

Cardiac Implantable Devices (CID)

Version 1.0.2024

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eviCore healthcare Clinical Decision Support Tool Diagnostic Strategies: This tool addresses common symptoms and symptom complexes. Imaging requests for individuals with atypical symptoms or clinical presentations that are not specifically addressed will require physician review. Consultation with the referring physician, specialist and/or individual's Primary Care Physician (PCP) may provide additional insight.

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General Information

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Abbreviations

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- ACE inhibitor Angiotensin-converting enzyme inhibitor
- AMI Acute myocardial infarction
- ARVC Arrhythmogenic right ventricular cardiomyopathy
- **AV** Atrioventricular
- CC Complications/comorbid conditions
- CHF Congestive heart failure
- CM Cardiomyopathy
- CRT Cardiac resynchronization therapy
- EP Electrophysiology
- **GDMT** Guideline-directed medical therapy
- HCM Hypertrophic cardiomyopathy
- **ICD** Implantable cardioverter defibrillator
- LBBB Left bundle branch block
- LV Left ventricle
- LVEF Left ventricular ejection fraction
- MCC Major complications/comorbid conditions
- **MI** Myocardial infarction
- NCCM Non-compaction cardiomyopathy
- **NYHA** New York Heart Association functional classification
- RBBB Right bundle branch block
- **RV** Right ventricle
- TAVR Transcatheter aortic valve replacement
- VF Ventricular fibrillation
- VT Ventricular tachycardia

Glossary

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- NYHA Heart Failure Definitions <u>class I</u> No symptoms and no limitation in ordinary physical activity, e.g. shortness of breath when walking, climbing stairs etc. <u>class II</u> Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
 - **class III** Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g. walking short distances (20–100 m). Comfortable only at rest.
 - **class IV** Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients
- Abnormal blood pressure response to exercise Flat response/failure to augment; rise then fall during exercise; vasoactive cardiovascular drugs may result in an abnormal blood pressure response to exercise
- **Ambulatory class IV CHF** Class IV heart failure with: 1) no active acute coronary syndrome; 2) no inotropes; and 3) on GDMT
- Incessant VT: Frequent recurrences of ongoing hemodynamically stable VT
- Hypertrophic cardiomyopathy Hypertrophic Cardiomyopathy (HCM) is a clinical diagnosis, established by imaging with 2D echocardiography or cardiovascular magnetic resonance (CMR) showing a maximal end-diastolic wall thickness of ≥15 mm anywhere in the left ventricle, in the absence of another cause of hypertrophy in adults. More limited hypertrophy (13–14 mm) can be diagnostic, particularly when present in family members of a patient with HCM or in conjunction with a positive genetic test, and/or associated with typical dynamic outflow obstruction, or distinctly abnormal ECG patterns.
- Long QT Syndrome (LQTS): A congenital disorder characterized by a prolongation of the QT interval on ECG and a propensity to ventricular tachyarrhythmias, which may lead to syncope, cardiac arrest, or sudden death. The QT interval on the ECG, measured from the beginning of the QRS complex to the end of the T wave, represents the duration of activation and recovery of the ventricular myocardium. QT intervals corrected for heart rate (QTc) longer than 0.44 seconds are generally considered abnormal, though a normal QTc can be more prolonged in females (up to 0.46 sec). The Bazett formula is the formula most commonly used to calculate the QTc, as follows: QTc = AT/square root of the R-R interval (in seconds).
- Non-Compaction Cardiomyopathy: A rare congenital cardiomyopathy that
 affects children and adults. It results from the failure of myocardial development
 during embryogenesis. It is also called spongiform cardiomyopathy. Symptoms are
 often a result of a poor pumping performance by the heart. The disease can be
 associated with other problems with the heart and the body.

- Non-Sustained Ventricular Tachycardia (NSVT): Three or more consecutive ventricular beats at a rate of greater than 120 beats/min with a duration of less than 30 seconds
- **Optimal Medical Therapy:** Optimal medical therapy for heart failure should include a beta-blocker and one of the following:
 - o ACE inhibitor
 - o angiotensin II receptor blocker
 - angiotensin receptor-neprilysin inhibitor
- **Structural Heart Disease:** A structural or functional abnormality of the heart, or of the blood vessels supplying the heart, that impairs its normal functioning.

Cardiac Implantable Devices (CID) Guideli

Preface to the Cardiac Implantable Device (CID) guideline

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Guideline development (Preface-1)

- The eviCore evidence-based, proprietary clinical guidelines evaluate a range of advanced imaging and procedures, including CT, MRI, PET, and Radiation Oncology, Sleep Studies, and Cardiac and Spine interventions.
- eviCore healthcare reserves the right to change and update the guidelines. The
 guidelines undergo a formal review annually. eviCore's guidelines are based upon
 major national and international association and society guidelines and criteria,
 peer-reviewed literature, major treatises, and input from health plans, practicing
 academic and community-based physicians.
- These guidelines are not intended to supersede or replace sound medical
 judgment, but instead should facilitate the identification of the most appropriate
 imaging procedure, given the patient's clinical condition. These guidelines are
 written to cover medical conditions as experienced by the majority of patients.
 However, these guidelines may not be applicable in certain clinical circumstances,
 and physician judgment can override the guidelines.
- Clinical decisions, including treatment decisions, are the responsibility of the patient and his/her provider. Clinicians are expected to use independent medical judgment which takes into account the clinical circumstances to determine patient management decisions.
- eviCore supports the Choosing Wisely[®] initiative (www.choosingwisely.org) by the American Board of Internal Medicine (ABIM) Foundation and many national physician organizations, to reduce the overuse of diagnostic tests that are low value, no value, or whose risks are greater than the benefits.
- eviCore's guidelines are based upon expert consensus and analysis reported by the following specialty societies, publications, studies and trials:
 - The American College of Cardiology (ACC)
 - The American Heart Association (AHA)
 - The Heart Rhythm Society (HRS)

- The Multicenter Automatic Defibrillator Implantation Trial (MADIT/MADIT-2)
- The Multicenter Unsustained Tachycardia Trial (MUSTT)
- The Defibrillator in Acute Myocardial Infarction Trial (DINAMIT)
- The Resynchronization/defibrillation for Ambulatory Heart Failure Trial (RAFT)
- The Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT)
- The Resynchronization Reverses Remodeling in Systolic Left Ventricular Dysfunction trial (REVERSE)
- Immediate Risk Stratification Improves Survival trial (IRIS)
- The Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure trial (COMPANION)
- The Antiarrhythmic Versus Implantable Defibrillators trial (AVID)
- The Canadian Implantable Defibrillator Study (CIDS)
- The Cardiac Arrest Study Hamburg (CASH)

Benefits, coverage policies, and eligibility issues (Preface-2)

- Benefits, coverage policies, and eligibility issues pertaining to each Health Plan may take precedence over eviCore's guidelines. Providers are urged to obtain written instructions and requirements directly from each payer.
- Medicare Coverage Policies
 - For Medicare and Medicare Advantage enrollees, the coverage policies of CMS (Centers for Medicare and Medicaid Services) may take precedence over eviCore's guidelines
 - Payors may choose to adopt other evidence-based guidelines (such as eviCore's guidelines) rather than using Local Coverage Determinations and other Medicare coverage policy
- Investigational and Experimental Studies
 - Certain imaging studies described in these guidelines are considered investigational by various payors, and their coverage policies may take precedence over eviCore's guidelines
- Clinical and Research Trials
 - Similar to investigational and experimental studies, clinical trial imaging requests will be considered to determine whether they meet health plan coverage and eviCore's evidence-based guidelines
- State and federal legislations may need to be considered in the review of advanced imaging requests

Clinical information (Preface-3)

- The philosophy behind eviCore guidelines entails using an evidence-based approach to determine the most appropriate procedure for each individual, at the most appropriate time in the diagnostic and treatment cycle.
- Procedures should be requested after initial consultation and physician treatment planning, and following full counseling of the individual.

- Current clinical information, which may include history, physical examination, symptoms, laboratory results, and imaging reports, are necessary for determining the medical necessity of implantable cardiac devices.
- The information provided to eviCore should have clinical relevance to the request.
- If the information provided makes no reference to the potential indication for the request, then the medical necessity for the procedure(s) cannot be supported.

References (Preface-4)

References are available at the end of the guidelines

Copyright information (Preface-5)

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General information (CRID-1)

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General Guidelines (CRID-1.0)

- Current clinical information, which may include history, physical examination, symptoms, laboratory results, and imaging reports, are necessary for determining the medical necessity of implantable cardiac devices.
- The information provided to eviCore should have clinical relevance to the request.
- If the information provided makes no reference to the potential indication for the request, then the medical necessity for the procedure(s) cannot be supported.
- Requests for a device when a same or similar device has already been placed is not supported without clear documentation that fulfills guideline criteria.

Procedure codes (CRID-1.1)

Procedure description	CPT®
Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial	33206
Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular	33207
Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular	33208
Insertion of pacemaker pulse generator only; single existing single lead	33212
Insertion of pacemaker pulse generator only; with existing dual leads	33213
Upgrade of implanted pacemaker system, conversion of single chamber system to dual chamber system (includes removal of previously placed pulse generator, testing of existing lead, insertion of new lead, insertion of new pulse generator)	33214
Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; single lead system	33227
Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; dual lead system	33228
Insertion of pacemaker pulse generator only; with existing multiple leads	33221

Procedure description	CPT®
Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or pacing cardioverter-defibrillator pulse generator	33224
Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator pulse generator (including upgrade to dual chamber system and pocket revision)	33225
Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; multiple lead system	33229
Insertion of pacing cardioverter-defibrillator pulse generator only; with existing dual leads	33230
Insertion of pacing cardioverter-defibrillator pulse generator only; with existing multiple leads	33231
Insertion of pacing cardioverter-defibrillator pulse generator only; with existing single leads	33240
Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber	33249
Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; single lead system	33262
Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; dual lead system	33263
Removal of pacing cardioverter-defibrillator pulse generator with replacement of pacing cardioverter-defibrillator pulse generator; multiple lead system	33264
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	33270
Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed	33274

Procedure description	CPT ®
Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed	33289
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])	0515T
Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; electrode only	0516T
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	0517T
Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter)	0519T
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	0520T
Insertion or replacement of implantable cardioverter-defibrillator system with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters), when performed	0571T
Insertion of substernal implantable defibrillator electrode	0572T
Removal and replacement of substernal implantable defibrillator pulse generator	0614T
Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; complete system (ie, right atrial and right ventricular pacemaker components)	0795T
Transcatheter insertion of right atrial pacemaker component (when an existing right ventricular single leadless pacemaker exists to create a dual-chamber leadless pacemaker system)	0796T

Procedure description	CPT [®]
Transcatheter insertion of right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)	0797T
Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; complete system (ie, right atrial and right ventricular pacemaker components)	0798T
Transcatheter removal of right atrial pacemaker component	0799T
Transcatheter removal of right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)	0800T
Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; dual-chamber system (ie, right atrial and right ventricular pacemaker components)	0801T
Transcatheter removal and replacement of right atrial pacemaker component	0802T
Transcatheter removal and replacement of right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)	0803T
Transcatheter insertion of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (eg, interrogation or programming), when performed	0823T
Transcatheter removal of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography), when performed	0824T
Transcatheter removal and replacement of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (eg, interrogation or programming), when performed	0825T

Removal and replacement (CRID-1.2)

- Generator replacement (CPT® 33212, 33213, 33221, 33227, 33228, 33229, 33230, 33231, 33240, 33262, 33263, 33264, 0614T, 0801T, 0802T, 0803T) with a same or similar device is indicated when:
 - Interrogation shows device is nearing Elective Replacement Indicator (ERI) or End of Life (EOL).
 - Interrogation report documents the device is not functioning correctly and requires replacement.

Pacemaker Devices

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Indications for Permanent Pacemaker Implantation (CRID-7)

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CPT® 33206, 33207, 33208

Sinus node dysfunction

Permanent pacemaker implantation is indicated for any of the following:

- Symptomatic sinus node dysfunction as evidenced by both of the following:
 - Documented sinus node dysfunction including one of the below:
 - Sinus bradycardia at rate <50 beats per minute
 - Sinus pauses >3 seconds
 - Symptoms attributable to sinus node dysfunction including one of the below:
 - Syncope or pre-syncope
 - Heart failure symptoms
 - Exertional fatigue and impaired exercise tolerance
- Sinus bradycardia at rate <40 beats per minute and symptoms possibly related to bradycardia
- Symptomatic sinus bradycardia (as defined above) as a consequence of guideline directed management and continued treatment is clinically necessary
- Symptoms attributable to bradycardia as listed above and evidence of tachy-brady syndrome (sinus bradycardia, ectopic atrial bradycardia, or sinus pause alternating with periods of atrial flutter or atrial fibrillation)
- Symptomatic chronotropic incompetence defined as limitations due to the inability to achieve 80% of maximum predicted heart rate (220-age)

Atrioventricular block (AVB)

Permanent pacemaker implantation is indicated for any of the following:

- AVB including one of the below with or without symptoms:
 - Second-degree Mobitz type II
 - High-grade (≥2 consecutive P waves at a constant physiologic rate that do not conduct to the ventricles)
 - Third-degree (complete heart block)
- Any degree of AVB with one of the following symptoms that are clearly attributable to the AVB:
 - Syncope or pre-syncope

- Heart failure symptoms
- Exertional fatigue and impaired exercise tolerance
- Third-degree and advanced second-degree AV block at any anatomic level associated with sustained or non-sustained ventricular tachycardia (ventricular rhythm at rate >100 bpm lasting ≥3 consecutive beats) presumed due to AV block
- Marked first-degree AVB (PR interval >0.3 seconds) or second-degree AVB with symptoms similar to those of pacemaker syndrome
- Symptomatic AVB as a consequence of guideline directed management and continued treatment is clinically necessary
- Persistent or permanent atrial fibrillation and symptomatic bradycardia including one of the following:
 - o Rate <50 beats per minute
 - o Regular QRS intervals indicating complete AVB
- Second degree AV block with a documented pause of ≥5 seconds during waking in the presence of atrial fibrillation, with or without symptoms
- Second degree AV block with documented periods of asystole ≥3.0 seconds in the presence of sinus rhythm, with or without symptoms
- Second-degree AVB noted to be located at intra- or infra-His levels at electrophysiology study (EPS), with or without symptoms
- Any AVB indication listed above occurring after acute myocardial infarction that does not resolve within 5 days
- Congenital complete or high-degree AVB in the presence of any of the following:
 - o Symptoms
 - Wide QRS escape rhythm
 - o Mean daytime heart rate below 50 bpm
 - \circ Pauses >3 times the cycle length of the ventricular escape rhythm
 - Complex ventricular ectopy
 - Prolonged QT interval
 - o Ventricular dysfunction, ventricular dilatation or significant mitral regurgitation

Conduction Disorders with 1:1 Atrioventricular Conduction

Permanent pacemaker implantation is indicated for any of the following:

- Individuals with syncope and bundle branch block and one of the following at electrophysiology study (EPS):
 - Baseline HV interval ≥70 ms
 - Second- or third-degree intra- or infra-Hisian block during incremental atrial pacing
- Alternating bundle branch block with or without symptoms
- HV interval ≥100 milliseconds noted at EPS, with or without symptoms
- Intra- or infra- Hisian block noted at EPS, with or without symptoms

Recurrent syncope

Permanent pacemaker implantation is indicated for individuals with recurrent syncope and any of the following:

- Spontaneous documented symptomatic asystolic pause >3 seconds due to sinus arrest or atrioventricular block (AVB)
- Spontaneous documented asymptomatic asystolic pause >6 seconds due to sinus arrest or AVB
- Cardioinhibitory carotid sinus syndrome as documented by one of the below:
 - Syncope caused by spontaneously occurring carotid sinus stimulation
 - Carotid sinus pressure that induces syncope and/or ventricular asystole of ≥3 seconds
- Syncope associated with asystole of ≥3 seconds during tilt testing
- Bundle branch block and one of the following at electrophysiology study (EPS):
 - Baseline HV interval ≥70 ms
 - Second- or third-degree intra- or infra-Hisian block during incremental atrial pacing
- Syncope after cardiac transplantation with or without documentation of bradyarrhythmia

Peri-procedural and post-operative indications

Permanent pacemaker implantation is indicated for any of the following:

- Prior to a planned catheter ablation of the atrioventricular (AV) junction for one of the following:
 - o Rate control strategy for management of atrial fibrillation
 - Supraventricular tachycardia resulting in tachycardia induced cardiomyopathy that is not controlled with ablation or medical therapy
- Post Transcatheter Aortic Valve Implantation (TAVI) for any of the following:
 - Complete or high-degree atrioventricular block (AVB) that persists for 24 to 48 hours after TAVI
 - New-onset alternating bundle branch block after TAVI
 - Pre-existing right bundle branch block (RBBB) and new conduction abnormality onset during or after (TAVI) such as:
 - Transient high-degree AVB
 - PR prolongation
 - QRS axis change

- Sinus node dysfunction or AVB associated with symptoms or hemodynamic instability occurring after cardiac surgery that does not resolve within 5 days
- Post cardiac transplant for any of the following:
 - Relative bradycardia that is prolonged or recurrent, which limits rehabilitation or discharge after postoperative recovery
 - Syncope with or without documentation of bradyarrhythmia

Neuromuscular diseases known to involve the heart

Permanent pacemaker implantation may be considered for progressive neuromuscular diseases known to involve the heart with any degree of atrioventricular (AV) block including first degree AV block or any fascicular block, with or without symptoms, because there may be unpredictable progression of AV conduction disease. Progressive neuromuscular diseases known to involve the heart include:

- Myotonic muscular dystrophy
- Kearns-Sayre syndrome
- Erb dystrophy (limb-girdle muscular dystrophy)
- Peroneal muscular atrophy

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Permanent Pacemaker Implantation - Non-indications (CRID-9)

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- Permanent pacemaker implantation is <u>not</u> indicated in any of the following settings:
 - Sinus node dysfunction when there is documentation of any of the following
 - Individual is asymptomatic
 - The symptoms suggestive of bradycardia have been clearly documented to occur in the absence of bradycardia
 - Sinus node dysfunction is due to nonessential drug therapy
 - Fascicular block without AV block or without symptoms concerning for AV block
 - Incidentally noted hypersensitive cardioinhibitory response to carotid sinus stimulation when the individual remains asymptomatic or has vague symptoms
 - Asymptomatic first-degree AV block
 - Asymptomatic type-1 second-degree AV block at the supra-His (AV node) level or that which is not known to be intra- or infra-Hisian
 - Asymptomatic transient AV block in the absence of intraventricular conduction defects or in isolated single fascicular block
 - Situational vasovagal syncope when avoidance behavior is effectively preventing syncopal episodes
 - Prior to Transcatheter Aortic Valve Replacement (TAVR) as a prophylactic measure in individuals with right bundle branch block (RBBB) when there is no indication for permanent pacing
 - For the purpose of cardiac contractility modulation

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Leadless pacemaker (CRID-11.1)

CID.PM.104.A

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Leadless right ventricular pacemaker (CRID-11.1.1)

Indications for permanent right ventricular leadless pacemaker (CPT® 33274) implant - **all** of the following must be met:

- Meets <u>one</u> of the following indications for leadless right ventricular pacemaker:
 - Symptomatic paroxysmal or permanent high-grade AV block in the presence of Atrial Fibrillation (AF)
 - 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
 - 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
- The following contraindications for leadless pacemaker are **not** present:
 - An implanted inferior vena cava filter
 - A mechanical tricuspid valve

Leadless dual chamber pacemaker system (CRID-11.1.2)

Indications for permanent dual chamber leadless pacemaker implant (CPT® 0795T) - **all** of the following must be met:

- Meets one of the following indications for leadless dual chamber pacemaker:
 - Sick sinus syndrome
 - Chronic, symptomatic second- and third-degree AV block
 - Recurrent Adams-Stokes syndrome
 - Symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out
- The following contraindications for leadless pacemaker are **not** present:
 - An implanted inferior vena cava filter
 - A mechanical tricuspid valve

Leadless right atrial pacemaker (CRID-11.1.3)

Indications for permanent leadless right atrial pacemaker implant (CPT $^{\otimes}$ 0823T) - <u>all</u> of the following must be met:

- Meets the following indication for leadless right atrial pacemaker:
 - Sinus node dysfunction with normal AV and intraventricular conduction systems
- The following contraindications for leadless pacemaker are not present:

- An implanted inferior vena cava filter
- A mechanical tricuspid valve

General information

Right ventricular leadless pacemaker

The permanent right ventricular leadless pacemakers (CPT® 33274) consists of a single leadless device implanted directly into the right ventricle. The Medtronic Micra™ VR and Abbott Aveir™ VR right ventricular leadless pacemakers are capable only of VVI and VVIR pacing. The Medtronic Micra™ AV right ventricular leadless pacemaker is also capable of VDD pacing. The right ventricular leadless pacemakers do not have capability for atrial pacing. The estimated battery life is about 10 years

Dual chamber leadless pacemaker

In contrast to the right ventricular leadless pacemakers referred to above, the dual chamber leadless pacemaker (i.e., Abbott Aveir™ DR leadless pacemaker system) has dual-chamber sensing and pacing functionality. The Abbott Aveir™ DR leadless pacemaker system consists of two separate components: one implanted in the right atrium and the other in the right ventricle.

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Implantable cardioverterdefibrillator (ICD) Devices

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Definite indications for ICD implantation (CRID-2)

CID.ICD.100.A

v1.0.2024

Procedures included

CPT® 33249, 33270

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Survivors of cardiac arrest (CRID-2.1)

 ICD implantation is indicated in individuals who are survivors of cardiac arrest due to ventricular tachycardia (VT) or ventricular fibrillation (VF) after evaluation has excluded any completely reversible causes

Structural heart disease with sustained VT (CRID-2.2)

 ICD implantation is indicated in individuals with structural heart disease (such as prior myocardial infarction (MI), congenital heart disease, and/or ventricular dysfunction) and spontaneous, sustained VT (greater than 30 seconds), whether hemodynamically stable or unstable

Syncope of undetermined origin and positive EP study (CRID-2.3)

ICD implantation is indicated in individuals with syncope of undetermined origin who
have clinically relevant, hemodynamically significant sustained VT or VF induced at
electrophysiology (EP) study

Unexplained syncope (CRID-2.4)

 ICD implantation is indicated in individuals with unexplained syncope, significant left ventricular (LV) dysfunction (LV ejection fraction less than 50%), and structural heart disease such as prior myocardial infarction (MI), congenital heart disease, and/or ventricular dysfunction

Ischemic cardiomyopathy (CRID-2.5)

ICD implantation is indicated in individuals with <u>any</u> of the following:

- Left ventricular systolic dysfunction due to ischemic heart disease and <u>all</u> of the following:
 - LV ejection fraction ≤35% despite ≥3 months of <u>optimal medical therapy</u>
 - Symptomatic heart failure (NYHA functional Class II or III)
- Left ventricular systolic dysfunction due to ischemic heart disease and <u>all</u> of the following:
 - LV ejection fraction ≤30% despite ≥3 months of optimal medical therapy
 - NYHA functional Class I
- Left ventricular systolic dysfunction due to ischemic heart disease and <u>all</u> of the following:
 - LV ejection fraction ≤ 40% despite ≥3 months of <u>optimal medical therapy</u>
 - Non-sustained ventricular tachycardia
 - Inducible sustained monomorphic ventricular tachycardia at electrophysiological (EP) study

Optimal medical therapy should include a beta-blocker and **one** of the following:

- ACE inhibitor
- · angiotensin II receptor blocker
- · angiotensin receptor-neprilysin inhibitor

Non-ischemic dilated cardiomyopathy (DCM) (CRID-2.6)

- ICD implantation is indicated in individuals with nonischemic dilated cardiomyopathy who have **all** of the following:
 - o LV ejection fraction ≤35% despite ≥3 months of optimal medical therapy
 - Symptomatic heart failure (NYHA Class II or III CHF)

Reasonable indications for ICD implantation (CRID-3)

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Procedures included

CPT® 33249, 33270

General considerations (CRID-3.1)

For the "reasonable" or "considered" indications listed in this CRID-3 guideline, consensus opinion is less clear about the use of ICD implantation in these settings. Limited evidence suggests that ICD placement may be reasonable or may be considered; this category includes VF or hypotensive VT events where pharmaceutical or ablative techniques are indicated but the results of treatment are too unpredictable to withhold ICD implantation.

Sustained ventricular tachycardia with normal LV function (CRID-3.2)

 ICD implantation is reasonable for individuals with sustained VT and normal or near-normal ventricular function

Cardiomyopathy (CRID-3.3)

Individuals with cardiomyopathy who have one or more risk factors for sudden cardiac death

Hypertrophic Cardiomyopathy:

ICD implantation is reasonable for individuals with hypertrophic cardiomyopathy who have one or more risk factors for sudden cardiac death including the following:

- Unheralded syncope
- o Family history of sudden death
- Septal wall thickness ≥ 30 mm

- Abnormal blood pressure response to exercise (SBP increase of <20mm/hg with exercise or a drop in BP)
- Ventricular tachycardia, sustained or nonsustained
- o LV apical aneurysm, independent of size
- LV ejection fraction < 50%

Cardiomyopathy due to Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC):

ICD implantation is reasonable for individuals with ARVC who have one or more risk factors for sudden cardiac death Risk factors for sudden cardiac death include the following:

- Unheralded syncope
- o Family history of sudden death
- Ventricular tachycardia, sustained or nonsustained
- Clinical signs of RV failure

Long QT syndrome (CRID-3.4)

- ICD implantation is reasonable in Long-QT Syndrome in the following settings:
 - Syncope and/or VT while receiving beta-blockers or if beta-blockers are contraindicated
 - o Asymptomatic with other risk factors for sudden cardiac death
 - Risk factors for sudden cardiac death include the following:
 - QTc greater than 500 msec or
 - LQT 2 or 3
 - · Family history of sudden death

Brugada syndrome(CRID-3.5)

- ICD implantation is reasonable for individuals with Brugada Syndrome who have had the following:
 - Syncope <u>or</u>
 - Documented or inducible VT or VF

Catecholaminergic polymorphic ventricular tachycardia (CRID-3.6)

 ICD implantation is reasonable for individuals with catecholaminergic polymorphic VT who have syncope and/or documented sustained VT while receiving betablockers.

Muscular Dystrophy (CRID-3.8)

- ICD implantation is reasonable, regardless of LV ejection fraction for <u>any</u> of the following:
 - Emery-Dreifuss muscular dystrophy (EDMD)
 - Limb-Girdle Type 1B muscular dystrophy (LGMD1B)
 - Myotonic Dystrophy Type 1 with an indication for a permanent pacemaker
 - Lamin A/C (LMNA) mutation (for patients who don't meet the above criteria of EDMD or LGMD1B) when there is documentation of <u>two or more</u> of the following risk factors for sudden cardiac death:
 - Non-sustained ventricular tachycardia
 - LVEF < 45%
 - Non-missense mutation (ins-del/truncating or mutations affecting splicing)
 - Male sex at birth
 - For sustained VT see <u>Sustained Ventricular Tachycardia with Normal LV</u>
 Function

Other indications (CRID-3.7)

- ICD implantation is reasonable, regardless of LV ejection fraction measurement, for individuals with:
 - Cardiac sarcoidosis
 - o Giant cell myocarditis
 - Chagas disease
- LV non compaction
 - ICD implantation should be considered for the primary prevention of sudden cardiac death due to malignant ventricular arrhythmias in individuals with noncompaction cardiomyopathy and impaired LV function (LV ejection fraction less than 50%)
 - ICD implantation is also indicated for normal LV function (LVEF greater than 50%) primary prevention cases with positive family history of sudden cardiac death. This exception is due to the presence of sarcomeric gene mutations reported in non-compaction cardiomyopathy
- ICD implantation may be considered in affected individuals with a familial cardiomyopathy associated with sudden death

ICD implantation non-indications (CRID-4)

CID.ICD.102.A

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Ischemic cardiomyopathy (CRID-4.1)

- ICD implantation is <u>not</u> indicated in individuals who have had a myocardial infarction within the past 40 days or who have had coronary revascularization within the past 90 days <u>unless</u> the following applies:
 - A separate indication for permanent pacemaker implantation exists (thus preventing a likely repeat procedure for an upgraded device in the near future)

NYHA class IV CHF (CRID-4.2)

- ICD implantation is <u>not</u> indicated for individuals with NYHA functional class IV symptoms <u>unless</u> one of the following applies:
 - It is a CRT-D device meeting the indications for CRT-D implantation listed in <u>Sinus Rhythm, Dilated Cardiomyopathy with NYHA Class II, III, or IV</u> <u>Congestive Heart Failure (CHF)</u>
 - The individual is awaiting heart transplantation
 - o Left ventricular assist device (LVAD) is being used as destination therapy

Limited life expectancy (CRID-4.3)

- ICD implantation is <u>not</u> indicated for individuals who do not have a reasonable expectation of survival with an acceptable functional status for at least one year, even if they meet ICD implantation criteria listed in:
 - o Definite Indications for ICD Implantation or
 - Reasonable Indications for ICD Implantation

Incessant VT or VF (CRID-4.4)

ICD implantation is <u>not</u> indicated for individuals with incessant VT or VF

 Incessant VT or VF is defined as hemodynamically stable VT or VF continuing for hours

Psychiatric conditions (CRID-4.5)

 ICD implantation is <u>not</u> indicated in individuals with significant psychiatric illnesses that may be aggravated by device implantation or that may preclude systematic follow-up.

Reversible causes of VT/VF (CRID-4.6)

- ICD implantation is <u>not</u> indicated when VF or VT is due to a reversible cause such as:
 - Severe electrolyte disturbance
 - Drug-induced torsades de pointes
 - o Acute, reperfused myocardial infarction with preserved ejection fraction

Ablation candidate, no structural heart disease (CRID-4.7)

 ICD implantation is <u>not</u> indicated if the individual has no structural heart disease and is a candidate for ablation. Surgical or catheter ablation can be curative in this setting.

Substernal implantable cardioverter-defibrillator (CRID-4.8)

CPT® 0571T

- Substernal implantable cardioverter-defibrillator systems involve inserting a
 defibrillator lead directly beneath the sternum anterior to the heart, and is intended
 to provide anti-tachycardia pacing as well as post-shock pacing without intravenous
 leads.
- At this time substernal implantable cardioverter-defibrillator systems are considered experimental and investigational.

Cardiac Resynchronization Therapy (CRT) Devices

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Indications for cardiac resynchronization therapy (CRT)-D implantation (CRID-5)

CID.CRT.100.A

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Procedures included

CPT® 33224, 33225, 33208, 33229, 33249, 33264

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Sinus rhythm, dilated cardiomyopathy with LBBB (CRID-5.1)

- CRT-D is indicated in individuals with ischemic or nonischemic dilated cardiomyopathy who have <u>all</u> of the following
 - o LV ejection fraction ≤35% despite optimal medical therapy (OMT)
 - o Left bundle branch block with QRS ≥120 msec
 - Symptomatic heart failure NYHA functional Class II, III, or ambulatory class IV
- CRT-P can be indicated when all of the requirements of CRT-D have been met and the individual in consultation with the providing physician declines the ICD function

Sinus rhythm, dilated cardiomyopathy with non-LBBB (CRID-5.3)

- CRT-D is indicated in individuals with ischemic or nonischemic dilated cardiomyopathy who have <u>all</u> of the following
 - o LV ejection fraction ≤35% despite optimal medical therapy (OMT)
 - Non-LBBB pattern with QRS duration ≥150 ms
 - o Symptomatic heart failure NYHA class III, or ambulatory class IV
- CRT-P can be indicated when all of the requirements of CRT-D have been met and the individual in consultation with the providing physician declines the ICD function

Atrial fibrillation and NYHA class II, III, or IV Congestive Heart Failure (CRID-5.4)

• CRT-D is indicated in individuals with atrial fibrillation who have <u>all</u> of the following:

- LV ejection fraction ≤35% despite <u>optimal medical therapy (OMT)</u>
- Meet one of the following CRT criteria:
 - Left bundle branch block (LBBB) with a QRS duration ≥120 ms and symptomatic heart failure New York Heart Association (NYHA) functional class II, III, or ambulatory class IV
 - Non-LBBB pattern with a QRS duration ≥150 and symptomatic heart failure NYHA class III or ambulatory class IV
- Non-pharmacologic or pharmacologic rate control will allow near 100% biventricular pacing with CRT
- CRT-P can be indicated when all of the requirements of CRT-D have been met and the individual in consultation with the providing physician declines the ICD function

Dilated Cardiomyopathy with atrial fibrillation requiring AV Junction ablation for heart rate control (CRID-5.5)

CRT-D is indicated in individuals with atrial fibrillation and <u>all</u> of the following:

- LV ejection fraction ≤35% optimal medical therapy (OMT)
- Uncontrolled heart rate requiring atrioventricular (AV) Junction ablation

CRT-P can be indicated when all of the requirements of CRT-D have been met and the individual in consultation with the providing physician declines the ICD function

Dilated Cardiomyopathy with high-grade AV block (CRID-5.6)

CRT-D is indicated in individuals in sinus rhythm or atrial fibrillation who have <u>all</u> of the following:

- LV ejection fraction ≤35% despite optimal medical therapy (OMT)
- High-grade atrioventricular (AV) block requiring ventricular pacing

CRT-P can be indicated when all of the requirements of CRT-D have been met and the individual in consultation with the providing physician declines the ICD function

Indications for upgrade to CRT-D (CRID-5.7)

Upgrade to CRT-D is indicated in individuals who have $\underline{\textbf{all}}$ of the following:

- LV ejection fraction ≤35% despite optimal medical therapy (OMT)
- New or worsening symptomatic heart failure (NYHA functional Class II, III, or ambulatory class IV) following implantation of a non-CRT pacemaker or cardioverter-defibrillator (ICD)
- Ventricular pacing >40%

CRT-P can be indicated when all of the requirements of CRT-D have been met and the individual in consultation with the providing physician declines the ICD function

Cardiac resynchronization therapy (CRT)-D implantation - non-indications (CRID-6)

CID.CRT.101.A

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Ischemic cardiomyopathy (CRID-6.1)

- CRT-D or CRT-P implantation is <u>not</u> indicated in individuals who have had a
 myocardial infarction within the past 40 days or who have had coronary
 revascularization within the past 90 days <u>unless</u> the following applies
 - A separate indication for permanent pacemaker implantation exists (thus preventing a likely repeat procedure for an upgraded device in the near future)

Reversible causes of cardiomyopathy (CRID-6.2)

- CRT-D implantation is <u>not</u> indicated in the setting of a reversible cardiomyopathy such as: toxic, metabolic, or tachycardia induced cardiomyopathy
 - Once the reversible aberration is corrected, clinical reassessment is indicated

Cardiac resynchronization therapy (CRT)-P (CRID-10)

CID.CRT.102.A

v1.0.2024

Indications for CRT-P (CRID-10.1)

Procedures included

CPT® 33224, 33225, 33208, 33229

CRT-P is indicated for any of the following:

- High grade AV block and NYHA Class I, II or III Congestive Heart Failure:
 - o CRT-P implantation is indicated in individuals who have <u>all</u> of the following:
 - LV ejection fraction <50%
 - NYHA Class I, II, or III heart failure
 - High grade AV block, including AV nodal ablation, requiring more than 40% ventricular pacing (CRT)-P
- Pacing-induced cardiomyopathy
 - Upgrade from non-CRT pacemaker to CRT-P is indicated in individuals who have <u>all</u> of the following:
 - LV EF >50% prior to implantation of non-CRT pacemaker
 - Right ventricular pacing burden ≥40%
 - One of the following occurring after implantation of non-CRT pacemaker:
 - Decline in LV EF ≥10%
 - New or worsening heart failure symptoms NYHA Class II or III
- See also <u>Indications for Cardiac Resynchronization Therapy (CRT)-D</u>
 <u>Implantation</u> for individuals who have met requirements for CRT-D, but decline the ICD function

Indications for conduction system pacing

His bundle pacing or left bundle branch area pacing (CPT® 33207 or CPT® 33208) may be considered when CRID 10.1 indications for CRT-P are met and one of the following applies:

- LV lead placement was attempted and was unsuccessful or suboptimal
- His bundle pacing or left bundle branch area pacing is planned in place of biventricular pacing

Wireless Cardiac Resynchronization (CRID-11.2)

CID.CRT.104.A

v1.0.2024

Wireless cardiac resynchronization - Criteria (CRID-11.2)

 Permanent LV leadless pacemakers (CPT® 0515T) are implanted directly in the left ventricle for synchronization with RV leads in the setting of cardiac resynchronization therapy. At this time they are considered experimental and investigational.

Other Cardiac Implantable Devices

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Wireless Pulmonary Artery Pressure Sensor (CRID-11.3)

CID.OD.100.A

v1.0.2024

Wireless pulmonary artery pressure sensor - Criteria

Wireless Pulmonary Artery Pressure Sensor devices (CPT® 33289) such as, CardioMEMS™ HF System, are implanted into a branch of the pulmonary artery during right heart catheterization and require a specialized delivery system. These devices monitor constant pulmonary artery pressures over time, utilizing the concept that as pulmonary artery pressures increase, outpatient medical therapy can be adjusted. This can potentially reduce inpatient admissions and treatment.

 Although FDA approved, these devices have yet to be incorporated into the standard of care and remain investigational and experimental at this time.

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