Medical Policy

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

Biventricular Pacing/Cardiac Resynchronization Therapy

Policy Number: PG0233
Last Review: 11/01/2021

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE:

X Professional
X Facility

DESCRIPTION:

It is estimated that 20% to 30% of patients with heart failure have intraventricular conduction disorders resulting in a contraction pattern that is not coordinated and a wide QRS interval on the electrocardiogram. This abnormality appears to be associated with increased morbidity and mortality.

Cardiac Resynchronization Therapy (CRT), also called biventricular pacing, is a technique used to synchronize pacing of the left and right ventricles, thus improving the hemodynamic status of the patient with congestive heart failure. Biventricular pacemakers are manufactured as "stand alone" devices (CRT) or with a built-in automatic implantable cardioverter defibrillator system (CRT-D). There are numerous CRT devices, combined implantable cardioverter defibrillator (ICD) plus CRT devices (CRT-D), and combined CRT plus fluid monitoring devices. The combination devices provide treatment of ventricular dyssynchrony and ventricular tachyarrhythmias associated with sudden cardiac death.

The New York Heart Association (NYHA) classification of heart failure is a 4-tier system that categorizes patients based on subjective impression of the degree of functional compromise. The chart below defines the four NYHA functional classes. Advanced heart failure is categorized as NYHA Class III and Class IV.

CLASS	PATIENT SYMPTOMS
Class I (Mild)	Patients with cardiac disease but without resulting in limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation (rapid or pounding heartbeat), dyspnea (shortness of breath), or anginal pain (chest pain). No symptoms
Class II (Mild)	Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain. Mild symptoms
Class III (Moderate)	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.
Class IV (Severe)	Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If

	any physical activity is undertaken, discomfort is increased. Severe symptoms even while at rest.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans
Cardiac Resynchronization Therapy (**with or without an accompanying implantable cardiac defibrillator) does not require prior authorization. Coverage Criteria as indicated below.**

Procedures 0408T, 0409T, 0410T, 0411T, 0412T, 0413T, 0414T, 0415T, 0416T, 0417T, 0418T, 0515T, 0516T, 0517T, 0518T, 0519T, 0520T, 0521T, 0522T are not covered.

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Biventricular pacemakers with or without an accompanying implantable cardiac defibrillator as a treatment of heart failure may be considered medically necessary in either of the following criteria:

I. New York Heart Association (NYHA) class III or IV and all the following:
- A. Left ventricular ejection fraction less than or equal to 35% with either of the following:
  - 1. Left bundle branch block (LBBB)
  - 2. QRS interval greater than or equal to 120 ms (*The Food and Drug Administration (FDA) labeled indications for QRS duration vary by device. For some devices, FDA approval is based on QRS duration of ≥130 (e.g., InSync®‡ device), while for others, it is based on QRS duration ≥120 ms (e.g., CONTAK CD®‡ CRT-D System). These differences in QRS duration arise from differences in the eligibility criteria in the trials on which the FDA approval is based.)*
- B. Member is on an optimal pharmacologic regimen, defined as 3 months of maximally titrated doses as tolerated, before implantation. As indicated by; treated with guideline-directed medical therapy per the 2013 American College of Cardiology Foundation and American Heart Association guidelines for the management of heart failure (such as an angiotensin-converting enzyme (ACE) inhibitor (or an angiotensin receptor blocker) and a beta blocker, digoxin, and/or diuretics)
- C. Sinus rhythm

II. New York Heart Association (NYHA) class II and all the following:
- A. Left ventricular ejection fraction less than or equal to 30% with either of the following:
  - 1. Left bundle branch block (LBBB)
  - 2. QRS interval greater than or equal to 120 ms *(The Food and Drug Administration (FDA) labeled indications for QRS duration vary by device. For some devices, FDA approval is based on QRS duration of ≥130 (e.g., InSync®‡ device), while for others, it is based on QRS duration ≥120 ms (e.g., CONTAK CD®‡ CRT-D System). These differences in QRS duration arise from differences in the eligibility criteria in the trials on which the FDA approval is based.)*
- B. Member is on an optimal pharmacologic regimen, defined as 3 months of maximally titrated doses as tolerated, before implantation. As indicated by; treated with a guideline-directed medical therapy per the 2013 American College of Cardiology Foundation and American Heart Association guidelines for the management of heart failure (such as an angiotensin-converting enzyme (ACE) inhibitor (or an angiotensin receptor blocker) and a beta blocker, digoxin, and/or diuretics)
- C. Sinus rhythm

Biventricular pacemakers with or without an accompanying implantable cardiac defibrillator, as an alternative to a right ventricular pacemaker (with or without an accompanying implantable cardiac defibrillator) may be considered medically necessary when all the following are present:

I. Left ventricular ejection fraction less than or equal to 50%

II. New York Heart Association (NYHA) class I, II, III, or IV heart failure

III. Patients treated with guideline-directed medical therapy per the 2013 American College of Cardiology Foundation and American Heart Association guidelines for the management of heart failure (such as an angiotensin-converting enzyme (ACE) inhibitor (or an angiotensin receptor blocker) and a beta blocker, digoxin, and/or diuretics)

IV. The presence of atrioventricular (AV) block with requirement for a high percentage of ventricular pacing and one or more of the following:

A. Second-degree AV block or a PR interval of 300 ms or more when paced at 100 beats per minute

B. Third-degree AV block

Biventricular pacemakers with or without an accompanying implantable cardiac defibrillator are considered medically necessary for members who are at high-risk for sudden cardiac death when the afore-mentioned criteria are fulfilled and any of the criteria listed below is met:

1. Members have at least 1 episode of cardiac arrest as a result of ventricular tachyarrhythmia; or
2. Members have recurring, poorly tolerated sustained ventricular tachycardia; or
3. Members have a prior heart attack and a documented episode of non-sustained ventricular tachycardia, with an inducible ventricular tachyarrhythmia; or
4. Members have a prior heart attack and a LVEF of less than or equal to 30 %

Necessary documentation elements for a patient in whom CRT implantation is planned:

- Most recent EF measured by echocardiography, radionuclide (nuclear medicine) imaging, cardiac Magnetic Resonance Imaging (MRI), or catheter angiography
- QRS duration in milliseconds (ms)
- QRS morphology such as LBBB, non-LBBB (with additional clarifying comments as applicable), right bundle branch block (RBBB)
- If present, any markedly prolonged first degree atrioventricular (AV) block or second- or third-degree AV block
- Any plan for AV nodal ablation
- NYHA class and any trends up or down within that classification
- Frequent hospitalizations or office visits for acute exacerbations of HF - if occurring
- Complete operative report outlining operative approach used and all the components of the biventricular pacemaker insertion
- If applicable, the need for a pacemaker and an expectation that pacing is likely to occur much of the time

The implanted CRT device must be United States Food and Drug Administration (FDA) approved for the CRT indication.

Biventricular pacemakers, with or without an accompanying implantable cardiac defibrillator are considered investigational in any of the following situations:

I. Treatment for patients with NYHA class I heart failure unless all the following are present:

A. Left ventricular ejection fraction less than or equal to 50%

B. Treated with guideline-directed medical therapy per the 2013 American College of Cardiology Foundation and American Heart Association guidelines for the management of heart failure.

C. Atrioventricular block with requirement for a high percentage of ventricular pacing) and 1 or more of the following:

1. Second-degree AV block or a PR interval of 300 ms or more when paced at 100 beats per minute
2. Third-degree AV block

II. Treatment for heart failure in patients with atrial fibrillation

The following are considered investigational, not an all-inclusive listing:

- Triple-site (triventricular or quadripolar) cardiac resynchronization therapy, using an additional pacing lead
- An intrathoracic fluid-monitoring sensor as a component of a biventricular pacemaker
- Cardiac resynchronization therapy with wireless left ventricular endocardial pacing (0515T, 0516T, 0517T, 0518T, 0519T, 0520T, 0521T, 0522T)
- His bundle pacing for cardiac resynchronization therapy, because the effectiveness of this approach has

not been established
- The use of Cardiac Contractility Modulation (CCM) Therapy is considered experimental and investigational for treatment of heart failure. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure. (0408T-0418T)

CODING/BILLING INFORMATION:
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES	
33202	Insertion of epicardial electrode(s); open incision (e.g., thoracotomy, median sternotomy, subxiphoid approach)
33203	Insertion of epicardial electrode(s); endoscopic approach (e.g., thoracoscopy, pericardioscopy)
33206	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial
33207	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular
33208	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular
33211	Insertion or replacement of temporary transvenous dual chamber pacing electrodes
33212	Insertion of pacemaker pulse generator only; with existing single lead
33213	Insertion of pacemaker pulse generator only, with existing dual leads
33214	Upgrade of implanted pacemaker system, conversion of single chamber to dual chamber system (includes removal of previously placed generator, testing of existing lead, insertion of new lead, insertion of new pulse generator)
33215	Repositioning of previously implanted transvenous pacemaker or implantable defibrillator (right atrial or right ventricular) electrode
33216	Insertion of a single transvenous electrode, permanent pacemaker, or cardioverter-defibrillator
33217	Insertion of 2 transvenous electrodes, permanent pacemaker, or cardioverter-defibrillator
33218	Repair of single transvenous electrode, permanent pacemaker, or implantable defibrillator
33220	Repair of 2 transvenous electrodes, permanent pacemaker, or implantable defibrillator
33221	Insertion of pacemaker pulse generator only, with existing multiple leads
33222	Relocation of skin pocket for pacemaker
33223	Relocation of skin pocket for implantable defibrillator
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or pacing cardioverter-defibrillator pulse generator (including revision of pocket, removal, insertion and /or replacement of existing generator)
33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (including upgrade to dual chamber system and pocket revision)
33226	Repositioning of previously implanted cardiac venous system (left ventricular) electrode (including removal, insertion and/or replacement of existing generator)
33228	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; dual lead system
33229	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; multiple lead system
33230	Insertion of pacing cardioverter-defibrillator pulse generator only, with existing dual leads
33231	Insertion of pacing cardioverter-defibrillator pulse generator only, with existing multiple leads
33240	Insertion of pacing cardioverter-defibrillator pulse generator only, with existing single lead
33249	Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s) single or dual chamber
33262	Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; single lead system
33263	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; dual lead system
33264	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; multiple lead system
33243	Removal of single or dual chamber implantable defibrillator electrode(s); by thoracotomy

33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber
33270	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed
33271	Insertion of subcutaneous implantable defibrillator electrode
33272	Removal of subcutaneous implantable defibrillator electrode
0408T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator with transvenous electrodes
0409T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator only
0410T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; atrial electrode only
0411T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; ventricular electrode only
0412T	Removal or permanent cardiac contractility modulation system; pulse generator only
0413T	Removal or permanent cardiac contractility modulation system; transvenous electrode (atrial or ventricular)
0414T	Removal and replacement of permanent cardiac contractility modulation system pulse generator only
0415T	Repositioning of previously implanted cardiac contractility modulation transvenous electrode (atrial or ventricular lead)
0416T	Relocation of skin pocket for implanted cardiac contractility modulation pulse generator
0417T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report, implantable cardiac contractility modulation system
0418T	Interrogation device evaluation (in person) with analysis, review, and report, includes connection recording and disconnection per patient encounter, implantable cardiac contractility modulation system
0515T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; complete system (includes electrode and generator [transmitter and battery])
0516T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; electrode only
0517T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; pulse generator component(s) (battery and/or transmitter) only
0518T	Removal of only pulse generator component(s) (battery and/or transmitter) of wireless cardiac stimulator for left ventricular pacing
0519T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter)
0520T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter), including placement of a new electrode
0521T	Interrogation device evaluation (in person) with analysis, review, and report, includes connection, recording, and disconnection per patient encounter, wireless cardiac stimulator for left ventricular pacing
0522T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report, wireless cardiac stimulator for left ventricular pacing
HCPCS CODE	
G0448	Insertion or replacement of a permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber with insertion of pacing electrode, cardiac venous system, for left ventricular pacing

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 03/30/2009

Date	Explanation & Changes
12/23/11	• Updated
06/01/12	• Updated

	• Effective 06/01/12 - Per TAWG determination and MAC notification, a prior-authorization will no longer be required
01/14/14	• Deleted facility codes: 00.50, 00.51, 00.52, 00.53, 00.54, 37.94, 37.95, 37.96, 37.97, 37.98. Deleted ICD-9 codes 425.11, 425.18, 425.4, 427.1, 427.41, 427.42, 427.9. • Added codes 33202, 33203, 33207, 33208, 33214, C1779, C1898, C1900, C2620, G0448 • Changed name of policy from Biventricular Pacemakers, Implantable Defibrillators, Automatic Cardioverter Defibrillator, and Cardiac Resynchronization Therapy to Biventricular Pacing/Cardiac Resynchronization Therapy • Policy reviewed and updated to reflect most current clinical evidence • Approved by Medical Policy Steering Committee as revised.
08/08/17	• Removed codes C1721, C1722, C1777, C1779, C1785, C1882, C1895, C1896, C1898, C1899, C1900, C2619, C2620, C2621 • Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee
12/16/2020	• Medical policy placed on the new Paramount Medical Policy Format

11/02/2021	• Policy reviewed and updated to reflect most current clinical evidence
	• Coverage criteria updated
	• Non-Covered/Investigational services/procedures documented
	  ○ Triple-site (triventricular or quadripolar) cardiac resynchronization therapy, using an additional pacing lead
	  ○ An intrathoracic fluid-monitoring sensor as a component of a biventricular pacemaker
	  ○ Cardiac resynchronization therapy with wireless left ventricular endocardial pacing (0515T, 0516T, 0517T, 0518T, 0519T, 0520T, 0521T, 0522T)
	  ○ His bundle pacing for cardiac resynchronization therapy, because the effectiveness of this approach has not been established
	  ○ The use of Cardiac Contractility Modulation (CCM) Therapy is considered experimental and investigational for treatment of heart failure. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure. (0408T-0418T)

01/03/2022	• Placed the not covered procedure codes 0408T, 0409T, 0410T, 0411T, 0412T, 0413T, 0414T, 0415T, 0416T, 0417T, 0418T, 0515T, 0516T, 0517T, 0518T, 0519T, 0520T, 0521T, 0522T within the green box of the medical policy.
02/15/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
03/06/2024	• Medical Policy placed on the new Paramount Medical Policy format

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/
Industry Standard Review

Hayes, Inc., https://www.hayesinc.com/