

Cardio Policy:

Pacemaker Implantation

POLICY NUMBER UM CARDIO_1147	SUBJECT Pacemaker Implantation		DEPT/PROGRAM UM Dept	PAGE 1 OF 4
DATES COMMITTEE REVIEWED 08/03/11, 12/12/12, 08/22/13, 06/30/14, 08/12/15, 11/23/16, 12/21/16, 11/03/17, 02/08/18, 02/13/19, 03/08/19, 04/25/19, 07/30/19, 12/11/19, 02/12/20, 01/13/21, 08/11/21, 01/12/22, 01/11/23, 12/20/23	APPROVAL DATE December 20, 2023	EFFECTIVE DATE December 22, 2023	COMMITTEE APPROVAL DATES 08/03/11, 12/12/12, 08/22/13, 06/30/14, 08/12/15, 11/23/16, 12/21/16, 11/03/17, 02/08/18, 02/13/19, 03/08/19, 04/25/19, 07/30/19, 12/11/19, 02/12/20, 01/13/21, 08/11/21, 01/12/22, 01/11/23, 12/20/23	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

Indications for determining medical necessity for Pacemaker Implantation.

II. DEFINITIONS

A pacemaker is a medical device which uses electrical impulses, delivered by electrodes contacting the heart muscles, to regulate the beating of the heart. The primary purpose of a pacemaker is to maintain an adequate heart rate, either because the heart's native pacemaker is not fast enough, or there is a block in the heart's electrical conduction system.

Leadless pacemaker devices are self-contained enclosed capsules that include the pacemaker electronics and battery (size range from around 26 mm to 42 mm in length and have a maximum diameter between six mm and seven mm) and are delivered via catheter to the right ventricle of the heart. Leadless pacemakers function similarly to traditional single-chamber ventricular pacemakers without requiring transvenous leads or the need for a surgical pocket.

Appropriate Use Criteria (AUC score) for a service is one in which the expected incremental information, combined with clinical judgment, exceeds the expected negative consequences by a sufficiently wide margin for a specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication. The ultimate objective of AUC is to improve patient care and health outcomes in a cost-effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

- A. Recommendations for permanent pacing in sinus node dysfunction
 - 1. Sinus node dysfunction (SND) with documented symptomatic bradycardia, including frequent sinus pauses that produce symptoms. **(AUC Score 9)^{1,2,3}**
 - 2. Symptomatic chronotropic incompetence. **(AUC Score 8)^{1,2,3}**
- B. Symptomatic sinus bradycardia that results from required drug therapy for medical conditions. **(AUC Score 8)^{1,2,3}**
- C. Recommendations for acquired atrioventricular block in adults:
 - 1. Third-degree and advanced second-degree atrioventricular (AV) block at any anatomic level associated with bradycardia with symptoms (including heart failure) or ventricular arrhythmias presumed to be due to AV block. **(AUC Score 9)^{1,2,3}**
 - 2. Third-degree and advanced second-degree AV block at any anatomic level associated with arrhythmias and other medical conditions that require drug therapy that results in symptomatic bradycardia. **(AUC Score 9)^{1,2,3}**
 - 3. Third-degree and advanced second-degree AV block at any anatomic level in awake, symptom-free patients in sinus rhythm, with documented periods of asystole greater than or equal to 3.0 seconds or any escape rate less than 40 bpm, or with an escape rhythm that is below the AV node. **(AUC Score 9)¹**
 - 4. Third-degree and advanced second-degree AV block at any anatomic level in awake, symptom-free patients with atrial fibrillation and bradycardia with 1 or more pauses of at least 5 seconds or longer. **(AUC Score 9)^{1,2,3}**
 - 5. Third-degree and advanced second-degree AV block at any anatomic level after catheter ablation of the AV junction. **(AUC Score 9)^{1,2,3}**
 - 6. Third-degree and advanced second-degree AV block at any anatomic level associated with postoperative AV block that is not expected to resolve after cardiac surgery. **(AUC Score 9)^{1,2,3}**
 - 7. Third-degree and advanced second-degree AV block at any anatomic level associated with neuromuscular diseases with AV block, such as myotonic muscular dystrophy, Kearns-Sayre syndrome, Erb dystrophy (limb-girdle muscular dystrophy), and peroneal muscular atrophy, with or without symptoms. **(AUC Score 8)^{1,2,3}**
 - 8. Second-degree AV block with associated symptomatic bradycardia regardless of type or site of block. **(AUC Score 8)^{1,2,3}**
 - 9. Asymptomatic persistent third-degree AV block at any anatomic site with average awake ventricular rates of 40 bpm or faster if cardiomegaly or left ventricular (LV) dysfunction is present or if the site of block is below the AV node. **(AUC Score 8)^{1,2,3,4}**
 - 10. Second- or third-degree AV block during exercise in the absence of myocardial ischemia. **(AUC Score 8)^{1,2,3}**
- D. Recommendations for permanent pacing in chronic bifascicular block:
 - 1. Advanced second-degree AV block or intermittent third-degree AV block. **(AUC Score 9)^{1,2,3}**
 - 2. Type II second-degree AV block. **(AUC Score 9)^{1,2,3}**
 - 3. Alternating bundle-branch block. **(AUC Score 8)^{1,2,3}**
- E. Recommendations for permanent pacing in hypersensitive carotid sinus syndrome and neuro-cardiogenic syncope:

1. Permanent pacing is indicated for recurrent syncope caused by spontaneously occurring carotid sinus stimulation and carotid sinus pressure that induces ventricular asystole of more than 3 seconds. **(AUC Score 9)^{1,2,3}**
- F. Recommendations for permanent pacing after cardiac transplantation:
1. Permanent pacing is indicated for persistent inappropriate or symptomatic bradycardia not expected to resolve and for other indications for permanent pacing. **(AUC Score 9)^{1,2,3}**
- G. Recommendations for permanent pacing to prevent tachycardia:
1. Permanent pacing is indicated for sustained pause-dependent VT, with or without QT prolongation. **(AUC Score 8)^{1,2,3}**
 2. Permanent pacing is reasonable for symptomatic recurrent SVT that is reproducibly terminated by pacing when catheter ablation and/or drugs fail to control the arrhythmia or produce intolerable side effects. **(AUC Score 7)^{1,2,3}**
- H. Recommendations for permanent pacing in patients with Hypertrophic Cardiomyopathy (HCM):
1. Permanent pacing is indicated for sinus node dysfunction or AV blocks in patients with HCM. **(AUC Score 8)^{1,2,3}**
 2. Permanent pacing may be considered in medically refractory symptomatic patients with HCM and significant resting or provoked LV outflow tract obstruction. **(AUC Score 7)^{1,2,3}**
- I. Recommendations for leadless pacemaker include: **(AUC Score 8)^{1,2,3}**
1. Patients with bradycardia and need only single chamber (RV) pacing in VVI or VVIR mode:
 - a. Symptomatic paroxysmal or permanent high-grade AV block in the presence of atrial fibrillation (AF).
 - b. Symptomatic paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when atrial lead placement is considered difficult, high-risk, or not deemed necessary for effective therapy.
 - c. Symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when atrial lead placement is considered difficult, high-risk, or not deemed necessary for effective therapy.
 - d. Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity

Limitations/Contraindications:

- A. Leadless pacemakers are contraindicated in patients with implantable cardioverter-defibrillators, elevated right ventricular pressures because of higher theoretical risk of embolization, presence of mechanical tricuspid valves or inferior vena cava filters and individuals who require dual-chamber pacing or who have demonstrable pacemaker syndrome.
- B. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

- A. To review a request for medical necessity, the following items must be submitted for review
 1. Progress note that prompted request
 2. Recent EKG
 3. Holter/event monitor/loop recorder report (if applicable)

- B. Primary codes appropriate for this service: 33206 - Insertion of new or replacement pacemaker with atrial lead, 33207 - Insertion of new or replacement PM with ventricular lead, 33208 - Insertion of new or replacement PM with atrial and ventricular lead. 33274 - Leadless Pacemaker implantation, 33275 - Leadless Pacemaker removal, 33215 - Repositioning of PM or ICD lead, 33216 - Insertion of single lead, 33217 - Insertion of 2 leads PM or ICD, 33218 - Repair single lead PM or ICD, 33220 - Repair 2 leads for PM or ICD

V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

- A. None

VII. REFERENCES

1. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) (20.8.3). Cardiac Pacemakers: Single Chamber and Dual Chamber Permanent Cardiac Pacemakers. Retrieved from <https://www.cms.gov> [Accessed December 19, 2023].
2. National Coverage Determination (NCD) for Leadless Pacemakers (20.8.4). [Accessed December 19, 2023].
3. Epstein AE, et al. 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *Journal of the American College of Cardiology*. Jan 2013, Volume 61, Issue 3, Pages e6-75.
4. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. *Journal of the American College of Cardiology*. March 2013, Volume 61, Issue 12, Pages 1305-1317.
5. NCQA UM 2022 Standards and Elements.