

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-03 Medicare National Coverage Determinations</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 179</b>	<b>Date: February 20, 2015</b>
	<b>Change Request 9078</b>

**SUBJECT: National Coverage Determination (NCD) for Single Chamber and Dual Chamber Permanent Cardiac Pacemakers - This CR rescinds and fully replaces CR 8525**

**I. SUMMARY OF CHANGES:** The purpose of this CR is to inform contractors that CMS issued a National Coverage Determination (NCD) and concluded that implanted permanent cardiac pacemakers, single chamber or dual chamber, are reasonable and necessary for the treatment of non-reversible symptomatic bradycardia due to sinus node dysfunction and second and/or third degree atrioventricular block.

**EFFECTIVE DATE: August 13, 2013**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: July 6, 2015**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	1/20.8.3/Single Chamber and Dual Chamber Permanent Cardiac Pacemakers

**III. FUNDING:**

**For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**IV. ATTACHMENTS:**

**Business Requirements**

**Manual Instruction**

# Attachment - Business Requirements

Pub. 100-03	Transmittal: 179	Date: February 20, 2015	Change Request: 9078
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**SUBJECT: National Coverage Determination (NCD) for Single Chamber and Dual Chamber Permanent Cardiac Pacemakers - This CR rescinds and fully replaces CR 8525**

**EFFECTIVE DATE: August 13, 2013**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: July 6, 2015**

## I. GENERAL INFORMATION

**A. Background:** Permanent cardiac pacemakers refer to a group of self-contained, battery-operated, implanted devices that send electrical stimulation to the heart through one or more implanted leads. Single chamber pacemakers typically target either the right atrium or right ventricle. Dual chamber pacemakers stimulate both the right atrium and the right ventricle. The implantation procedure is typically performed under local anesthesia and requires only a brief hospitalization. A catheter is inserted into the chest and the pacemaker's leads are threaded through the catheter to the appropriate chamber(s) of the heart. The surgeon then makes a small "pocket" in the pad of the flesh under the skin on the upper portion of the chest wall to hold the power source. The pocket is then closed with stitches.

**B. Policy:** On August 13, 2013, the Centers for Medicare & Medicaid Services (CMS) issued a National Coverage Determination (NCD). In this NCD, CMS concluded that implanted permanent cardiac pacemakers, single chamber or dual chamber, are reasonable and necessary for the treatment of non-reversible, symptomatic bradycardia due to sinus node dysfunction and second and/or third degree atrioventricular block. Symptoms of bradycardia are symptoms that can be directly attributable to a heart rate less than 60 beats per minute (for example: syncope, seizures, congestive heart failure, dizziness, or confusion).

The following indications are covered for implanted permanent single chamber or dual chamber cardiac pacemakers:

1. Documented non-reversible symptomatic bradycardia due to sinus node dysfunction.
2. Documented non-reversible symptomatic bradycardia due to second degree and/or third degree atrioventricular block.

The following indications are non-covered for implanted permanent single chamber or dual chamber cardiac pacemakers:

1. Reversible causes of bradycardia such as electrolyte abnormalities, medications or drugs, and hypothermia.

2. Asymptomatic first degree atrioventricular block. \*(exception)

3. Asymptomatic sinus bradycardia.

4. Asymptomatic sino-atrial block or asymptomatic sinus arrest. \*(exception)

5. Ineffective atrial contractions (e.g., chronic atrial fibrillation or flutter, or giant left atrium) without symptomatic bradycardia. \*(exception)

6. Asymptomatic second degree atrioventricular block of Mobitz Type I unless the QRS complexes are prolonged or electrophysiological studies have demonstrated that the block is at or beyond the level of the His Bundle (a component of the electrical conduction system of the heart).

7. Syncope of undetermined cause. \*(exception)

8. Bradycardia during sleep.

9. Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent atrioventricular block. \*(exception)

10. Asymptomatic bradycardia in post-myocardial infarction patients about to initiate long-term beta-blocker drug therapy.

11. Frequent or persistent supraventricular tachycardias, except where the pacemaker is specifically for the control of tachycardia. \*(exception)

12. A clinical condition in which pacing takes place only intermittently and briefly, and which is not associated with a reasonable likelihood that pacing needs will become prolonged.

Medicare Administrative Contractors (MACs) will determine coverage under section 1862(a)(1)(A) of the Social Security Act for any other indications for the implantation and use of single chamber or dual chamber cardiac pacemakers that are not specifically addressed in this NCD.

**NOTES:**

Contractors shall accept the inclusion of the -KX modifier on the claim line(s) as an attestation by the practitioner and/or provider of the service that documentation is on file verifying the patient has non-reversible symptomatic bradycardia (symptoms of bradycardia are symptoms that can be directly attributable to a heart rate less than 60 beats per minute (for example: syncope, seizures, congestive heart failure, dizziness, or confusion)).

Contractors are reminded that the following business requirements should not be assumed to apply to related codes that are not specifically identified and listed within the business requirements or associated manual instructions.

NOTE: The final decision memorandum addresses Medicare policy specific to implanted permanent cardiac pacemakers, single chamber or dual chamber, for the treatment of non-reversible symptomatic bradycardia due to sinus node dysfunction and second and/or third degree atrioventricular block. Medicare coverage of removal/replacement of implanted permanent cardiac pacemakers, single chamber or dual chamber, for the above-noted indications, were not addressed in the final decision. Therefore, it is expected that MACs will continue to apply the reasonable and necessary standard in determining local coverage within their respective jurisdictions for removal/replacement of implanted permanent cardiac pacemakers, single chamber or dual chamber.

**II. BUSINESS REQUIREMENTS TABLE**

*"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.*

Number	Requirement	Responsibility								
		A/B MAC			D M E M A C	Shared-System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
9078 - 03.1	Effective for claims with dates of service on or after August 13, 2013, contractors shall cover implanted permanent cardiac pacemakers, single chamber or dual chamber, for the indications listed in Pub. 100-03, chapter 1, section 20.8.3 of the Medicare NCD Manual. Please refer to Pub. 100-04, chapter 32, section 320.4 of the CPM manual for claims processing information.	X	X							
9078 - 03.2	Effective for claims with dates of service on or after August 13, 2013, contractors shall non-cover implanted permanent cardiac pacemakers, single chamber or dual chamber, for the indications listed in Pub. 100-03, chapter 1, section 20.8.3 of the Medicare NCD Manual. Please refer to Pub. 100-04, chapter 32, section 320.4 of the CPM manual for claims	X	X							

Number	Requirement	Responsibility								
		A/B MAC			D M E M A C	Shared-System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
	processing information									

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E M A C	C E D I
		A	B	H H H		
9078 - 03.3	MLN Article : A provider education article related to this instruction will be available at <a href="http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/">http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X			

### IV. SUPPORTING INFORMATION

**Section A: Recommendations and supporting information associated with listed requirements: N/A**

*"Should" denotes a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:

**Section B: All other recommendations and supporting information: N/A**

### V. CONTACTS

**Pre-Implementation Contact(s):** Dennis Savedge, 410-786-0140 or [Dennis.Savedge@cms.hhs.gov](mailto:Dennis.Savedge@cms.hhs.gov) (Practitioner Part B Claims) , Jamie Hermansen, 410-786-2064 or [Jamie.Hermansen@cms.hhs.gov](mailto:Jamie.Hermansen@cms.hhs.gov) (Coverage) , Patti Brocato-Simons, 410-786-0260 or [Patricia.BrocatoSimons@cms.hhs.gov](mailto:Patricia.BrocatoSimons@cms.hhs.gov) (Coverage) , Wanda Belle, 410-786-7491 or [wanda.belle@cms.hhs.gov](mailto:wanda.belle@cms.hhs.gov) (Coverage) , William Ruiz, 410-786-9283 or [William.Ruiz@cms.hhs.gov](mailto:William.Ruiz@cms.hhs.gov) (Intermediary Part A Claims)

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

## **VI. FUNDING**

### **Section A: For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**ATTACHMENTS: 0**

# **Medicare National Coverage Determinations Manual**

## **Chapter 1, Part 1 (Sections 10 – 80.12)**

### **Coverage Determinations**

Table of Contents

*(Rev.179. Issued: 02-20-15)*

*20.8.3 – Single Chamber and Dual Chamber Permanent Cardiac Pacemakers*

### **20.8.3 – Single Chamber and Dual Chamber Permanent Cardiac Pacemakers (Rev.179, Issued: 02-20-15, Effective: 08-13-13, Implementation: 07-06-15)**

#### **A. General**

*Permanent cardiac pacemakers refer to a group of self-contained, battery operated, implanted devices that send electrical stimulation to the heart through one or more implanted leads. They are often classified by the number of chambers of the heart that the devices stimulate (pulse or depolarize). Single chamber pacemakers typically target either the right atrium or right ventricle. Dual chamber pacemakers stimulate both the right atrium and the right ventricle.*

*The implantation procedure is typically performed under local anesthesia and requires only a brief hospitalization. A catheter is inserted into the chest and the pacemaker's leads are threaded through the catheter to the appropriate chamber(s) of the heart. The surgeon then makes a small "pocket" in the pad of the flesh under the skin on the upper portion of the chest wall to hold the power source. The pocket is then closed with stitches.*

*The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is sufficient to conclude that implanted permanent cardiac pacemakers, single chamber or dual chamber, are reasonable and necessary for the treatment of non-reversible symptomatic bradycardia due to sinus node dysfunction and second and/or third degree atrioventricular block. Symptoms of bradycardia are symptoms that can be directly attributable to a heart rate less than 60 beats per minute (for example: syncope, seizures, congestive heart failure, dizziness, or confusion).*

#### **B. Nationally Covered Indications**

*The following indications are covered for implanted permanent single chamber or dual chamber cardiac pacemakers:*

- 1. Documented non-reversible symptomatic bradycardia due to sinus node dysfunction, and*
- 2. Documented non-reversible symptomatic bradycardia due to second degree and/or third degree atrioventricular block.*

#### **C. Nationally Non-Covered Indications**

*The following indications are non-covered for implanted permanent single chamber or dual chamber cardiac pacemakers:*

- 1. Reversible causes of bradycardia such as electrolyte abnormalities, medications or drugs, and hypothermia,*
- 2. Asymptomatic first degree atrioventricular block,*
- 3. Asymptomatic sinus bradycardia,*
- 4. Asymptomatic sino-atrial block or asymptomatic sinus arrest,*
- 5. Ineffective atrial contractions (e.g., chronic atrial fibrillation or flutter, or giant left atrium) without symptomatic bradycardia,*
- 6. Asymptomatic second degree atrioventricular block of Mobitz Type I unless the QRS complexes are prolonged or electrophysiological studies have demonstrated that the block is at or beyond the level of the His Bundle (a component of the electrical conduction system of the heart),*
- 7. Syncope of undetermined cause,*
- 8. Bradycardia during sleep,*
- 9. Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent atrioventricular block,*
- 10. Asymptomatic bradycardia in post-myocardial infarction patients about to initiate long-term beta-blocker drug therapy,*



- 11. Frequent or persistent supraventricular tachycardias, except where the pacemaker is specifically for the control of tachycardia, and*
- 12. A clinical condition in which pacing takes place only intermittently and briefly, and which is not associated with a reasonable likelihood that pacing needs will become prolonged.*

***D. Other***

*Medicare Administrative Contractors will determine coverage under section 1862(a)(1)(A) of the Social Security Act for any other indications for the implantation and use of single chamber or dual chamber cardiac pacemakers that are not specifically addressed in this national coverage determination.*

*(This NCD last reviewed August 2013.)*