CMS Manual System	Department of Health & Human Services (DHHS)						
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)						
Transmittal 3421	Date: December 10, 2015						
	<b>Change Request 9078</b>						

Transmittal 3384, dated October 26, 2015, is being rescinded and replaced by Transmittal 3421, dated December 10, for the following reason: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, as well as all but two business requirements, to avoid confusion and better clarify that the MACs will use their discretionary authority to process these claims.

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

I. SUMMARY OF CHANGES: See above.

**EFFECTIVE DATE: August 13, 2013** 

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

**IMPLEMENTATION DATE: January 13, 2016** 

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.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE					
N/A						

#### 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

# **Attachment - Business Requirements**

Pub. 100-04	Transmittal: 3421	Date: December 10, 2015	Change Request: 9078
-------------	-------------------	-------------------------	----------------------

Transmittal 3384, dated October 26, 2015, is being rescinded and replaced by Transmittal 3421, 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, as well as all but two business requirements.

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

**EFFECTIVE DATE: August 13, 2013** 

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

**IMPLEMENTATION DATE: January 13, 2016** 

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).

# II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility																				
			A/B		D	Sh	arec	ļ-	Other													
		MAC		MAC		MAC		MAC		MAC		MAC		MAC		MAC M		M System		System		
					E	Mair	ıtair	ers														
		A	В	Н		F	1 V	C														
				Н	M	I	N	ı v	V													
				Н	A	$S \mid S$	S	F														
					C	S																
9078 -	Effective for claims with dates of service on or after	X	X																			
04.1	August 13, 2013, contractors shall allow payment for																					

Number	Requirement	Responsibility								
			A/B		D	5	Shared-			Other
		N	MAC		M	System				
					Е	Ma	Maintainers			
		A	В	Н		F	M	V	C	
				Н	M	I	C	M	W	
				Н	A	S	S	S	F	
					C	S				
	nationally covered implanted permanent cardiac									
	pacemakers, single chamber or dual chamber, for the									
	indications listed in Pub. 100-03, Medicare National									
	Coverage Determinations Manual, chapter 1, section									
	20.8.3.									

## III. PROVIDER EDUCATION TABLE

9078-	MLN Article: A provider education article related to	X	X					
04.2	this instruction will be available at							
	http://www.cms.gov/Outreach-and-							
	Education/Medicare-Learning-Network-							
	MLN/MLNMattersArticles/ 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 listsery 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.							

# IV. SUPPORTING INFORMATION

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

<sup>&</sup>quot;Should" denotes a recommendation.

X-Ref	Recommendations or other supporting information:
Requirement	
Number	

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

## V. CONTACTS

**Pre-Implementation Contact(s):** Patricia Brocato-Simons, 410-786-0261, or, Patricia.Brocato-Simons@cms.hhs.gov (Coverage), Sarah Fulton, 410-786-2749, or, Sarah.Fulton@cms.hhs.gov (Coverage), Wanda Belle, 410-786-7491, or, Wanda.Belle@cms.hhs.gov (Coverage), William Ruiz, 410-786-9283, or, William.Ruiz@cms.hhs.gov (Intermediary Part A Claims), Dennis Savedge, 410-786-0140, or, Dennis.Savedge@cms.hhs.gov (Practitioner Part B 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**