
18-44 Years	628	1,064	1,064	28,007	43,774	81.3	2	15,485,950	8,280,389.3	4.06	44.60	1.69	26.32	24.60
45-64 Years	10,175	19,115	19,115	512,710	736,863	1,457.0	16	11,342,135	6,267,617.5	89.71	50.39	1.88	26.82	10.98
65+ Years	30,207	60,976	60,976	1,674,842	2,066,669	4,705.9	127	4,638,750	2,923,607.0	651.19	55.45	2.02	27.47	26.99
Bradycardia or Pacemaker Insertion Events														
7-Day Episode														
0-17 Years	48	163	163	1,122	5,819	3.1	2	8,125,911	4,563,823.8	0.59	23.38	3.40	6.88	651.07
18-44 Years	619	1,494	1,494	10,218	15,576	28.1	6	15,483,977	8,274,420.0	4.00	16.51	2.41	6.84	213.41
45-64 Years	10,416	28,302	28,302	194,238	265,561	532.9	90	11,338,749	6,257,124.9	91.86	18.65	2.72	6.86	168.89
65+ Years	30,324	84,323	84,323	581,243	698,673	1,592.1	369	4,633,869	2,904,422.9	654.40	19.17	2.78	6.89	231.77
14-Day Episode														
0-17 Years	48	151	151	2,021	10,782	5.5	3	8,125,911	4,563,821.3	0.59	42.10	3.15	13.38	545.15
18-44 Years	619	1,481	1,481	19,699	29,286	54.7	10	15,483,977	8,274,393.9	4.00	31.82	2.39	13.30	182.72
45-64 Years	10,412	28,184	28,184	377,741	513,127	1,040.3	150	11,338,749	6,256,622.7	91.83	36.28	2.71	13.40	144.19
65+ Years	30,299	83,683	83,683	1,132,146	1,352,955	3,107.8	683	4,633,865	2,902,919.5	653.86	37.37	2.76	13.53	219.77
30-Day Episode														
0-17 Years	34	54	54	1,461	6,890	4.1	1	8,125,911	4,563,822.5	0.42	42.97	1.59	27.06	246.79
18-44 Years	560	962	962	25,502	39,736	73.2	14	15,483,977	8,274,375.1	3.62	45.54	1.72	26.51	191.16
45-64 Years	9,313	17,686	17,686	475,506	672,840	1,340.0	196	11,338,747	6,256,307.4	82.13	51.06	1.90	26.89	146.27
65+ Years	27,782	56,114	56,114	1,546,392	1,871,382	4,297.2	939	4,633,860	2,901,686.9	599.54	55.66	2.02	27.56	218.52

Table 3: Sofosbuvir and Amiodarone Use and Bradycardia or Pacemaker Insertion Outcomes in the Mini-Sentinel Distributed Database (MSDD) Between December 6, 2013 and July 15, 2015, by Exposure, Outcome, Episode Length, and Sex

	New Users	New Episodes	Days Dispensings Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 100K Eligible Members	Days Supplied / User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 1K Years at Risk
Incident Sofosbuvir with Amiodarone in the Previous 90 Days													
Bradycardia Events													
7-Day Episode													
Female	0	0	0	0	0.0	0	16,075	5,686.3	0.00	---	---	---	---
Male	4	4	4	28	0.1	0	35,622	12,454.4	11.23	7.00	1.00	7.00	0.00
Unknown	0	0	0	0	0.0	0	1	0.0	0.00	---	---	---	---
14-Day Episode													
Female	0	0	0	0	0.0	0	16,075	5,686.3	0.00	---	---	---	---
Male	4	4	4	56	0.2	0	35,622	12,454.4	11.23	14.00	1.00	14.00	0.00
Unknown	0	0	0	0	0.0	0	1	0.0	0.00	---	---	---	---
30-Day Episode													
Female	0	0	0	0	0.0	0	16,075	5,686.3	0.00	---	---	---	---
Male	4	4	4	92	0.3	0	35,622	12,454.4	11.23	23.00	1.00	23.00	0.00
Unknown	0	0	0	0	0.0	0	1	0.0	0.00	---	---	---	---
Restricted Bradycardia Definition Events													
14-Day Episode													
Female	0	0	0	0	0.0	0	16,228	5,776.2	0.00	---	---	---	---
Male	4	4	4	56	0.2	0	35,962	12,656.3	11.12	14.00	1.00	14.00	0.00
Unknown	0	0	0	0	0.0	0	1	0.0	0.00	---	---	---	---
Pacemaker Insertion Events													
7-Day Episode													
Female	0	0	0	0	0.0	0	16,789	6,144.8	0.00	---	---	---	---
Male	4	4	4	28	0.1	0	36,939	13,278.7	10.83	7.00	1.00	7.00	0.00
Unknown	0	0	0	0	0.0	0	1	0.3	0.00	---	---	---	---
14-Day Episode													
Female	0	0	0	0	0.0	0	16,789	6,144.8	0.00	---	---	---	---
Male	4	4	4	56	0.2	0	36,939	13,278.7	10.83	14.00	1.00	14.00	0.00
Unknown	0	0	0	0	0.0	0	1	0.3	0.00	---	---	---	---
30-Day Episode													
Female	0	0	0	0	0.0	0	16,789	6,144.8	0.00	---	---	---	---
Male	4	4	4	92	0.3	0	36,939	13,278.7	10.83	23.00	1.00	23.00	0.00
Unknown	0	0	0	0	0.0	0	1	0.3	0.00	---	---	---	---

Bradycardia or Pacemaker Insertion Events

7-Day Episode														
Female	0	0	0	0	0	0.0	0	16,075	5,686.3	0.00	---	---	---	---
Male	4	4	4	28	28	0.1	0	35,622	12,454.4	11.23	7.00	1.00	7.00	0.00
Unknown	0	0	0	0	0	0.0	0	1	0.0	0.00	---	---	---	---
14-Day Episode														
Female	0	0	0	0	0	0.0	0	16,075	5,686.3	0.00	---	---	---	---
Male	4	4	4	56	56	0.2	0	35,622	12,454.4	11.23	14.00	1.00	14.00	0.00
Unknown	0	0	0	0	0	0.0	0	1	0.0	0.00	---	---	---	---
30-Day Episode														
Female	0	0	0	0	0	0.0	0	16,075	5,686.3	0.00	---	---	---	---
Male	4	4	4	92	92	0.3	0	35,622	12,454.4	11.23	23.00	1.00	23.00	0.00
Unknown	0	0	0	0	0	0.0	0	1	0.0	0.00	---	---	---	---

Incident Amiodarone with Sofosbuvir in the Previous 30 Days
Bradycardia Events

7-Day Episode														
Female	1	1	1	7	28	0.0	0	2,174	429.9	46.00	7.00	1.00	7.00	0.00
Male	2	2	2	14	42	0.0	0	4,552	911.4	43.94	7.00	1.00	7.00	0.00
Unknown	0	0	0	0	0	0.0	0	0	0.0	---	---	---	---	---
14-Day Episode														
Female	1	1	1	14	56	0.0	0	2,174	429.9	46.00	14.00	1.00	14.00	0.00
Male	2	2	2	28	84	0.1	0	4,552	911.4	43.94	14.00	1.00	14.00	0.00
Unknown	0	0	0	0	0	0.0	0	0	0.0	---	---	---	---	---
30-Day Episode														
Female	1	1	1	30	120	0.1	0	2,174	429.9	46.00	30.00	1.00	30.00	0.00
Male	2	2	2	60	180	0.2	0	4,552	911.4	43.94	30.00	1.00	30.00	0.00
Unknown	0	0	0	0	0	0.0	0	0	0.0	---	---	---	---	---

Restricted Bradycardia Definition Events

14-Day Episode														
Female	1	1	1	14	56	0.0	0	2,174	430.6	46.00	14.00	1.00	14.00	0.00
Male	2	2	2	28	84	0.1	0	4,553	913.0	43.93	14.00	1.00	14.00	0.00
Unknown	0	0	0	0	0	0.0	0	0	0.0	---	---	---	---	---

Pacemaker Insertion Events

7-Day Episode														
Female	1	1	1	7	28	0.0	0	2,177	432.5	45.93	7.00	1.00	7.00	0.00
Male	4	4	4	28	63	0.1	0	4,556	917.0	87.80	7.00	1.00	7.00	0.00
Unknown	0	0	0	0	0	0.0	0	0	0.0	---	---	---	---	---
14-Day Episode														
Female	1	1	1	14	56	0.0	0	2,177	432.5	45.93	14.00	1.00	14.00	0.00
Male	4	4	4	56	126	0.2	0	4,556	917.0	87.80	14.00	1.00	14.00	0.00
Unknown	0	0	0	0	0	0.0	0	0	0.0	---	---	---	---	---
30-Day Episode														
Female	1	1	1	30	120	0.1	0	2,177	432.5	45.93	30.00	1.00	30.00	0.00
Male	4	4	4	113	256	0.3	0	4,556	917.0	87.80	28.25	1.00	28.25	0.00
Unknown	0	0	0	0	0	0.0	0	0	0.0	---	---	---	---	---

Bradycardia or Pacemaker Insertion Events

7-Day Episode														
Female	1	1	1	7	28	0.0	0	2,174	429.9	46.00	7.00	1.00	7.00	0.00
Male	2	2	2	14	42	0.0	0	4,552	911.4	43.94	7.00	1.00	7.00	0.00
Unknown	0	0	0	0	0	0.0	0	0	0.0	---	---	---	---	---
14-Day Episode														
Female	1	1	1	14	56	0.0	0	2,174	429.9	46.00	14.00	1.00	14.00	0.00
Male	2	2	2	28	84	0.1	0	4,552	911.4	43.94	14.00	1.00	14.00	0.00
Unknown	0	0	0	0	0	0.0	0	0	0.0	---	---	---	---	---
30-Day Episode														
Female	1	1	1	30	120	0.1	0	2,174	429.9	46.00	30.00	1.00	30.00	0.00
Male	2	2	2	60	180	0.2	0	4,552	911.4	43.94	30.00	1.00	30.00	0.00
Unknown	0	0	0	0	0	0.0	0	0	0.0	---	---	---	---	---

Prevalent Amiodarone
Bradycardia Events

7-Day Episode														
Female	12,940	36,298	36,298	250,055	302,789	685.0	176	19,078,659	10,772,847.9	67.82	19.32	2.81	6.89	256.95
Male	28,246	77,984	77,984	536,766	682,840	1,471.2	289	19,698,703	11,226,203.9	143.39	19.00	2.76	6.88	196.44
Unknown	0	0	0	0	0	0.0	0	1,255	739.7	0.00	---	---	---	---
14-Day Episode														
Female	12,930	35,988	35,988	486,147	585,685	1,334.4	327	19,078,659	10,772,204.0	67.77	37.60	2.78	13.51	245.05
Male	28,227	77,511	77,511	1,045,460	1,320,465	2,874.0	508	19,698,703	11,224,813.6	143.29	37.04	2.75	13.49	176.76
Unknown	0	0	0	0	0	0.0	0	1,255	739.7	0.00	---	---	---	---
30-Day Episode														
Female	11,709	23,243	23,243	637,507	780,235	1,774.7	427	19,078,659	10,771,743.9	61.37	54.45	1.99	27.43	240.60
Male	25,817	51,573	51,573	1,411,354	1,810,614	3,940.2	705	19,698,703	11,223,708.2	131.06	54.67	2.00	27.37	178.93
Unknown	0	0	0	0	0	0.0	0	1,255	739.7	0.00	---	---	---	---

Restricted Bradycardia Definition Events

14-Day Episode														
Female	13,150	36,636	36,636	494,853	598,486	1,359.3	288	19,079,471	10,775,851.9	68.92	37.63	2.79	13.51	211.87
Male	28,745	78,861	78,861	1,063,691	1,349,805	2,926.3	425	19,699,871	11,229,901.8	145.91	37.00	2.74	13.49	145.23
Unknown	0	0	0	0	0	0.0	0	1,255	739.7	0.00	---	---	---	---

Pacemaker Insertion Events

7-Day Episode														
Female	14,020	39,636	39,636	273,008	337,905	749.3	27	19,083,279	10,791,054.2	73.47	19.47	2.83	6.89	36.03
Male	30,352	83,787	83,787	576,801	746,748	1,583.6	26	19,704,141	11,248,532.8	154.04	19.00	2.76	6.88	16.42
Unknown	1	2	2	14	14	0.0	0	1,255	741.1	79.68	14.00	2.00	7.00	0.00
14-Day Episode														
Female	14,008	39,278	39,278	530,206	652,863	1,461.7	55	19,083,279	10,790,348.4	73.40	37.85	2.80	13.50	37.63
Male	30,332	83,244	83,244	1,122,615	1,442,908	3,097.3	54	19,704,141	11,247,033.8	153.94	37.01	2.74	13.49	17.43
Unknown	1	2	2	28	28	0.1	0	1,255	741.0	79.68	28.00	2.00	14.00	0.00
30-Day Episode														
Female	12,863	25,523	25,523	697,174	875,234	1,963.1	64	19,083,279	10,789,827.9	67.40	54.20	1.98	27.32	32.60
Male	28,016	55,700	55,700	1,520,210	1,986,040	4,286.3	81	19,704,141	11,245,807.6	142.18	54.26	1.99	27.29	18.90
Unknown	1	1	1	30	30	0.1	0	1,255	741.0	79.68	30.00	1.00	30.00	0.00

Bradycardia or Pacemaker Insertion Events

7-Day Episode														
Female	12,940	36,298	36,298	250,055	302,789	685.0	177	19,078,659	10,772,847.9	67.82	19.32	2.81	6.89	258.41
Male	28,246	77,984	77,984	536,766	682,840	1,471.2	290	19,698,703	11,226,203.9	143.39	19.00	2.76	6.88	197.12
Unknown	0	0	0	0	0	0.0	0	1,255	739.7	0.00	---	---	---	---
14-Day Episode														
Female	12,930	35,988	35,988	486,147	585,685	1,334.4	331	19,078,659	10,772,204.0	67.77	37.60	2.78	13.51	248.06
Male	28,227	77,511	77,511	1,045,460	1,320,465	2,873.9	515	19,698,703	11,224,813.6	143.29	37.04	2.75	13.49	179.20
Unknown	0	0	0	0	0	0.0	0	1,255	739.7	0.00	---	---	---	---
30-Day Episode														
Female	11,709	23,243	23,243	637,507	780,235	1,774.5	431	19,078,659	10,771,743.9	61.37	54.45	1.99	27.43	242.88
Male	25,817	51,573	51,573	1,411,354	1,810,614	3,939.9	719	19,698,703	11,223,708.2	131.06	54.67	2.00	27.37	182.49
Unknown	0	0	0	0	0	0.0	0	1,255	739.7	0.00	---	---	---	---

Table 4: Sofosbuvir and Amiodarone Use and Bradycardia or Pacemaker Insertion Outcomes in the Mini-Sentinel Distributed Database (MSDD) Between December 6, 2013 and July 15, 2015, by Exposure, Outcome, Episode Length, and Year

	New Users	New Episodes	Days Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 100K Eligible Members	Days Supplie d/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 1K Years at Risk
Incident Sofosbuvir with Amiodarone in the Previous 90 Days														
Bradycardia Events														
7-Day Episode														
2013	0	0	0	0	0	0.0	0	26,904	1,702.9	0.00	---	---	---	---
2014	3	3	3	21	21	0.1	0	46,466	15,944.6	6.46	7.00	1.00	7.00	0.00
2015	1	1	1	7	7	0.0	0	3,151	493.3	31.74	7.00	1.00	7.00	0.00
14-Day Episode														
2013	0	0	0	0	0	0.0	0	26,904	1,702.9	0.00	---	---	---	---
2014	3	3	3	42	42	0.1	0	46,466	15,944.6	6.46	14.00	1.00	14.00	0.00
2015	1	1	1	14	14	0.0	0	3,151	493.3	31.74	14.00	1.00	14.00	0.00
30-Day Episode														
2013	0	0	0	0	0	0.0	0	26,904	1,702.9	0.00	---	---	---	---
2014	3	3	3	78	78	0.2	0	46,466	15,944.6	6.46	26.00	1.00	26.00	0.00
2015	1	1	1	14	14	0.1	0	3,151	493.3	31.74	14.00	1.00	14.00	0.00
Restricted Bradycardia Definition Events														
14-Day Episode														
2013	0	0	0	0	0	0.0	0	27,304	1,730.1	0.00	---	---	---	---
2014	3	3	3	42	42	0.1	0	46,873	16,192.1	6.40	14.00	1.00	14.00	0.00
2015	1	1	1	14	14	0.0	0	3,226	510.4	31.00	14.00	1.00	14.00	0.00
Pacemaker Insertion Events														
7-Day Episode														
2013	0	0	0	0	0	0.0	0	28,572	1,823.5	0.00	---	---	---	---
2014	3	3	3	21	21	0.1	0	48,243	17,056.2	6.22	7.00	1.00	7.00	0.00
2015	1	1	1	7	7	0.0	0	3,348	544.0	29.87	7.00	1.00	7.00	0.00
14-Day Episode														
2013	0	0	0	0	0	0.0	0	28,572	1,823.5	0.00	---	---	---	---
2014	3	3	3	42	42	0.1	0	48,243	17,056.2	6.22	14.00	1.00	14.00	0.00
2015	1	1	1	14	14	0.0	0	3,348	544.0	29.87	14.00	1.00	14.00	0.00
30-Day Episode														
2013	0	0	0	0	0	0.0	0	28,572	1,823.5	0.00	---	---	---	---
2014	3	3	3	78	78	0.2	0	48,243	17,056.2	6.22	26.00	1.00	26.00	0.00
2015	1	1	1	14	14	0.1	0	3,348	544.0	29.87	14.00	1.00	14.00	0.00

Bradycardia or Pacemaker Insertion Events

7-Day Episode

2013	0	0	0	0	0	0.0	0	26,904	1,702.9	0.00	---	---	---	---
2014	3	3	3	21	21	0.1	0	46,466	15,944.6	6.46	7.00	1.00	7.00	0.00
2015	1	1	1	7	7	0.0	0	3,151	493.3	31.74	7.00	1.00	7.00	0.00

14-Day Episode

2013	0	0	0	0	0	0.0	0	26,904	1,702.9	0.00	---	---	---	---
2014	3	3	3	42	42	0.1	0	46,466	15,944.6	6.46	14.00	1.00	14.00	0.00
2015	1	1	1	14	14	0.0	0	3,151	493.3	31.74	14.00	1.00	14.00	0.00

30-Day Episode

2013	0	0	0	0	0	0.0	0	26,904	1,702.9	0.00	---	---	---	---
2014	3	3	3	78	78	0.2	0	46,466	15,944.6	6.46	26.00	1.00	26.00	0.00
2015	1	1	1	14	14	0.1	0	3,151	493.3	31.74	14.00	1.00	14.00	0.00

Incident Amiodarone with Sofosbuvir in the Previous 30 Days
Bradycardia Events

7-Day Episode

2013	0	0	0	0	0	0.0	0	183	5.2	0.00	---	---	---	---
2014	3	3	3	21	70	0.1	0	6,148	1,239.6	48.80	7.00	1.00	7.00	0.00
2015	0	0	0	0	0	0.0	0	769	96.4	0.00	---	---	---	---

14-Day Episode

2013	0	0	0	0	0	0.0	0	183	5.2	0.00	---	---	---	---
2014	3	3	3	42	140	0.1	0	6,148	1,239.6	48.80	14.00	1.00	14.00	0.00
2015	0	0	0	0	0	0.0	0	769	96.4	0.00	---	---	---	---

30-Day Episode

2013	0	0	0	0	0	0.0	0	183	5.2	0.00	---	---	---	---
2014	3	3	3	90	300	0.2	0	6,148	1,239.6	48.80	30.00	1.00	30.00	0.00
2015	0	0	0	0	0	0.0	0	769	96.4	0.00	---	---	---	---

Restricted Bradycardia Definition Events

14-Day Episode

2013	0	0	0	0	0	0.0	0	183	5.2	0.00	---	---	---	---
2014	3	3	3	42	140	0.1	0	6,149	1,241.6	48.79	14.00	1.00	14.00	0.00
2015	0	0	0	0	0	0.0	0	769	96.7	0.00	---	---	---	---

Pacemaker Insertion Events

7-Day Episode

2013	0	0	0	0	0	0.0	0	183	5.2	0.00	---	---	---	---
2014	5	5	5	35	91	0.1	0	6,155	1,247.0	81.23	7.00	1.00	7.00	0.00
2015	0	0	0	0	0	0.0	0	769	97.4	0.00	---	---	---	---

14-Day Episode

2013	0	0	0	0	0	0.0	0	183	5.2	0.00	---	---	---	---
2014	5	5	5	70	182	0.2	0	6,155	1,247.0	81.23	14.00	1.00	14.00	0.00
2015	0	0	0	0	0	0.0	0	769	97.4	0.00	---	---	---	---

30-Day Episode

2013	0	0	0	0	0	0.0	0	183	5.2	0.00	---	---	---	---
2014	5	5	5	143	376	0.4	0	6,155	1,247.0	81.23	28.60	1.00	28.60	0.00
2015	0	0	0	0	0	0.0	0	769	97.4	0.00	---	---	---	---

Bradycardia or Pacemaker Insertion Events															
7-Day Episode															
2013	0	0	0	0	0	0.0	0	183	5.2	0.00	---	---	---	---	
2014	3	3	3	21	70	0.1	0	6,148	1,239.6	48.80	7.00	1.00	7.00	0.00	
2015	0	0	0	0	0	0.0	0	769	96.4	0.00	---	---	---	---	
14-Day Episode															
2013	0	0	0	0	0	0.0	0	183	5.2	0.00	---	---	---	---	
2014	3	3	3	42	140	0.1	0	6,148	1,239.6	48.80	14.00	1.00	14.00	0.00	
2015	0	0	0	0	0	0.0	0	769	96.4	0.00	---	---	---	---	
30-Day Episode															
2013	0	0	0	0	0	0.0	0	183	5.2	0.00	---	---	---	---	
2014	3	3	3	90	300	0.2	0	6,148	1,239.6	48.80	30.00	1.00	30.00	0.00	
2015	0	0	0	0	0	0.0	0	769	96.4	0.00	---	---	---	---	
Prevalent Amiodarone															
Bradycardia Events															
7-Day Episode															
2013	10,876	10,954	10,954	75,383	93,381	206.7	45	31,961,583	2,200,807.9	34.03	6.93	1.01	6.88	217.73	
2014	37,771	101,220	101,220	697,232	872,084	1,910.7	408	33,993,442	19,021,630.2	111.11	18.46	2.68	6.89	213.54	
2015	1,969	2,108	2,108	14,206	20,164	38.8	12	3,533,254	777,353.5	55.73	7.21	1.07	6.74	309.01	
14-Day Episode															
2013	10,832	10,865	10,865	146,510	180,412	402.8	70	31,961,583	2,200,678.6	33.89	13.53	1.00	13.48	173.79	
2014	37,749	100,531	100,531	1,357,964	1,687,463	3,731.4	743	33,993,423	19,019,765.3	111.05	35.97	2.66	13.51	199.12	
2015	1,968	2,103	2,103	27,133	38,275	74.2	22	3,533,253	777,313.4	55.70	13.79	1.07	12.90	296.38	
30-Day Episode															
2013	6,809	6,809	6,809	187,032	236,023	521.2	93	31,961,583	2,200,730.3	21.30	27.47	1.00	27.47	178.44	
2014	34,613	65,987	65,987	1,812,297	2,287,664	5,056.8	1,003	33,993,368	19,018,232.7	101.82	52.36	1.91	27.46	198.35	
2015	1,940	2,020	2,020	49,532	67,162	136.9	36	3,533,240	777,228.8	54.91	25.53	1.04	24.52	262.90	
Restricted Bradycardia Definition Events															
14-Day Episode															
2013	11,030	11,063	11,063	149,133	184,290	410.4	62	31,970,125	2,201,467.6	34.50	13.52	1.00	13.48	151.09	
2014	38,395	102,237	102,237	1,381,058	1,723,370	3,797.5	636	33,994,604	19,027,238.7	112.94	35.97	2.66	13.51	167.48	
2015	2,047	2,197	2,197	28,353	40,631	77.7	15	3,533,633	777,787.1	57.93	13.85	1.07	12.91	192.97	
Pacemaker Insertion Events															
7-Day Episode															
2013	11,731	11,815	11,815	81,317	102,260	223.3	3	32,003,039	2,204,683.6	36.66	6.93	1.01	6.88	13.43	
2014	40,616	109,209	109,209	752,305	958,512	2,065.2	50	33,998,998	19,056,904.4	119.46	18.52	2.69	6.89	24.21	
2015	2,211	2,401	2,401	16,201	23,895	44.4	0	3,534,330	778,740.2	62.56	7.33	1.09	6.75	0.00	
14-Day Episode															
2013	11,678	11,713	11,713	157,966	197,435	435.8	8	32,003,039	2,204,543.8	36.49	13.53	1.00	13.49	18.36	
2014	40,595	108,416	108,416	1,463,943	1,852,988	4,038.2	99	33,998,979	19,054,885.1	119.40	36.06	2.67	13.50	24.52	
2015	2,210	2,395	2,395	30,940	45,376	85.1	2	3,534,329	778,694.3	62.53	14.00	1.08	12.92	23.52	
30-Day Episode															
2013	7,394	7,394	7,394	202,705	259,804	569.9	12	32,003,039	2,204,597.4	23.10	27.41	1.00	27.41	21.06	
2014	37,618	71,554	71,554	1,959,037	2,522,932	5,523.4	130	33,998,925	19,053,180.2	110.64	52.08	1.90	27.38	23.54	
2015	2,177	2,276	2,276	55,672	78,569	156.2	3	3,534,320	778,598.9	61.60	25.57	1.05	24.46	19.21	

Bradycardia or Pacemaker Insertion Events

7-Day Episode

2013	10,876	10,954	10,954	75,383	93,381	206.7	45	31,961,583	2,200,807.9	34.03	6.93	1.01	6.88	217.73
2014	37,771	101,220	101,220	697,232	872,084	1,910.7	410	33,993,442	19,021,630.2	111.11	18.46	2.68	6.89	214.58
2015	1,969	2,108	2,108	14,206	20,164	38.8	12	3,533,254	777,353.5	55.73	7.21	1.07	6.74	309.01

14-Day Episode

2013	10,832	10,865	10,865	146,510	180,412	402.8	70	31,961,583	2,200,678.6	33.89	13.53	1.00	13.48	173.79
2014	37,749	100,531	100,531	1,357,964	1,687,463	3,731.3	753	33,993,423	19,019,765.3	111.05	35.97	2.66	13.51	201.81
2015	1,968	2,103	2,103	27,133	38,275	74.2	23	3,533,253	777,313.4	55.70	13.79	1.07	12.90	309.85

30-Day Episode

2013	6,809	6,809	6,809	187,032	236,023	521.2	93	31,961,583	2,200,730.3	21.30	27.47	1.00	27.47	178.44
2014	34,613	65,987	65,987	1,812,297	2,287,664	5,056.3	1,020	33,993,368	19,018,232.7	101.82	52.36	1.91	27.46	201.73
2015	1,940	2,020	2,020	49,532	67,162	136.9	37	3,533,240	777,228.8	54.91	25.53	1.04	24.52	270.20

Appendix A. Generic and Brand Name Drugs Used for Exposures in this Request

Generic Name	Brand Name	Form
SOFOBUVIR	Sovaldi	tablet
LEDIPASVIR/SOFOBUVIR	Harvoni	tablet
AMIODARONE HCL	Amiodarone	tablet
AMIODARONE HCL	Cordarone	tablet
AMIODARONE HCL	Pacerone	tablet

Appendix B. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes and Current Procedural Terminology, Fourth Edition (CPT-4) Codes used for Outcomes in this Request

Code	Description	Code Type	Care Setting
Bradycardia			
426	CONDUCTION DISORDERS	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.0	ATRIOVENTRICULAR BLOCK, COMPLETE	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.1	ATRIOVENTRICULAR BLOCK OTHER AND UNSPECIFIED	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.10	ATRIOVENTRICULAR BLOCK, UNSPECIFIED	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.11	FIRST DEGREE ATRIOVENTRICULAR BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.12	MOBITZ (TYPE) II ATRIOVENTRICULAR BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.13	OTHER SECOND DEGREE ATRIOVENTRICULAR BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.2	LEFT BUNDLE BRANCH HEMIBLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.3	OTHER LEFT BUNDLE BRANCH BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.4	RIGHT BUNDLE BRANCH BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.5	BUNDLE BRANCH BLOCK OTHER AND UNSPECIFIED	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.50	BUNDLE BRANCH BLOCK, UNSPECIFIED	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.51	RIGHT BUNDLE BRANCH BLOCK AND LEFT POSTERIOR FASCICULAR BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.52	RIGHT BUNDLE BRANCH BLOCK AND LEFT ANTERIOR FASCICULAR BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.53	OTHER BILATERAL BUNDLE BRANCH BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.54	TRIFASCICULAR BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.6	OTHER HEART BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.7	ANOMALOUS ATRIOVENTRICULAR EXCITATION	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.8	OTHER SPECIFIED CONDUCTION DISORDERS	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.81	LOWN-GANONG-LEVINE SYNDROME	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.82	LONG QT SYNDROME	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.89	OTHER SPECIFIED CONDUCTION DISORDERS	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.9	CONDUCTION DISORDER, UNSPECIFIED	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
427.81	SINOATRIAL NODE DYSFUNCTION	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
427.89	OTHER SPECIFIED CARDIAC DYSRHYTHMIAS	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
Restricted Bradycardia Definition			
426.0	ATRIOVENTRICULAR BLOCK, COMPLETE	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.1	ATRIOVENTRICULAR BLOCK OTHER AND UNSPECIFIED	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.10	ATRIOVENTRICULAR BLOCK, UNSPECIFIED	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.11	FIRST DEGREE ATRIOVENTRICULAR BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.12	MOBITZ (TYPE) II ATRIOVENTRICULAR BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.13	OTHER SECOND DEGREE ATRIOVENTRICULAR BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.6	OTHER HEART BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
427.81	SINOATRIAL NODE DYSFUNCTION	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
427.89	OTHER SPECIFIED CARDIAC DYSRHYTHMIAS	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
Pacemaker Insertion			
00.50	IMPL CARD RESYNCHRNIZAT PACEMKR W/O DFIB TOT SYS	ICD-9-CM Procedure Code	Inpatient or Emergency Department
00.51	IMPL CARD RESYNCHRONIZATION DEFIB TOTAL SYSTEM	ICD-9-CM Procedure Code	Inpatient or Emergency Department
00.52	IMPL/REPLCMT TRNS LEAD IN LT VENT COR VENUS SYS	ICD-9-CM Procedure Code	Inpatient or Emergency Department
37.78	INSERTION TEMPORARY TRANSVENOUS PACEMAKER SYSTEM	ICD-9-CM Procedure Code	Inpatient or Emergency Department
37.80	INSRT PERM PACEMAKER INIT/REPLCMT-TYPE NOT SPEC	ICD-9-CM Procedure Code	Inpatient or Emergency Department
37.81	INIT INSRTION 1-CHAMB DEVC NOT RATE RESPONSIVE	ICD-9-CM Procedure Code	Inpatient or Emergency Department
37.82	INIT INSRTION 1-CHAMB DEVICE RATE RESPONSIVE	ICD-9-CM Procedure Code	Inpatient or Emergency Department
37.83	INITIAL INSERTION OF DUAL-CHAMBER DEVICE	ICD-9-CM Procedure Code	Inpatient or Emergency Department
33200	INSERTION OF HEART PACEMAKER	CPT-4	Inpatient or Emergency Department
33201	INSERTION OF HEART PACEMAKER	CPT-4	Inpatient or Emergency Department

Bradycardia or Pacemaker Insertion

426	CONDUCTION DISORDERS	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.0	ATRIOVENTRICULAR BLOCK, COMPLETE	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.1	ATRIOVENTRICULAR BLOCK OTHER AND UNSPECIFIED	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.10	ATRIOVENTRICULAR BLOCK, UNSPECIFIED	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.11	FIRST DEGREE ATRIOVENTRICULAR BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.12	MOBITZ (TYPE) II ATRIOVENTRICULAR BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.13	OTHER SECOND DEGREE ATRIOVENTRICULAR BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.2	LEFT BUNDLE BRANCH HEMIBLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.3	OTHER LEFT BUNDLE BRANCH BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.4	RIGHT BUNDLE BRANCH BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.5	BUNDLE BRANCH BLOCK OTHER AND UNSPECIFIED	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.50	BUNDLE BRANCH BLOCK, UNSPECIFIED	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.51	RIGHT BUNDLE BRANCH BLOCK AND LEFT POSTERIOR FASCICULAR BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.52	RIGHT BUNDLE BRANCH BLOCK AND LEFT ANTERIOR FASCICULAR BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.53	OTHER BILATERAL BUNDLE BRANCH BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.54	TRIFASCICULAR BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.6	OTHER HEART BLOCK	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.7	ANOMALOUS ATRIOVENTRICULAR EXCITATION	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.8	OTHER SPECIFIED CONDUCTION DISORDERS	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.81	LOWN-GANONG-LEVINE SYNDROME	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.82	LONG QT SYNDROME	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.89	OTHER SPECIFIED CONDUCTION DISORDERS	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
426.9	CONDUCTION DISORDER, UNSPECIFIED	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
427.81	SINOATRIAL NODE DYSFUNCTION	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
427.89	OTHER SPECIFIED CARDIAC DYSRHYTHMIAS	ICD-9-CM Diagnosis Code	Inpatient or Emergency Department
00.50	IMPL CARD RESYNCHRNIZAT PACEMKR W/O DFIB TOT SYS	ICD-9-CM Procedure Code	Inpatient or Emergency Department
00.51	IMPL CARD RESYNCHRONIZATION DEFIB TOTAL SYSTEM	ICD-9-CM Procedure Code	Inpatient or Emergency Department
00.52	IMPL/REPLCMT TRNS LEAD IN LT VENT COR VENUS SYS	ICD-9-CM Procedure Code	Inpatient or Emergency Department
37.78	INSERTION TEMPORARY TRANSVENOUS PACEMAKER SYSTEM	ICD-9-CM Procedure Code	Inpatient or Emergency Department
37.80	INSRT PERM PACEMAKER INIT/REPLCMT-TYPE NOT SPEC	ICD-9-CM Procedure Code	Inpatient or Emergency Department
37.81	INIT INSRTION 1-CHAMB DEVC NOT RATE RESPONSIVE	ICD-9-CM Procedure Code	Inpatient or Emergency Department
37.82	INIT INSRTION 1-CHAMB DEVICE RATE RESPONSIVE	ICD-9-CM Procedure Code	Inpatient or Emergency Department
37.83	INITIAL INSERTION OF DUAL-CHAMBER DEVICE	ICD-9-CM Procedure Code	Inpatient or Emergency Department
33200	INSERTION OF HEART PACEMAKER	CPT-4	Inpatient or Emergency Department
33201	INSERTION OF HEART PACEMAKER	CPT-4	Inpatient or Emergency Department

Appendix C. Generic and Brand Name Drugs Used for Exclusions in this Request

Generic Name	Brand Name	Form
LEVOTHYROXINE SODIUM	Levothroid	tablet
LEVOTHYROXINE SODIUM	levothyroxine	tablet
LEVOTHYROXINE SODIUM	Levoxyl	tablet
LEVOTHYROXINE SODIUM	Synthroid	tablet
LEVOTHYROXINE SODIUM	Tirosint	capsule
LEVOTHYROXINE SODIUM	Unithroid	tablet
LIOTHYRONINE SODIUM	Cytomel	tablet
LIOTHYRONINE SODIUM	liothyronine	tablet
LIOTRIX	Thyrolar	tablet
THYROID	thyroid	tablet
THYROID,PORK	Armour Thyroid	tablet
THYROID,PORK	Nature-Throid	tablet
THYROID,PORK	NP Thyroid	tablet
THYROID,PORK	Westhroid	tablet
THYROID,PORK	Westhroid-P	tablet
THYROID,PORK	WP Thyroid	tablet
METHIMAZOLE	methimazole	tablet
METHIMAZOLE	Tapazole	tablet
POTASSIUM IODIDE	losat	tablet
POTASSIUM IODIDE	potassium iodide	tablet
POTASSIUM IODIDE	SSKI	solution
POTASSIUM IODIDE	ThyroSafe	tablet
POTASSIUM IODIDE	ThyroShield	solution
PROPYLTHIOURACIL	propylthiouracil	tablet

Appendix D. List of List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes, Current Procedural Terminology, Fourth Edition (CPT-4) Codes, and Healthcare Common Procedure Coding System (HCPCS) Codes Used for Exclusions in this Request

Code	Description	Code Type	Care Setting
Hyperthyroidism			
242	Thyrotoxicosis With Or Without Goiter	ICD-9-CM Diagnosis	Any
242.0	Toxic Diffuse Goiter	ICD-9-CM Diagnosis	Any
242.1	Toxic Uninodular Goiter	ICD-9-CM Diagnosis	Any
242.3	Toxic Nodular Goiter Unspecified Type	ICD-9-CM Diagnosis	Any
242.4	Thyrotoxicosis From Ectopic Thyroid Nodule	ICD-9-CM Diagnosis	Any
242.8	Thyrotoxicosis Of Other Specified Origin	ICD-9-CM Diagnosis	Any
242.9	Thyrotoxicosis Without Mention Goiter/Oth Cause	ICD-9-CM Diagnosis	Any
Hypothyroidism			
240.0	Goiter, Specified As Simple	ICD-9-CM Diagnosis	Any
240.9	Goiter, Unspecified	ICD-9-CM Diagnosis	Any
241	Nontoxic Nodular Goiter	ICD-9-CM Diagnosis	Any
241.0	Nontoxic Uninodular Goiter	ICD-9-CM Diagnosis	Any
241.1	Nontoxic Multinodular Goiter	ICD-9-CM Diagnosis	Any
241.9	Unspecified Nontoxic Nodular Goiter	ICD-9-CM Diagnosis	Any
243	Congenital Hypothyroidism	ICD-9-CM Diagnosis	Any
244	Acquired Hypothyroidism	ICD-9-CM Diagnosis	Any
244.0	Postsurgical Hypothyroidism	ICD-9-CM Diagnosis	Any
244.1	Other Postablative Hypothyroidism	ICD-9-CM Diagnosis	Any
244.2	Iodine Hypothyroidism	ICD-9-CM Diagnosis	Any
244.3	Other Iatrogenic Hypothyroidism	ICD-9-CM Diagnosis	Any
244.8	Other Specified Acquired Hypothyroidism	ICD-9-CM Diagnosis	Any
244.9	Unspecified Hypothyroidism	ICD-9-CM Diagnosis	Any
245	Thyroiditis	ICD-9-CM Diagnosis	Any
245.0	Acute Thyroiditis	ICD-9-CM Diagnosis	Any
245.1	Subacute Thyroiditis	ICD-9-CM Diagnosis	Any
245.2	Chronic Lymphocytic Thyroiditis	ICD-9-CM Diagnosis	Any
245.3	Chronic Fibrous Thyroiditis	ICD-9-CM Diagnosis	Any
245.4	Iatrogenic Thyroiditis	ICD-9-CM Diagnosis	Any
245.8	Other And Unspecified Chronic Thyroiditis	ICD-9-CM Diagnosis	Any
245.9	Unspecified Thyroiditis	ICD-9-CM Diagnosis	Any
246	Other Disorders Of Thyroid	ICD-9-CM Diagnosis	Any
246.1	Dyshormonogenic Goiter	ICD-9-CM Diagnosis	Any
246.3	Hemorrhage And Infarction Of Thyroid	ICD-9-CM Diagnosis	Any
246.8	Other Specified Disorders Of Thyroid	ICD-9-CM Diagnosis	Any
246.9	Unspecified Disorder Of Thyroid	ICD-9-CM Diagnosis	Any

Pacemaker / implantable cardioverter defibrillator

00530	ANES PERMANENT TRANSVENOUS PACEMAKER INSERTION	CPT	Any
00534	ANES TRANSVENOUS INSJ/REPLACEMENT PACING CVDFB	CPT	Any
0319T	INS/REPLCMT SUBQ IMPLT DEFIB SYSTEM W/SUBQ ELTRD	CPT	Any
0320T	INSERTION SUBCUTANEOUS DEFIBRILLATOR ELECTRODE	CPT	Any
0321T	INSERTION SUBQ IMPLT DEFIB PLS GEN W/SUBQ ELTRD	CPT	Any
0322T	REMOVAL SUBQ IMPLT DEFIB PULSE GENERATOR	CPT	Any
0323T	RMVL W/REPLCMT SUBQ IMPLT DEFIB PULSE GENERATOR	CPT	Any
0324T	REMOVAL SUBCUTANEOUS DEFIBRILLATOR ELECTRODE	CPT	Any
0325T	REPOSITN SUBQ IMPLANT DEFIB ELECTRODE/PULSE GEN	CPT	Any
0326T	EPHYS EVAL SUBQ IMPLT DEFIB PRGRMG/REPRGRMG	CPT	Any
0327T	IMPLT SUBQ DEFIB SYS INTERROGATION DEVICE EVAL	CPT	Any
0328T	IMPLT SUBQ DEFIB SYS PROGRAMMING DEVICE EVAL	CPT	Any
33200	INSJ PRM PM W/EPICAR ELTRD THORCOM	CPT	Any
33201	INSJ PRM PM W/EPICAR ELTRD XIPHOID APPR	CPT	Any
33206	INS NEW/RPLCMT PRM PACEMAKR W/TRANS ELTRD ATRIAL	CPT	Any
33207	INS NEW/RPLC PRM PACEMAKER W/TRANSV ELTRD VENTR	CPT	Any
33208	INS NEW/RPLCMT PRM PM W/TRANSV ELTRD ATRIAL&VENT	CPT	Any
33213	INS PACEMAKER PULSE GEN ONLY W/EXIST DUAL LEADS	CPT	Any
33214	UPG PACEMAKER SYS CONVERT 1CHMBR SYS 2CHMBR SYS	CPT	Any
33215	RPSG PREV IMPLTED PM/DFB R ATR/R VENTR ELECTRODE	CPT	Any
33216	INSJ 1 TRANSVNS ELTRD PERM PACEMAKER/IMPLTBL DFB	CPT	Any
33218	RPR 1 TRANSVNS ELTRD PRM PM/PACING IMPLNTBL DFB	CPT	Any
33220	RPR 2 TRANSVNS ELECTRODES PRM PM/IMPLANTABLE DFB	CPT	Any
33221	INS PACEMAKER PULSE GEN ONLY W/EXIST MULT LEADS	CPT	Any
33222	RELOCATION OF SKIN POCKET FOR PACEMAKER	CPT	Any
33223	RELOCATE SKIN POCKET IMPLANTABLE DEFIBRILLATOR	CPT	Any
33230	INSJ IMPLNTBL DEFIB PULSE GEN W/EXIST DUAL LEADS	CPT	Any
33231	INSJ IMPLNTBL DEFIB PULSE GEN W/EXIST MULTILEADS	CPT	Any
33233	REMOVAL PERMANENT PACEMAKER PULSE GENERATOR ONLY	CPT	Any
33234	RMVL TRANSVNS PM ELTRD 1 LEAD SYS ATR/VENTR	CPT	Any
33235	RMVL TRANSVNS PM ELTRD DUAL LEAD SYS	CPT	Any
33236	RMVL PRM EPICAR PM&ELTRDS THORCOM 1 LEAD SYS	CPT	Any
33237	RMVL PRM EPICAR PM&ELTRDS THORCOM DUAL LEAD SY	CPT	Any
33240	INSJ IMPLNTBL DEFIB PULSE GEN W/1 EXISTING LD	CPT	Any
33241	REMOVAL IMPLANTABLE DEFIB PULSE GENERATOR ONLY	CPT	Any
33243	RMVL 1/DUAL CHAMBER DEFIB ELECTRODE BY THORACOM	CPT	Any
33245	INSJ EPICAR 1/2CHMBR PACG CVDFB ELTRDS THORCOM	CPT	Any
33247	INSRT/REPLAC IMPLNT CARDV-DEFIB NOT THORACOTOMY	CPT	Any
33249	INSJ/RPLCMT PERM DFB W/TRNSVNS LDS 1/DUAL CHMBR	CPT	Any
33270	INS/RPLCMNT PERM SUBQ IMPLTBL DFB W/SUBQ ELTRD	CPT	Any
33271	INSJ OF SUBQ IMPLANTABLE DEFIBRILLATOR ELECTRODE	CPT	Any
33272	RMVL OF SUBQ IMPLANTABLE DEFIBRILLATOR ELECTRODE	CPT	Any
4470F	IMPLANT CARDIOVERT-DEFIB (ICD) COUNSELING PROV	CPT	Any
71090	INSJ PM FLUOR&RADIOGRAPY RS&I	CPT	Any
93261	INTERROGATION EVAL F2F IMPLANT SUBQ LEAD DEFIB	CPT	Any

93279	PROGRAM EVAL IMPLANTABLE IN PRSN 1 LD PACEMAKER	CPT	Any
93286	PERI-PX EVAL&PROGRAM IN PRSN PACEMAKER SYSTEM	CPT	Any
93292	INTERROGATION EVAL IN PERSON WR DEFIBRILLATOR	CPT	Any
93293	TRANSTELEPHONIC RHYTHM STRIP PACEMAKER EVAL	CPT	Any
93296	INTERROGATION REMOTE </90 D TECHNICIAN REVIEW	CPT	Any
93644	EPHYS EVAL SUBQ IMPLANTABLE DEFIBRILLATOR	CPT	Any
93724	ELECTRONIC ANALYSIS ANTITACHY PACEMAKER SYSTEM	CPT	Any
93731	ELEC ALYS 2CHMBR PM SYS W/O REPRGRMG	CPT	Any
93732	ELEC ALYS 2CHMBR PM SYS W/REPRGRMG	CPT	Any
93733	ELEC ALYS 2CHMBR INT PM SYS TELEPHONIC ALYS	CPT	Any
93734	ELEC ALYS 1CHMBR PM SYS W/O REPRGRMG	CPT	Any
93735	ELEC ALYS 1CHMBR PM SYS W/REPRGRMG	CPT	Any
93736	ELEC ALYS 1CHMBR INT PM SYS TELEPHONIC ALYS	CPT	Any
93737	ELECT ANALY CARDIOVERTER/DEFIB; WO REPROGRAM	CPT	Any
93738	ELECT ANALY CARDIOVERTER/DEFIB; W/REPROGRAM	CPT	Any
93745	1ST SET-UP & PRGRMG PHYS/QHP OF WEARABLE CVDFB	CPT	Any
A0384	BLS SPECIALIZED SERVICE DISPBL SUPPLIES; DEFIB	HCPCS	Any
A0392	ALS SPECIALIZED SERVICE DISPBL SUPPLIES; DEFIB	HCPCS	Any
C1063	LEAD DEFIB ENDOTAK ENDURANCE EZ/RX	HCPCS	Any
C1068	PACEMAKER DUAL CHMBR PULSAR DDD	HCPCS	Any
C1069	PACEMAKER DUAL CHMBR DISCOVERY DR	HCPCS	Any
C1071	PACEMAKER SNGL CHMBR PULSAR MAX SR PULSAR SR	HCPCS	Any
C1075	LEAD PCMKR--SP/SWTPRX/SWTTRX/F/FEZ/T/TEZ	HCPCS	Any
C1076	VENTAK MINI SNGL CHMBR DEFIB	HCPCS	Any
C1077	VENTAK PRIZM VR SNGL CHMBR DEFIB	HCPCS	Any
C1078	VENTAK PRIZM AV III DR DUAL CHMBR AUTO IMP DEFIB	HCPCS	Any
C1103	DEFIB IMPLNT MICRO JEWEL MICRO JEWEL II	HCPCS	Any
C1105	PACEMAKER DUAL CHMBR SIGMA 300 VDD	HCPCS	Any
C1115	LEAD PACEMAKER 5038S 5038 5038L	HCPCS	Any
C1116	LEAD PACEMAKER CAPSURE SP NOVUS	HCPCS	Any
C1118	PACEMKR DUAL CHMBR SIGMA 300 DR LEGACY II DR	HCPCS	Any
C1119	LEAD DEFIB SPRINT 6932 SPRINT 6943	HCPCS	Any
C1120	LEAD DEFIB SPRINT 6942 SPRINT 6945	HCPCS	Any
C1121	DEFIB IMPLNT GEM	HCPCS	Any
C1123	DEFIB IMPLNT GEM II VR	HCPCS	Any
C1125	PACEMAKER SNGL CHMBR KAPPA 400 SR TOPAZ II SR	HCPCS	Any
C1126	PACEMAKER DUAL CHMBR KAPPA 700 DR (ALL MDLS)	HCPCS	Any
C1127	PACEMAKER SNGL CHMBR KAPPA 700 SR	HCPCS	Any
C1128	PACEMAKER DUAL CHMBR KAPPA 700 D RUBY II D	HCPCS	Any
C1129	PACEMAKER KAPPA 700 VDD	HCPCS	Any
C1130	PACEMAKER DUAL CHMBR SIGMA 200 D LEGACY II D	HCPCS	Any
C1131	PACEMAKER DUAL CHMBR SIGMA 200 DR	HCPCS	Any
C1132	PACEMAKR SNGL CHMBR SIGMA 200 SR LEGACY II SR	HCPCS	Any
C1133	PACEMAKER SNGL CHMBR SIGMA 300 SR VITA SR	HCPCS	Any
C1134	PACEMAKER DUAL CHMBR SIGMA 300 D	HCPCS	Any
C1135	PACEMKR DUAL CHMBR RATE-RESP ENTITY DR 5326L/R	HCPCS	Any

C1136	PACEMKR DUAL CHMBR RATE-RESP AFFINITY DR 5330L/R	HCPCS	Any
C1143	PACEMAKER DUAL CHMBR ADDVENT 2060BL	HCPCS	Any
C1144	PMKR SNGL CHMBR RAT-RESP AFF SR 5130 INT SR 5142	HCPCS	Any
C1147	LEAD PACEMAKER AV PLUS DX 1368/52 58 65	HCPCS	Any
C1148	DEFIB SNGL CHMBR IMP CONTOUR MD V-175/A/AC/B/C/D	HCPCS	Any
C1149	PMKR DUAL CHMBR NON-RATE RESP ENTITY DC 5226/R	HCPCS	Any
C1151	PASSIVE PLUS DX LEAD PACEMAKER - 10 DIFF MODELS	HCPCS	Any
C1153	PACEMAKER SNGL CHMBR REGENCY SC+ 2402L	HCPCS	Any
C1154	LEAD DEFIB SPL SP01 SP02 SPL 04	HCPCS	Any
C1157	PACEMAKER DUAL CHMBR TRILOGY DC+2318L	HCPCS	Any
C1158	LEAD DEFIB TVL SV01/SV02/SV04	HCPCS	Any
C1159	LEAD DEFIB TVL RV02/RV06/RV07	HCPCS	Any
C1160	LEAD DEFIB TVL-ADX 1559/65	HCPCS	Any
C1161	LEAD PACEMAKER TENDRIL DX 1388K/T/C	HCPCS	Any
C1172	SPACEMAKER TISS DISSECTOR BALLOON	HCPCS	Any
C1180	PACEMAKER SNGL CHMBR VIGOR SR	HCPCS	Any
C1181	PACEMAKER SNGL CHMBR MERIDIAN SSI	HCPCS	Any
C1182	PACEMAKER SNGL CHMBR PULSAR SSI	HCPCS	Any
C1183	PACEMAKER SNGL CHMBR JADE II S SIGMA 300 S	HCPCS	Any
C1184	PACEMAKER SNGL CHMBR SIGMA 200 S	HCPCS	Any
C1302	LEAD DEFIBRILLATOR TVL SQ01	HCPCS	Any
C1303	LEAD DEFIB CAPSR FIX 6940 CAPSR FIX 4068-110	HCPCS	Any
C1311	PACEMAKER DUAL CHMBR TRILOGY DR+/DAO	HCPCS	Any
C1315	PACEMAKER DUAL CHMBR VIGOR DR MERIDIAN DR	HCPCS	Any
C1316	PACEMAKER DUAL CHMBR MERIDIAN DDD	HCPCS	Any
C1317	PACEMAKER SNGL CHMBR DISCOVERY SR	HCPCS	Any
C1318	PACEMAKER SNGL CHMBR MERIDIAN SR	HCPCS	Any
C1351	LEAD PACEMAKER CAPSUREFIX SUREFIX PIROUET + S+	HCPCS	Any
C1352	DEFIB DUAL CHMBR IMPLNT GEM II DR	HCPCS	Any
C1355	PACEMAKER DUAL CHMBR KAPPA 600 DR VITA DR	HCPCS	Any
C1356	DEFIB SNGL CHMBR IMPLNT PROFILE MD V-186HV3	HCPCS	Any
C1357	DEFIB SNGL CHMBR IMP ANGSTROM MD V-190HV3	HCPCS	Any
C1363	DEFIB IMPLNT DUAL CHMBR GEM DR	HCPCS	Any
C1364	DEFIB DUAL CHMBR PHOTON DR V-230HV3	HCPCS	Any
C1721	CARDIOVERTER-DEFIBRILLATOR DUAL CHAMBER	HCPCS	Any
C1722	CARDIOVERTER-DEFIBRILLATOR SINGLE CHAMBER	HCPCS	Any
C1777	LEAD CARDIOVERT-DEFIB ENDOCARDIAL SINGLE COIL	HCPCS	Any
C1779	LEAD PACEMAKER TRANSVENOUS VDD SINGLE PASS	HCPCS	Any
C1785	PACEMAKER DUAL CHAMBER RATE-RESPONSIVE	HCPCS	Any
C1786	PACEMAKER SINGLE CHAMBER RATE-RESPONSIVE	HCPCS	Any
C1882	CARDIOVERT-DEFIB OTH THAN SINGLE/DUAL CHAMB	HCPCS	Any
C1895	LEAD CARDIOVERT-DEFIB ENDOCARDIAL DUAL COIL	HCPCS	Any
C1898	LEAD PACEMKR OTH THAN TRNS VDD SINGLE PASS	HCPCS	Any
C1899	LEAD PACEMAKER/CARDIOVERT-DEFIB COMBINATION	HCPCS	Any
C2619	PACEMAKER DUAL CHAMBER NON RATE-RESPONSIVE	HCPCS	Any
C2620	PACEMAKER SINGLE CHAMBER NON RATE-RESPONSIVE	HCPCS	Any

C2621	PACEMAKER OTHER THAN SINGLE OR DUAL CHAMBER	HCPCS	Any
C2700	DEFIB SNGL CHMBR IMPLNT MYCROPHYLAX PLUS	HCPCS	Any
C2701	DEFIB SNGL CHMBR IMPLNT PHYLAX XM	HCPCS	Any
C2702	DEFIB SNGL CHMBR IMPLNT VENTAK PRIZM 2 VR 1860	HCPCS	Any
C2703	DEFIB SGL CHMB IMPLNT VENTAK PRIZM VR HE 1857/58	HCPCS	Any
C2704	DEFIB SNGL CHMBR IMPLNT VENTAK MINI IV+	HCPCS	Any
C2801	DEFIB DUAL CHMBR IMPLNT ELA MED DFNDR IV DR 612	HCPCS	Any
C2802	DEFIB DUAL CHMBR IMPLNT PHYLAX AV	HCPCS	Any
C2803	DEFIB DU CHMBR IMPL VENTAK PRIZM DR HE 1852/53	HCPCS	Any
C2804	DEFIB DUAL CHMBR IMPLNT VENTAK PRIZM 2 DR 1861	HCPCS	Any
C2805	DEFIB DUAL CHMBR IMPLNT JEWEL AF 7250	HCPCS	Any
C2806	DEFIB IMPLNT GEM VR 7227	HCPCS	Any
C2807	DEFIB IMPLNT CONTACT CD 1823	HCPCS	Any
C2808	DEFIB IMPLNT CONTACT TR 1241	HCPCS	Any
C3001	LEAD DEFIB IMPLNT KAINOX SL KAINOX RV	HCPCS	Any
C3002	LEAD DEFIB IMPLNT ESYTRAK 4510 4511 4512 4513	HCPCS	Any
C3003	LEAD DEFIB IMPLNT ENDOTAK SQ ARRAY XP 0085	HCPCS	Any
C3004	LEAD DEFIB IMPLNT INTERVENE 497-23 497-24	HCPCS	Any
C4000	PACEMKR SNGL CHMBR ELA MED OPUS G MDL 4621 4624	HCPCS	Any
C4001	PACEMKR SNGL CHMBR ELA MED OPUS S MDL 4121 4124	HCPCS	Any
C4002	PACEMAKER SNGL CHMBR ELA MED TALENT MODEL 113	HCPCS	Any
C4003	PACEMAKER SNGL CHMBR KAIROS SR	HCPCS	Any
C4004	PACEMAKER SNGL CHMBR ACTROS SR+ ACTROS SR-B+	HCPCS	Any
C4005	PACEMAKER SNGL CHMBR PHILOS SR PHILOS SR-B	HCPCS	Any
C4006	PACEMAKER SNGL CHMBR PULSAR MAX II SR 1180 1181	HCPCS	Any
C4007	PACEMAKER SNGL CHMBR MARATHON SR	HCPCS	Any
C4008	PACEMAKER SNGL CHMBR DISCOVERY II SSI 481	HCPCS	Any
C4009	PACEMAKER SC DISCOVERY II SR 1184 1185 1186 1187	HCPCS	Any
C4300	PACEMAKER DUAL CHMBR INTEGRITY AFX DR MODEL 5342	HCPCS	Any
C4301	PACEMAKER DUAL CHMBR INTEGRITY AFX DR MODEL 5346	HCPCS	Any
C4302	PACEMAKER DUAL CHMBR AFFINITY VDR 5430	HCPCS	Any
C4303	PACEMAKER DC ELA BRIO MDL 112 PACEMAKER SYST	HCPCS	Any
C4305	PACEMAKER DUAL CHMBR ELA MED BRIO MODEL 222	HCPCS	Any
C4306	PACEMAKER DUAL CHMBR ELA MED BRIO MODEL 220	HCPCS	Any
C4307	PACEMAKER DUAL CHMBR KAIROS DR	HCPCS	Any
C4308	PACEMAKER DUAL CHMBR INOS 2 INOS 2+	HCPCS	Any
C4309	PACEMAKER DUAL CHMBR ACTROS DR+/D+/DR-A+/SLR+	HCPCS	Any
C4310	PACEMAKER DUAL CHMBR ACTROS DR-B+	HCPCS	Any
C4312	PACEMAKER DUAL CHMBR PULSAR MAX II DR 1280	HCPCS	Any
C4314	PACEMAKER DUAL CHMBR MOMENTUM DR 294-23	HCPCS	Any
C4315	PACEMAKER DUAL CHMBR SELECT AFM 902 SLC 902C	HCPCS	Any
C4316	PACEMAKER DC DISCOVERY II DR 1283 1284 1285 1286	HCPCS	Any
C4317	PACEMAKER DUAL CHMBR DISCOVERY II DDD 981	HCPCS	Any
C4600	LEAD PACEMKR SYNOX POLYROX ELOX RETROX SL-BP ELC	HCPCS	Any
C4601	LEAD PMKR AESCULA LV 1055K	HCPCS	Any
C4603	LEAD PACEMAKER OSCOR/FLEX 4015/4016/4017/4018	HCPCS	Any

C4605	LEAD PACEMAKER CAPSURE EPI 4968	HCPCS	Any
C4606	LEAD PACEMAKER FLEXTEND 4080 4081 4082	HCPCS	Any
C8501	PACEMAKER SGL CHMBR VIGOR SSI	HCPCS	Any
C8506	LEAD PMKR 4057M 4058/4557/4558-M	HCPCS	Any
C8507	PMKR-6721L/M/S/6939-OVL PTCH LEAD	HCPCS	Any
C8508	LEAD DEFIBRILLATOR CAPSURE 4965	HCPCS	Any
C8509	LEAD DEFIB TRANSVENE 6933/6937	HCPCS	Any
C8510	LEAD DEFIBRILLATOR DP-3238	HCPCS	Any
C8511	LEAD DEFIBRILLATOR ENDOTAK DSP	HCPCS	Any
C8518	PMKR DUAL CHMBR VIGOR DDD	HCPCS	Any
C8519	PMKR DUAL CHMBR VISTA DDD	HCPCS	Any
C8520	PMKR SGL CHMBR LEGACY II S	HCPCS	Any
C8748	LEAD DEFIB ENDOTAK SQ PTCH 0047/	HCPCS	Any
C8749	LEAD DEFIB ENDOTAK SQ ARRAY 0048/	HCPCS	Any
C8750	PMKR DUAL CHMBR UNITY VDDR 292-07	HCPCS	Any
C8775	LEAD PMKR 2188 COR SINUS LEAD	HCPCS	Any
C8777	LEAD PMKR UNIPASS 425-02/04/06	HCPCS	Any
E0610	PACEMKR MON CHECKS BATTERY DEPLET W/AUDIBL&VISIBL	HCPCS	Any
E0615	PACEMKR MON CHECKS BATTERY DEPLET W/DIGTL/VISIBL	HCPCS	Any
E0617	EXTERNAL DEFIB W/INTEGRATED ECG ANALY	HCPCS	Any
K0606	AUTO EXT DEFIB W/INTGR ECG ANALY GARMENT TYPE	HCPCS	Any
K0607	REPL BATTERY AUTO EXT DEFIB GARMNT TYPE ONLY EA	HCPCS	Any
K0608	REPLACEMENT GARMENT USE W/AUTO EXTERNAL DEFIB EA	HCPCS	Any
K0609	REPL ELEC W/AUTO EXT DEFIB GARMNT TYPE ONLY EA	HCPCS	Any
00.50	IMPL CARD RESYNCHRONIZATION PACEMKR W/O DFIB TOT SYS	ICD-9-CM Procedure	Any
00.51	IMPL CARD RESYNCHRONIZATION DEFIB TOTAL SYSTEM	ICD-9-CM Procedure	Any
00.52	IMPL/REPLCMT TRNS LEAD IN LT VENT COR VENUS SYS	ICD-9-CM Procedure	Any
00.53	IMPL/REPLCMT CARD RESYNC PACEMKR PULSE GEN ONLY	ICD-9-CM Procedure	Any
34.85	IMPLANTATION OF DIAPHRAGMATIC PACEMAKER	ICD-9-CM Procedure	Any
37.78	INSERTION TEMPORARY TRANSVENOUS PACEMAKER SYSTEM	ICD-9-CM Procedure	Any
37.8	INSERTION REPLACEMENT REMOVAL&REV PACEMKR DEVICE	ICD-9-CM Procedure	Any
37.80	INSRT PERM PACEMAKER INIT/REPLCMT-TYPE NOT SPEC	ICD-9-CM Procedure	Any
37.81	INIT INSRTION 1-CHAMB DEVC NOT RATE RESPONSIVE	ICD-9-CM Procedure	Any
37.82	INIT INSRTION 1-CHAMB DEVICE RATE RESPONSIVE	ICD-9-CM Procedure	Any
37.83	INITIAL INSERTION OF DUAL-CHAMBER DEVICE	ICD-9-CM Procedure	Any
37.85	REPLCMT PACEMAKER W/SNGL CHAMBR-NOT RATE RESPONS	ICD-9-CM Procedure	Any
37.86	REPLCMT PACEMAKER W/SNGL CHAMBR-RATE RESPONS	ICD-9-CM Procedure	Any
37.87	REPLCMT TYPE PACEMKR DEVICE W/DUL-CHAMB DEVICE	ICD-9-CM Procedure	Any
37.89	REVISION OR REMOVAL OF PACEMAKER DEVICE	ICD-9-CM Procedure	Any
37.94	IMPL/REPLCMT AUTO CARDIOVERT/ DEFIB TOTAL SYSTEM	ICD-9-CM Procedure	Any
37.95	IMPLANTATION AUTO CARDIOVERT/DEFIB LEADS ONLY	ICD-9-CM Procedure	Any
37.96	IMPL AUTO CARDIOVERT/DEFIB PULSE GEN ONLY	ICD-9-CM Procedure	Any
37.97	REPLACEMENT AUTO CARDIOVERT/DEFIB LEADS ONLY	ICD-9-CM Procedure	Any
37.98	REPLACEMENT AUTO CARDIOVERT/DEFIB PULSE GEN ONLY	ICD-9-CM Procedure	Any
39.64	INTRAOPERATIVE CARDIAC PACEMAKER	ICD-9-CM Procedure	Any
89.4	CARD STRESS TEST PACEMAKER&DEFIBRILLATOR CHECKS	ICD-9-CM Procedure	Any

89.45	ARTIFICIAL PACEMAKER RATE CHECK	ICD-9-CM Procedure	Any
89.46	ARTIFICIAL PACEMAKER ARTIFACT WAVE FORM CHECK	ICD-9-CM Procedure	Any
89.47	ARTIFICIAL PACEMAKER ELECTRODE IMPEDANCE CHECK	ICD-9-CM Procedure	Any
89.48	ARTIFICAL PACEMKR VOLTAGE/AMPERAGE THRESHOLD CHECK	ICD-9-CM Procedure	Any
89.49	AUTO IMPLANTABLE CARDIOVERT/DEFIBRILLATOR CHECK	ICD-9-CM Procedure	Any

Appendix E. Modular Program Specifications for Request ID: to16_cap_mpl1r_wp034_nsdp_v01													
The Center for Drug Evaluation and Research (CDER) has requested execution of the Cohort Identification and Descriptive Analysis (CIDA) tool version 2.0.8 to investigate use of Sofosbuvir and Amiodarone and subsequent bradycardia and/or pacemaker insertion in the Mini-Sentinel Distributed Database (MSDD).													
Enrollment Gap: 45 days Age Groups: 0-<18, 18-<45, 45-<65, 65+ Query Period: December 6, 2013 - All data available as of July 15, 2015 Coverage Requirement: Medical and Drug Coverage Enrollment Requirement: 183 days													
Scenario	Drug/Exposure				Pre-Existing Condition					Event/Outcome			
	Incident exposure	Incident w/ respect to:	Washout (days)	Cohort Definition	Episode Length (days)	Pre-Existing Condition	Include or Exclude	Lookback Start	Lookback End	Event/Outcome*	Care Setting/ PDX	Washout (days)	Blackout Period
1	Sofosbuvir	Sofosbuvir	183	01	7	Amiodarone	Include	-90	0	Bradycardia	ED or IP	90	0
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				
						Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0				
						Amiodarone	Include	-90	0				
2	Sofosbuvir	Sofosbuvir	183	01	7	Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1	Pacemaker insertion	ED or IP	90	0
						Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0				
						Amiodarone	Include	-90	0				
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				
3	Sofosbuvir	Sofosbuvir	183	01	7	Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0	Bradycardia or Pacemaker insertion	ED or IP	90	0
						Amiodarone	Include	-90	0				
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				
						Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0				
4	Amiodarone	Amiodarone	183	01	7	Sofosbuvir	Include	-30	0	Bradycardia	ED or IP	90	0
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				
						Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0				
						Sofosbuvir	Include	-30	0				
5	Amiodarone	Amiodarone	183	01	7	Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1	Pacemaker insertion	ED or IP	90	0
						Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0				
						Sofosbuvir	Include	-30	0				
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				
6	Amiodarone	Amiodarone	183	01	7	Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0	Bradycardia or Pacemaker insertion	ED or IP	90	0
						Sofosbuvir	Include	-30	0				
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				
						Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0				
7	Amiodarone	Amiodarone	0	02	7	Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1	Bradycardia	ED or IP	90	0
						Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0				
						Sofosbuvir	Include	-30	0				
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				
8	Amiodarone	Amiodarone	0	02	7	Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0	Pacemaker insertion	ED or IP	90	0
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				
						Sofosbuvir	Include	-30	0				
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				
9	Amiodarone	Amiodarone	0	02	7	Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0	Bradycardia or Pacemaker insertion	ED or IP	90	0
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				
						Sofosbuvir	Include	-30	0				
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	0				

10	Sofosbuvir	Sofosbuvir	183	01	14	Amiodarone	Include	-90	0	Bradycardia	ED or IP	90	0
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				
11	Sofosbuvir	Sofosbuvir	183	01	14	Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0	Restricted Bradycardia Definition	ED or IP	90	0
						Amiodarone	Include	-90	0				
12	Sofosbuvir	Sofosbuvir	183	01	14	Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1	Pacemaker insertion	ED or IP	90	0
						Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0				
13	Sofosbuvir	Sofosbuvir	183	01	14	Amiodarone	Include	-90	0	Bradycardia or Pacemaker insertion	ED or IP	90	0
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				
14	Amiodarone	Amiodarone	183	01	14	Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0	Bradycardia	ED or IP	90	0
						Sofosbuvir	Include	-30	0				
15	Amiodarone	Amiodarone	183	01	14	Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1	Restricted Bradycardia Definition	ED or IP	90	0
						Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0				
16	Amiodarone	Amiodarone	183	01	14	Amiodarone	Include	-90	0	Pacemaker insertion	ED or IP	90	0
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				
17	Amiodarone	Amiodarone	183	01	14	Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0	Bradycardia or Pacemaker insertion	ED or IP	90	0
						Sofosbuvir	Include	-30	0				
18	Amiodarone	Amiodarone	0	02	14	Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1	Bradycardia	ED or IP	90	0
						Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0				
19	Amiodarone	Amiodarone	0	02	14	Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1	Restricted Bradycardia Definition	ED or IP	90	0
						Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0				
20	Amiodarone	Amiodarone	0	02	14	Amiodarone	Include	-90	0	Pacemaker insertion	ED or IP	90	0
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				
21	Amiodarone	Amiodarone	0	02	14	Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0	Bradycardia or Pacemaker insertion	ED or IP	90	0
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				

22	Sofosbuvir	Sofosbuvir	183	01	30	Amiodarone	Include	-90	0	Bradycardia	ED or IP	90	0
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				
23	Sofosbuvir	Sofosbuvir	183	01	30	Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0	Pacemaker insertion	ED or IP	90	0
						Amiodarone	Include	-90	0				
24	Sofosbuvir	Sofosbuvir	183	01	30	Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1	Bradycardia or Pacemaker insertion	ED or IP	90	0
						Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0				
25	Amiodarone	Amiodarone	183	01	30	Amiodarone	Include	-30	0	Bradycardia	ED or IP	90	0
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				
26	Amiodarone	Amiodarone	183	01	30	Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0	Pacemaker insertion	ED or IP	90	0
						Sofosbuvir	Include	-30	0				
27	Amiodarone	Amiodarone	183	01	30	Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1	Bradycardia or Pacemaker insertion	ED or IP	90	0
						Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0				
28	Amiodarone	Amiodarone	0	02	30	Sofosbuvir	Include	-30	0	Bradycardia	ED or IP	90	0
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				
29	Amiodarone	Amiodarone	0	02	30	Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0	Pacemaker insertion	ED or IP	90	0
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				
30	Amiodarone	Amiodarone	0	02	30	Amiodarone	Include	-30	0	Bradycardia or Pacemaker insertion	ED or IP	90	0
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				
						Hyperthyroidism diagnosis/treatment, hypothyroidism diagnosis/treatment	Exclude	-183	0				
						Pacemaker, implantable cardioverter defibrillator	Exclude	-183	-1				

*See Appendix B for codes used in each outcome definition.

NDC codes checked against First Data Bank's "National Drug Data File (NDDF®) Plus"
 ICD-9-CM diagnosis and procedure codes checked against "Ingenix 2012 ICD-9-CM Data File" provided by OptumInsight
 HCPCS codes checked against "Optum 2012 HCPCS Level II Data File" provided by OptumInsight
 CPT codes checked against "Optum 2012 Current Procedure Codes & Relative Values Data File" provided by OptumInsight

Appendix F. Data Partner Data Availability End Date as of Request Send Date

Data Partner ID	Start Date	End Date
DP001	1/1/2000	12/31/2012
DP002	1/1/2000	4/30/2014
DP003	1/1/2006	4/30/2014
DP004	1/1/2008	9/30/2014
DP005	1/1/2004	10/31/2014
DP006	1/1/2000	8/31/2014
DP007	1/1/2000	5/31/2014
DP008	1/1/2005	4/30/2014
DP009	1/1/2008	12/31/2014
DP010	1/1/2000	3/31/2015
DP011	1/2/2000	6/30/2012
DP012	1/2/2000	7/31/2014
DP013	1/1/2000	10/31/2014
DP014	1/1/2000	10/31/2014
DP015	6/1/2007	10/31/2014