

National Coverage Determination (NCD) for Cardiac Pacemakers: Single Chamber and Dual Chamber Permanent Cardiac Pacemakers (20.8.3)

- Tracking Information

Publication Number 100-3	Manual Section Number 20.8.3	Manual Section Title Cardiac Pacemakers: Single Chamber and Dual Chamber Permanent Cardiac Pacemakers
Version Number 2	Effective Date of this Version 8/13/2013	Implementation Date 1/13/2016

- Description Information

Benefit Category

Inpatient Hospital Services
Physicians' Services
Prosthetic Devices

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Item/Service Description

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).

Indications and Limitations of Coverage

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.)

Claims Processing Instructions

- TN 3204 (Medicare Claims Processing)
- TN 3384 (Medicare Claims Processing)
- TN 3421 (Medicare Claims Processing)

- Transmittal Information

Transmittal Number

187

Coverage Transmittal Link

<http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R187NCD.pdf>

Revision History

02/2014 - The purpose of this Change Request (CR) is effective for claims with dates of service on or after August 13, 2013, contractors shall allow payment for nationally covered implanted permanent cardiac pacemakers, single chamber or dual chamber, for the indications outlined in the manuals for this CR. Effective date: 08/13/2013 Implementation date: 07/07/2014 ([TN 161](#)) (CR8525)

07/2014 - MEDICARE ADMINISTRATIVE CONTRACTOR (A/MAC, B/MAC) IMPLEMENTATION OF CR 8525 IS DELAYED UNTIL FURTHER DIRECTION FROM CMS. THEREFORE, TRANSMITTAL 161, DATED FEBRUARY 6, 2014, IS RESCINDED AND REPLACED BY TRANSMITTAL 170, dated July 10, 2014 TO INDICATE AN IMPLEMENTATION DATE YET TO BE DETERMINED. ([TN 170](#)) (CR8525)

02/2015 - 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: 08/13/2013 Implementation date: 07/06/2015 ([TN 179](#)) (CR9078)

10/2015 - Transmittal 179, dated February 20, 2015, is being rescinded and replaced by Transmittal 186, dated October 26, 2015, for the following reason: The National Coverage Determination (NCD) for Cardiac Pacemakers: Single Chamber and Dual Chamber Permanent Cardiac Pacemakers (NCD20.8.3) was effective on August 13, 2013, and remains in effect. In order to address claims processing issues that were brought to the attention of the Centers for Medicare & Medicaid Services, we have instructed Medicare Administrative Contractors (MACs) to implement this NCD at the local level until CMS is able to revise the formal claims processing instructions. All aspects of the NCD policy in Publication 100-03, NCD Manual, section 20.8.3, remain in effect. Additionally, we are temporarily removing the corresponding Claims Processing Manual, Chapter 32, section 320, and reference to the manual in requirement 9078-03.1 and 9078-03.2. All other information remains the same. ([TN 186](#)) (CR9078)

12/2015 - Transmittal 186, dated October 26, 2015, is being rescinded and replaced by Transmittal 187, dated December 10, for the following reason:

The National Coverage Determination (NCD) for Cardiac Pacemakers: Single Chamber and Dual Chamber Permanent

Cardiac Pacemakers (NCD20.8.3) was effective on August 13, 2013, and remains in effect. In order to address claims processing issues that were brought to the attention of the Centers for Medicare & Medicaid Services, we have instructed Medicare Administrative Contractors (MACs) to implement this NCD at the local level until CMS is able to revise the formal claims processing instructions. All aspects of the NCD policy in Publication 100-03, NCD Manual, section 20.8.3, remain in effect. Additionally, we are temporarily removing the corresponding Claims Processing Manual, Publication 100-04, chapter 32, section 320, and all but two business requirements to avoid confusion and better clarify that the MACs will use their discretionary authority to process these claims. ([TN 187](#)) (CR9078)

- **National Coverage Analyses (NCAs)**

National Coverage Analyses (NCAs)

This NCD has been or is currently being reviewed under the National Coverage Determination process. The following are existing associations with NCAs, from the National Coverage Analyses database.

- Third reconsideration for Cardiac Pacemakers: Single-Chamber and Dual-Chamber Permanent Cardiac Pacemakers (CAG-00063R3)

- **Additional Information**

Other Versions

- Cardiac Pacemakers: Single Chamber and Dual Chamber Permanent Cardiac Pacemakers - Version 1, Effective between 8/13/2013 - 8/13/2013