Cardiomyopathies

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Other Notices:

Guideline Information:

Disease Area: Cardiology
Care Path Group: General Cardiology
Care Path Name: Cardiomyopathies
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Care Path Overview

Care Path Clinical Discussion

Cardiomyopathy, which means heart muscle disease, is separated into hypertrophic, dilated, and restrictive categories. Hypertrophic cardiomyopathy is the most common inherited cardiomyopathy and can cause many symptoms, including atypical chest pain, exertional dyspnea, heart failure, presyncope, and sudden cardiac death. Dilated cardiomyopathy can be genetic or acquired and usually presents with classic symptoms of heart failure. Restrictive cardiomyopathy is less common and often associated with systemic disease.[1] Diagnosis of cardiomyopathy starts with a history and physical examination and typically includes ECG and echocardiography.[1]

Hypertrophic Cardiomyopathy

Hypertrophic cardiomyopathy (HCM) is a genetic disease of the development of cardiomyocytes resulting in structural muscle abnormalities of the left ventricle over time.

These muscle abnormalities may result in asymmetric left ventricular hypertrophy, impaired ventricular relaxation, or muscular left ventricular outflow tract obstruction (LVOTO). Other forms of focal regions of abnormal cellular maturity (e.g., non-compaction cardiomyopathy, right ventricular cardiomyopathy) also occur. Consequently, arrhythmias, heart failure, and sudden cardiac death accompany these conditions.[2] Symptoms, cardiac events, detection of heart murmurs, abnormal 12-lead ECGs, and cardiac imaging during family studies can all trigger an HCM evaluation.[2] In some circumstances, physicians should discuss genetic transmission, including screening of first-degree relatives. Genetic testing or an imaging/ECG surveillance protocol can begin at any age, influenced by specifics of the patient/family history and family preference.[2]

Left ventricular outflow tract obstruction (LVOTO) may co-occur with impaired ventricular emptying, a reduced stroke volume, an increased risk of heart failure (HF), and higher mortality.[2] Because many HCM patients develop LVOTO, obstruction should be investigated with both resting echo (with Valsalva) and stress echocardiography. If a significant gradient is provokable with this testing, activity limitation is indicated. In symptomatic patients with significant LVOT obstruction, initiate medical therapy (i.e., beta-blockers, calcium channel blockers, disopyramide) to improve the outflow mechanics. Rapid atrial fibrillation is poorly tolerated in patients with HCM, so it is crucial

to maintain sinus rhythm and rate control.[1] Oral anticoagulation is recommended for these patients as primary stroke prophylaxis regardless of CHA_2DS_2-VASc score.[2,3] Catheter ablation may be a treatment option. Patients undergoing surgical myectomy may also have surgical AF ablation performed at the same time.[2]

Adult patients with HCM may additionally develop coronary artery disease and experience dyspnea and chest discomfort. Therefore, physicians should complete a routine evaluation for suspected coronary artery disease in addition to evaluating and managing the cardiomyopathy.[2]

Patients with HCM are at increased risk for sudden cardiac death, so risk stratification for implantable cardioverter-defibrillator (ICD) intervention is critical.[2,3] Primary prevention of sudden cardiac death (SCD) with an ICD is appropriate for patients with severe hypertrophy (greater than 30 mm), a family history of SCD in a first-degree relative, or recent unexplained syncope. Other considerations for ICD placement for primary prevention include marked late-gadolinium enhancement on MRI, an apical aneurysm, the discovery of ventricular tachycardia on ambulatory monitoring, and a falling blood pressure response to exercise. Patients who survive SCD or patients with documented ventricular tachycardia (VT) are frequently candidates for ICD implantation. A thorough evaluation for provokable obstruction is needed to avoid ICD implantation for syncope related to LVOTO rather than ventricular arrhythmias in patients with syncope.[2,3] ICD shocks can impair the quality of life and worsen outcomes in HCM patients, so preventing recurrent VT is crucial.[2]

In patients with HCM, ejection fraction (EF) often overestimates myocardial systolic function, so an EF of less than 50% indicates significantly reduced systolic function and worse outcomes.[2] Per the American College of Cardiology Heart Failure Guidelines, physicians should initiate guideline-directed medical therapy for heart failure when EF is less than 50% (compared to less than 40% in other heart failure populations).[2]

In addition to treating LVOTO, appropriate activity restriction, evaluation for implantable cardioverter-defibrillator placement, and management of atrial fibrillation are key. Cardiac transplantation may also be therapeutically appropriate.[1]

Dilated Cardiomyopathy

Dilated cardiomyopathy (DCM) is characterized by dilation and impaired contraction of one or both ventricles. However, patients may have impaired ventricular function without symptoms. Heart failure is best classified in clinical degrees from minimal to severe (see Definitions: NYHA Classification),

and this is a significant cause of hospitalizations and mortality. The presenting manifestations are various. DCM may begin with an acute myocardial infarction or present insidiously as with exercise limitations, atrial or ventricular arrhythmias, syncope, and even sudden death. Additionally, patients may develop a DCM secondary to abnormal valve function, metabolic abnormalities, the influence of toxic therapeutic agents, or pericardial restriction.[4]

Placement of an ICD to prevent sudden death is appropriate in patients with asymptomatic ischemic cardiomyopathy who are at least 40 days post-MI and have an LVEF of 30% or less, or in patients with ischemic or nonischemic dilated cardiomyopathy who have an LVEF of 35% or less, have NYHA Class II or III symptoms on appropriate medical therapy, and who have an anticipated good functional status for more than one year.[4] Cardiac resynchronization therapy (CRT) is appropriate for patients with 1) LVEF of 35% or less; 2) sinus rhythm; 3) left bundle-branch block (LBBB) with a QRS duration of 150 ms or greater; and 4) NYHA class II, III, or ambulatory IV patients on guideline-directed medical therapy.[4]

Restrictive Cardiomyopathy

Restrictive cardiomyopathy is a rare disease of the myocardium characterized by diastolic dysfunction with restrictive ventricular physiology. Restrictive cardiomyopathy can cause right, left, or biventricular failure. Restrictive cardiomyopathy may be primary or secondary, with causes including amyloidosis, sarcoidosis, hemochromatosis, radiation therapy, and scleroderma.[1]

Cardiac amyloidosis is a frequent cause of unexplained left ventricular hypertrophy (LVH). Various pathologic subtypes have differing prognoses and treatments. Light chain amyloidosis (AL) is a rare but treatable condition resulting from the deposition of immunoglobulin light chains from plasma cell dyscrasia. ATTR amyloidosis results from the deposition of transthyretin (TTR) and includes both hereditary and nonhereditary variants. Hereditary ATTR (ATTRm) amyloidosis stems from several heritable genetic mutations of the TTR protein. It is prevalent in African Americans and individuals from northwest Ireland and central-northern Italy. Wild type (nonhereditary) ATTR, previously referred to as senile amyloidosis, is from deposition of wild-type TTR and is more prevalent in men greater than 60 years of age.

Left ventricular ejection fraction (LVEF) is typically normal unless the patient has advanced disease. Atrial enlargement may occur due to impaired ventricular filling during diastole due to increased myocardial stiffness, but the volume and wall thickness of the ventricles are usually normal. Atrial enlargement can lead to atrial arrhythmias and secondary atrioventricular

valve regurgitation. Patients may experience thromboembolic complications due to atrial enlargement.[5]

Currently, there is no known cure for RCM. Treatment of RCM includes treating the underlying cause and heart failure symptoms. Patients with sarcoidosis may receive immunosuppressive agents such as corticosteroids and steroid-sparing agents. For hemochromatosis, therapeutic phlebotomy is the treatment of choice.[6] Amyloidosis treatments depend on the disease type. AL amyloidosis treatment involves chemotherapy or autologous stem cell transplantation for the underlying plasma cell dyscrasia. ATTR amyloidosis patients may benefit from treatment with tafamidis to stabilize the TTR protein, as well as mRNA silencers such as patisiran. Liver transplantation can cure some patients with hereditary ATTRm.

The information contained herein gives a general overview of the pathway of this specific diagnosis, beginning with the initial presentation, recommended assessments, and treatment options as supported by the medical literature and existing guidelines. It should be noted that the care of patients can be complex. The information below is meant to support clinical decision-making in adult patients. It is not necessarily applicable to every case, as the entire clinical picture (including comorbidities, history, etc.) should be considered.

Key Information

- A patient with cardiomyopathy may present with heart failure, sudden cardiac arrest, shortness of breath, decreased exercise tolerance, fatigue, edema, a heart murmur, an abnormal ECG, or during echocardiography performed for other indications. Cardiomyopathy diagnosis may also follow the evaluation of a family member with HCM.
- HF is the primary diagnosis in over one million hospitalizations annually. Patients hospitalized for heart failure have a 25% chance of being readmitted for any reason within one month. The total cost of care for heart failure in the United States exceeds $30 billion annually.[4]
- After a comprehensive history and physical exam, perform an ECG, chest x-ray, and echocardiogram.
- Physicians should treat comorbidities including hypertension, hyperlipidemia, diabetes, obesity, and reduce risk factors for ischemic heart disease.[4]
- Rule out ischemic CAD as a cause of ventricular dysfunction. In patients with stable or chronic symptoms, perform non-invasive testing with imaging. The American College of Cardiology, the American Heart Association, and the Heart Rhythm Society have evidence-based guidelines for interventional and medical management decisions.

Definitions

- **CHA_2DS_2-VASc:** The most commonly utilized method to predict thromboembolic risk in atrial fibrillation. CHA_2DS_2 stands for: **C**ongestive Heart Failure (+1), **H**ypertension (+1), **A**ge greater than or equal to 75y (+2), **D**iabetes (+1), **S**troke history, TIA, or thromboembolism (+2), **V**ascular disease, e.g., prior MI, PVD, aortic plaque (+1), **A**ge 65-74y, and **S**ex **c**ategory (Female +1).
- **Left Ventricular Outflow Tract Obstruction (LVOTO):** Left Ventricular Outflow Tract Obstruction may occur in some patients with Hypertrophic Cardiomyopathy where the hypertrophied septum abuts against the anterior leaflet of the mitral valve resulting in obstruction to LV outflow just below the aortic valve. Typically there is a pressure gradient measurable by echocardiography or cardiac catheterization.
- **Amyloidosis:** A systemic disorder due to deposition of amyloid myofibrillar proteins in various organ systems, including the heart, central and peripheral nervous system, liver, pancreas, eye, and more.
- **Sarcoidosis:** A multisystem disorder of unknown etiology characterized by the accumulation of noncaseating granulomas in involved tissues, including the lungs, heart, GI tract, nervous system, skin, etc.
- **Hemochromatosis:** A multisystem disorder due to excess iron deposits in various organs resulting in a variety of symptoms including sexual dysfunction, joint pains, changes in skin coloration, heart failure, diabetes mellitus, and, rarely, thyroid disease or liver cancer.
- **B-type natriuretic peptide (BNP):** Useful marker for the diagnosis, severity, and prognosis in patients with heart failure. Serial BNP levels may help assess treatment efficacy and prognosis.
- **New York Heart Association (NYHA) Classification:** A common measure of heart failure.
    - Class I: The patient has a cardiac disease that does not limit ordinary physical activity.
    - Class II (Mild): The patient has cardiac disease, causing slight limitations in physical activity. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain. Comfortable at rest.
    - Class III (Moderate): The patient has a cardiac disease that noticeably limits physical activity. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain. Comfortable at rest.
    - Class IV (Severe): The patient has a cardiac disease that prevents them from physical activity. Experiences symptoms and discomfort at rest.[7]
- **Pre-Test Probability:** The pretest probability of CAD is the likelihood that the patient has CAD, calculated before the test result is known. These

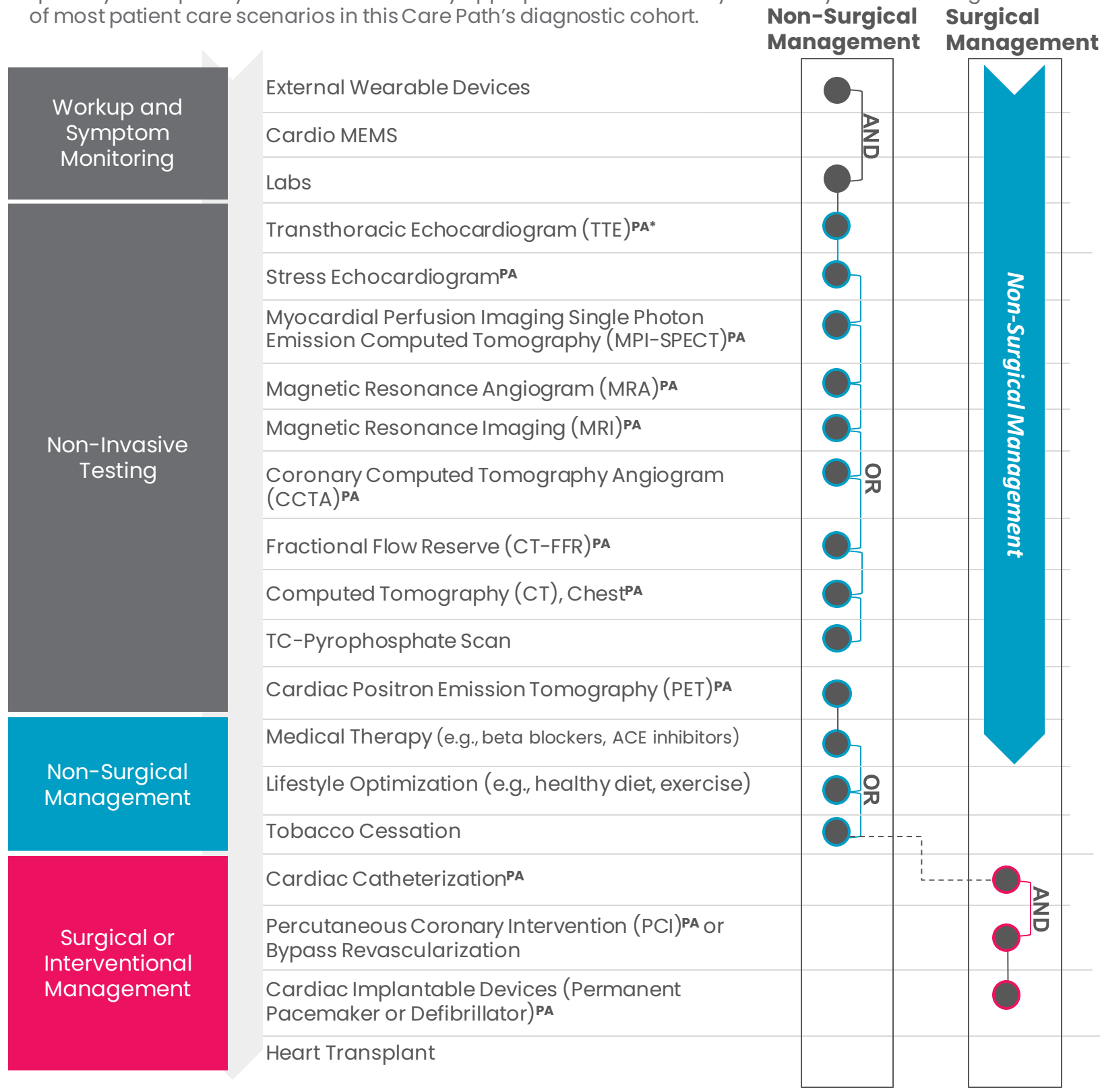
guidelines reference the 2019 European Society of Cardiology (ESC) Guidelines for the diagnosis and management of chronic coronary syndromes model to calculate the pretest probability based on age, sex, and type of chest pain.[8,9]

- **Canadian Cardiovascular Society grading of Angina Pectoris**:
    - Grade I: Ordinary physical activity, such as walking and climbing stairs, does not cause angina. Angina with strenuous or rapid or prolonged exertion at work or recreation.
    - Grade II: Slight limitation of ordinary activity. Angina while walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in the cold, or in the wind, or under emotional stress, or only during the few hours after awakening. Angina with walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.
    - Grade III: Marked limitation of ordinary physical activity. Angina while walking one or two blocks on the level and climbing one flight of stairs in normal conditions and at normal pace.
    - Grade IV: Inability to carry on any physical activity without discomfort; anginal syndrome may be present at rest.

Cardiomyopathies

What is a "Cohere Care Path"?

These Care Paths organize the services typically considered most clinically optimal and likely to be automatically approved. These service recommendations also include the suggested sequencing and quantity or frequency determined clinically appropriate and medically necessary for the management of most patient care scenarios in this Care Path's diagnostic cohort.



Key

PA = Service may require prior authorization
★ = Denotes preferred service
AND = Services completed concurrently
OR = Services generally mutually exclusive

= Non-surgical management prior authorization group of services
= Surgical management prior authorization group of services
= Subsequent service
= Management path moves to a different management path

Care Path Diagnostic Criteria

Disease Classification:

Cardiomyopathies; Hypertrophic Cardiomyopathy (HCM), Dilated Cardiomyopathy, Restrictive Cardiomyopathy, Reversible Cardiomyopathies

ICD-10 Codes Associated with Classification

ICD-10 Code	Code Description/Definition
B33.22	Viral myocarditis
B33.24	Viral cardiomyopathy
D86.85	Sarcoid myocarditis
D86.9	Sarcoidosis, unspecified
E85.4	Organ-limited amyloidosis
E85.9	Amyloidosis, unspecified
I11.0	Hypertensive heart disease with heart failure
I11.9	Hypertensive heart disease without heart failure
I25.5	Ischemic cardiomyopathy
I27.22	Pulmonary hypertension due to left heart disease
I27.81	Cor pulmonale (chronic)
I40.9	Acute myocarditis, unspecified
I42.0	Dilated cardiomyopathy
I42.1	Obstructive hypertrophic cardiomyopathy
I42.2	Other hypertrophic cardiomyopathy
I42.5	Other restrictive cardiomyopathy
I42.6	Alcoholic cardiomyopathy
I42.7	Cardiomyopathy due to drug and external agent
I42.8	Other cardiomyopathies
I42.9	Cardiomyopathy, unspecified
I50.1	Left ventricular failure, unspecified

I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.810	Right heart failure, unspecified
I50.811	Acute right heart failure
I50.812	Chronic right heart failure
I50.813	Acute on chronic right heart failure
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure
I50.83	High output heart failure
I50.84	End stage heart failure
I50.89	Other heart failure
I50.9	Heart failure, unspecified
I51.4	Myocarditis, unspecified
I51.5	Myocardial degeneration
I51.7	Cardiomegaly
I51.81	Takotsubo syndrome

I51.9	Heart disease, unspecified
O90.3	Peripartum cardiomyopathy
T86.20	Unspecified complication of heart transplant
T86.22	Heart transplant failure
T86.23	Heart transplant infection
T86.298	Other complications of heart transplant
I11	Hypertensive heart disease
I40	Acute myocarditis
I40.0	Infective myocarditis
I40.1	Isolated myocarditis
I40.8	Other acute myocarditis
I42	Cardiomyopathy
I42.3	Endomyocardial (eosinophilic) disease
I42.4	Endocardial fibroelastosis
I5A	Non-ischemic myocardial injury (non-traumatic)
I50	Heart failure
I50.2	Systolic (congestive) heart failure
I50.3	Diastolic (congestive) heart failure
I50.4	Combined systolic (congestive) and diastolic (congestive) heart failure
I50.8	Other heart failure
I50.81	Right heart failure
I51	Complications and ill-defined descriptions of heart disease
I51.3	Intracardiac thrombosis, not elsewhere classified
I51.8	Other ill-defined heart diseases
I51.89	Other ill-defined heart diseases
I51.9	Heart disease, unspecified

Presentation and Etiology

Causes and Risk Factors

Hypertrophic cardiomyopathy is a genetic condition characterized as follows[2]:

- Hypertrophic cardiomyopathy with Left Ventricular Outflow Tract (LVOT) obstruction.
- Hypertrophic cardiomyopathy without LVOT obstruction.

Dilated cardiomyopathy causes include:

- Ischemic coronary artery disease.
- Hypertension.
- Diabetes mellitus.
- Antineoplastic medications.
- Substance abuse - alcohol, cocaine, methamphetamine.
- Malnutrition.
- Tachycardia-induced cardiomyopathy - i.e., rapid atrial fibrillation.
- Peripartum cardiomyopathy.

Restrictive cardiomyopathy causes include:

- Amyloidosis - the most common restrictive CM in the USA.
- Sarcoidosis.
- Hemochromatosis.

Cardiomyopathy may have genetic origins, such as arrhythmogenic right ventricular cardiomyopathy. It can be a consequence of systemic disorders like scleroderma, lupus or viral illness such as hepatitis or HIV.

Clinical Presentation

History

Patients with cardiomyopathy may present with the following:

- Heart failure.
- Sudden cardiac arrest.
- Shortness of breath.
- Decreased exercise tolerance.
- Fatigue.
- Edema.
- Syncope.

The following may trigger a clinical evaluation for HCM:

- Diagnosis of HCM in a family member.
- Heart murmur.

- Abnormal ECG.
- During echocardiography performed for other indications.

Typical Physical Exam Findings

The following findings physical exam findings may appear singularly or in combination:

- Rapid or irregular pulse.
- Evidence of congestive heart failure, such as abnormal breath sounds, liver enlargement, and peripheral edema.
- Palpable cardiac enlargement.[10]
- Distended neck veins with abnormal pulsations.
- Low blood pressure.
- Abnormal heart sounds (murmurs and a third heart sound).

Typical Diagnostic Evaluation and Findings

Essential office-based testing for cardiomyopathy includes:

- Blood tests:
    - Basic metabolic panel
    - B-type natriuretic peptide (BNP)
    - Lipid panel.
- 12-lead electrocardiogram (ECG).[4]
- Chest x-ray.
- Echocardiography.

ECG findings in cardiomyopathy include:

- Abnormal P-waves indicating atrial enlargement.
- QRS complex abnormalities suggesting ventricular hypertrophy and conduction abnormalities.
- Repolarization abnormalities, especially T wave inversions, suggesting myocardial hypertrophy and fibrosis.
- Cardiac rhythm abnormalities, such as atrial fibrillation.
- Cardiac conduction abnormalities, such as heart block or bundle branch block.[4]

A chest x-ray may reveal:

- Cardiomegaly.
- Pulmonary congestion and interstitial edema.
- Pleural effusions.

Typical transthoracic echocardiography (TTE) findings include:

- Increased chamber dimensions.
- Reduced ejection fraction (LVEF) or fractional shortening.

- Myocardial wall thickening (hypertrophy or infiltration).
- Regional wall motion abnormalities.
- Mitral and tricuspid valvular regurgitation.

In certain circumstances, a repeat TTE may be appropriate for monitoring a patient's condition and response to therapy, including:[4]

- Studies to monitor the benefit of drug therapy or surgical intervention.
- Studies anticipating the need for device therapy (e.g., pacemaker or ICD).[4]
- Studies anticipating surgical intervention (e.g., septal ablation or revascularization).
- Patients who have had a significant change of clinical status.
- Patients receiving medications known to have cardiac toxicity.

Tc99m-pyrophosphate bone scintigraphy is particularly useful in differentiating ATTR from AL amyloidosis and may be sufficient to diagnose this condition without a tissue biopsy.

Care Path Services & Medical Necessity Criteria

Workup and Symptom Monitoring

Service: Genetic Testing, Cardiomyopathy

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** Complete testing for a specific genetic disease only once unless new capabilities for detecting additional mutations develop.
- **Recommended Clinical Approach:** Cardiomyopathies with a known genetic cause include hypertrophic (HCM), dilated (DCM), restrictive (RCM), arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVD/C), and left ventricular noncompaction (LVNC).[11] The available clinical genetics data for each of the cardiomyopathies varies greatly in content and quality with the strongest validated data for HCM.[12]
    - Genetic testing is recommended for first-degree relatives of a person (the proband) diagnosed with hypertrophic cardiomyopathy.[13] Hypertrophic cardiomyopathy is inherited as an autosomal dominant trait in most cases, with offspring having a 50% chance of inheriting the same disease-causing genetic variant.[14] In first-degree relatives of people with HCM, both clinical screening (ECG and 2D echocardiogram) and cascade genetic testing [when a pathogenic/likely pathogenic variant has been identified in the proband (MYH7, MYBPC3, TNNI3, TNNT2, TPM1, MYL2, MYL3, or ACTC1 genes)] should be offered.[2,16]
    - For Dilated cardiomyopathy (DCM) or Arrhythmogenic right ventricular dysplasia/cardiomyopathy(ARVD/C), genetic testing should be considered for the one most clearly affected person in a family to facilitate family screening and management.[17] Specific genes available for screening should be based on the cardiac phenotype (DCM: LMNA, MYH7, TNNT2, RBM20, TTN, BAG3, SCN5A, TNNI3, TNNC1, TPM1, PLN, and FLNC. ARVD/C: DSP, PKP2, DSG2, DSC2, JUP, and TMEM43).[12,18]
- **Exclusions:** None.

Medical Necessity Criteria

Indications

- ➔ **Genetic testing** is considered appropriate if **ANY** of the following is **TRUE**:
  - ◆ The patient is a first-degree family member of a person diagnosed with hypertrophic cardiomyopathy when a pathogenic/likely pathogenic variant has been identified in the proband.[16]
  - ◆ The patient is the one most clearly affected person in a family, to facilitate family screening and management in cases of dilated cardiomyopathy or arrhythmogenic right ventricular dysplasia/cardiomyopathy.[13]

Non-Indications

- ➔ **Genetic testing** is not considered appropriate if **ANY** of the following is **TRUE**:
  - ◆ Genetic testing for cardiomyopathy was already completed.

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
S3866	Genetic analysis for a specific gene mutation for hypertrophic cardiomyopathy (HCM) in an individual with a known HCM mutation in the family
81439	Hereditary cardiomyopathy (eg, hypertrophic cardiomyopathy, dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy), genomic sequence analysis panel, must include sequencing of at least 5 cardiomyopathy-related genes (eg, DSG2, MYBPC3, MYH7, PKP2, TTN)

Service: External Wearable Devices

General Guidelines

- **Units, Frequency, & Duration:** When medical necessity is met based on described clinical criteria AND exclusionary criteria are absent, noninvasive external cardiac monitoring may be appropriate. Use external wearable devices for a duration between 24 hours and 30 days, depending on symptom frequency.[19]
- **Criteria for Subsequent Requests:** Subsequent requests may be appropriate if assessing the response to medical therapy or evaluating persistent or worsening symptoms.
- **Recommended Clinical Approach:** External wearable devices are appropriate for patients with known or suspected cardiomyopathy who have symptoms of palpitations, syncope or near syncope, or are at-risk of serious ventricular arrhythmias and sudden cardiac death. The most appropriate external wearable monitor should be selected based on clinical history, physical exam, 12-lead ECG, symptom frequency, and suspected duration of the episodes. Address daily symptoms and brief ongoing palpitations with a 24-48 hour Holter monitor. Less frequent or asymptomatic events are more likely to be captured with more prolonged monitoring, either an extended-wear patch device, a 30-day loop recorder, or cardiac mobile telemetry. Consideration of patient ability to trigger a device effectively may also guide device selection in favor of those with more passive event recording capability.[19]
- **Exclusions:** 2 types of monitors cannot be ordered simultaneously.

Medical Necessity Criteria

Indications

➔ **External wearable devices** are considered appropriate if **ALL** of the following are **TRUE**[19]:

- ◆ The patient has **ANY** positive findings from the clinical presentation or typical physical exam findings lists, such as:
  - Syncope or near-syncope
  - Palpitations
  - Dizziness
  - In patients with hypertrophic cardiomyopathy (HCM), 24- to 48-hour ambulatory electrocardiographic monitoring for **ANY** of the following:
    - Initial evaluation

        - Periodic follow-up (every 1 to 2 years)[2]
    - The patient does not have superseding symptoms of a more urgent cardiac condition that ambulatory cardiac monitoring would delay.
    - The patient does not have an implantable cardiac device capable of acquiring similar clinical information.
    - If the patient has had 3 or more external wearable devices in the last six months, consider an internal loop recorder.

Non-Indications

➔ **External wearable devices** are not considered appropriate if **ANY** of the following is **TRUE**:

- Suspected arrhythmia is angina-related, and coronary artery disease characterization is a priority.
- The patient has an implantable cardiac device capable of acquiring clinical data of a similar or equivalent quality to an external cardiac monitor.
- The patient presents in atrial fibrillation with rapid ventricular response or ventricular tachyarrhythmias - these patients require acute treatment for rhythm control or anticoagulation.

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
93228	Other qualified health care professional review and interpretation with report of external mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis, and greater than 24 hours of accessible electrocardiogram (ECG) data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days
93229	Technical support for connection and patient instructions for use, attended surveillance for up to 30 days, analysis and other qualified health care professional prescribed transmission of daily and emergent data reports of external mobile cardiovascular telemetry with

	electrocardiographic recording, concurrent computerized real time data analysis, and greater than 24 hours of accessible electrocardiogram (ECG) data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center

Service: CardioMEMS

General Guidelines

- **Units, Frequency, & Duration:** One-time implantation.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** The CardioMEMS device may be indicated for wirelessly measuring and monitoring pulmonary artery (PA) pressure and heart rate in certain patients with New York Heart Association (NYHA) Class III heart failure patients hospitalized for heart failure in the previous year. Physicians use the hemodynamic data for heart failure management to reduce heart failure hospitalizations. Dual antiplatelet therapy is required during the first-month post-implantation.[20] According to the 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure, the usefulness of wireless monitoring of PA pressure by an implanted hemodynamic monitor to reduce the risk of subsequent HF hospitalizations is uncertain.[21]
- **Exclusions:** Patients who are unable to take dual antiplatelet therapy for one month.[22]

Medical Necessity Criteria

Indications

➔ **CardioMEMS** may be considered appropriate if **ALL** of the following are **TRUE**[20]:

- ◆ NYHA class III HF and history of a HF hospitalization in the past year or elevated natriuretic peptide levels, on maximally tolerated stable doses of GDMT with optimal device therapy.[21]
- ◆ All of the Inclusion Criteria should be met and no Exclusion Criteria should be present from at least one of the following trials (CardioMEMS HF System Post Approval Study or GUIDE-HF Trial)[69,70]
- ◆ The patient can take dual antiplatelet therapy for the first month following device implantation.

Non-Indications

➔ **CardioMEMS** is not considered appropriate if **ANY** of the following is **TRUE**[22]:

- ◆ The patient is unable to take dual antiplatelet therapy for one month.[20]

Site of Service Criteria

Inpatient or outpatient, cardiac catheterization lab.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
33289	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
93264	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional.
C2624	Wireless pressure sensor

Non-Invasive Testing

Service: Computed Tomography (CT), Chest

General Guidelines

- **Units, Frequency, & Duration:** Single request based on medical necessity criteria.
- **Criteria for Subsequent Requests:** New indication or follow-up after an intervention.
- **Recommended Clinical Approach:** Chest computed tomography (CT) can evaluate extracardiac manifestations of cardiomyopathies such as hilar adenopathy in sarcoidosis.[23]
- **Exclusions:** Renal insufficiency (eGFR less than 30 mL/min), a history of allergic reaction to iodinated contrast agents, or an inability to cooperate with breath-holding and other technical requirements.[23-24]

Medical Necessity Criteria

Indications

➔ **Chest CT** is considered appropriate if **ANY** of the following is **TRUE**[23]:
- ◆ The cardiomyopathy would be better defined by imaging the lungs or thorax (e.g., amyloidosis, sarcoidosis.)
- ◆ Echocardiography did not adequately image the cardiac chambers valves, great vessels, and pericardium.

Non-Indications

➔ **Chest CT** may not be considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Non-rate-controlled (i.e., rapid) atrial fibrillation or other tachyarrhythmias.
- ◆ Renal failure if angiographic contrast is needed.
- ◆ Contrast dye allergy.
- ◆ In a patient who takes metformin.
- ◆ In pregnant patients.
- ◆ Unable to cooperate with breath-holding.

Site of Service Criteria

Outpatient service.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
71250	Computed tomography (CT) of thorax without contrast material
71260	Computed tomography (CT) of thorax with contrast material
71270	Computed tomography (CT) of thorax without contrast material, followed by contrast and further sections
76380	Limited follow-up computed tomography (CT)

Service: Coronary Computed Tomography Angiography (CCTA)

General Guidelines

- **Units, Frequency, & Duration:** Single request based on medical necessity criteria.
- **Criteria for Subsequent Requests:** New indication or follow-up after an intervention.
- **Recommended Clinical Approach:** Coronary CTA may help diagnose or define coronary artery stenoses in patients with chest pain or unexplained left ventricular (LV) dysfunction.[25]
- **Exclusions:** Renal insufficiency (eGFR less than 30 mL/min), a history of allergic reaction to iodinated contrast agents, or an inability to cooperate with breath-holding and other technical requirements.[24]

Medical Necessity Criteria

Indications

➔ **CCTA** is considered appropriate if **ANY** of the following is **TRUE**[25]:
- ◆ The patient has symptoms suggesting ischemic coronary artery disease (CAD) and an intermediate to high pretest probability of obstructive CAD.
- ◆ The patient presents with unexplained LV dysfunction, which may be due to underlying CAD.

Non-Indications

➔ **CCTA** may not be considered appropriate if **ANY** of the following is **TRUE**[26]:
- ◆ Non-rate-controlled (i.e., rapid) atrial fibrillation or other tachyarrhythmias.
- ◆ Renal failure if angiographic contrast is needed.
- ◆ Contrast dye allergy.
- ◆ In a patient who takes metformin.
- ◆ In pregnant patients.
- ◆ Unable to cooperate with breath-holding.

Site of Service Criteria

Outpatient service.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition

75574	Computed tomographic angiography (CTA) of coronary arteries and bypass grafts, with contrast material and 3-dimensional (3D) image postprocessing

Service: Fractional Flow Reserve (CT-FFR)

General Guidelines

- **Units, Frequency, & Duration:** Single instance, fractional flow reserve (FFR) must be ordered in conjunction with coronary computed tomography angiogram (CTA) imaging.
- **Criteria for Subsequent Requests:** For periodic surveillance of coronary artery lesions or new clinical indications.
- **Recommended Clinical Approach:** The use of noninvasive fractional flow reserve (FFR) following a positive CCTA may be considered medically necessary to guide decisions about the use of invasive coronary angiography in patients with intermediate to high-risk coronary lesions on imaging.[27]
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **FFR***** is considered appropriate if **ANY** of the following is **TRUE**[28]:
- ◆ For functional evaluation of coronary CTA lesions with 40-90% stenosis in a proximal to a middle coronary segment on CCTA.[27,29]
- ◆ FFR is needed to evaluate multivessel disease and to identify culprit lesions causing symptoms.
- ◆ FFR is needed to evaluate the physiologic severity of multiple lesions in a single vessel.

***FFR can only be requested with a coronary CTA or after a recently performed coronary CTA.

Non-Indications

➔ **FFR** is not considered appropriate if **ANY** of the following is **TRUE**[30]:
- ◆ The original CCTA was of suboptimal quality.
- ◆ The patient is not a candidate for revascularization.
- ◆ The patient is post-coronary artery bypass surgery.
- ◆ The patient has a metal intracoronary stent in the vessel needing to be studied.[27]
- ◆ Coronary anatomy that is low risk (is less than 30% stenosis).
- ◆ In cases of complex congenital heart disease.

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
0501T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease.
0502T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission
0503T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model
0504T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report
0523T	Intraprocedural coronary fractional flow reserve (FFR) with 3D functional mapping of color-coded FFR values for the coronary tree, derived from coronary angiogram data, for real-time review and interpretation of possible atherosclerotic stenosis(es) intervention (List separately in addition to code for primary procedure)

Service: Cardiac Positron Emission Tomography (PET)

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach**[31]: Positron emission tomography (PET) is a minimally invasive diagnostic imaging procedure used to evaluate metabolism in normal tissues and diseased tissues (e.g., in ischemic heart disease and cardiomyopathies like amyloidosis, sarcoidosis, HCM, and myocarditis.) It provides information about myocardial viability, which may result in revascularization. It also provides prognostic information regarding the risk of ventricular arrhythmias and sudden cardiac death. The benefits of PET scan include greater accuracy for patients who cannot adequately exercise and less radiation exposure than SPECT. It is particularly beneficial in obese patients and others prone to SPECT attenuation artifact, in younger patients (men less than 40, women less than 50) to reduce radiation exposure compared to single-photon emission computed tomography (SPECT) and following equivocal or nondiagnostic testing.
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Cardiac PET** is considered appropriate if **ALL** of the following are **TRUE**:
- ◆ The patient has chest pain (or an ischemic equivalent) and **ANY** of the following[32]:
  - No known CAD with an intermediate or high pretest probability of CAD
  - History of CAD with symptoms on optimal guideline-directed medical therapy (GDMT) or documented intolerance to GDMT.
- ◆ The patient has **ANY** of the following[32]:
  - A technical limitation to echocardiography or perfusion imaging (e.g., morbid obesity, large breasts, breast implants, previous mastectomy or chest wall deformity, pleural/pericardial effusion).[33]
  - Previous imaging had inadequate findings, technical difficulties with interpretation, or discordant results with previous clinical data.

Non-Indications

- ➔ **Cardiac PET** may not be considered appropriate if **ANY** of the following is **TRUE**[32]:
  - The patient is pregnant.
  - The patient has allergic reactions or intolerance to radiotracers.
  - Normal coronary angiogram or CCTA within the last two years and with no stenosis or plaque.
  - Normal stress test (given adequate stress) within the last year.

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
78429	Single positron emission tomography (PET) myocardial imaging study for metabolic evaluation with concurrently acquired computed tomography (CT) transmission scan
78430	Single positron emission tomography (PET) myocardial perfusion imaging study with evaluation of ejection fraction, at rest, with concurrently acquired computed tomography (CT) transmission scan
78431	Multiple positron emission tomography (PET) myocardial perfusion imaging studies with evaluation of ejection fraction, at rest, with concurrently acquired computed tomography (CT) transmission scan
78432	Positron emission tomography (PET) combined myocardial perfusion imaging study and metabolic evaluation study using dual radiotracer
78433	Positron emission tomography (PET) combined myocardial perfusion imaging and metabolic evaluation study using dual radiotracer, with concurrently acquired computed tomography (CT) transmission scan
78459	Single positron emission tomography (PET) myocardial imaging study for metabolic evaluation
78491	Single positron emission tomography (PET) myocardial perfusion imaging study with evaluation of ejection

	fraction, at rest
78492	Multiple positron emission tomography (PET) myocardial perfusion imaging studies with evaluation of ejection fraction, at rest and with exercise stress
78811	Positron emission tomography (PET) imaging of chest
G0235	Pet not otherwise specified
G0252	Pet imaging initial dx

Service: Magnetic Resonance Imaging (MRI)/Magnetic Resonance Angiogram (MRA)

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** Considerations of additional phase, dynamic sequences, positioning of the patient, and use of markers at the discretion of the protocoling radiologist.
- **Recommended Clinical Approach:** Cardiac MRI helps diagnose a wide range of myocardial diseases, from ischemic to inflammatory and infiltrative cardiomyopathies (e.g., hypertrophic cardiomyopathy (HCM), myocarditis, sarcoidosis, amyloidosis, hemochromatosis.) Cardiac MRI is beneficial in differentiating between restrictive cardiomyopathy from constrictive pericarditis and in the identification of intracavitary thrombus. Late gadolinium enhancement is useful in evaluating myocardial scar and fibrosis and in the determination of myocardial viability with low dose dobutamine. The extent of myocardial scar/fibrosis is directly related to the risk of ventricular arrhythmias and sudden cardiac death. Cardiac MRA can also evaluate the aorta and main pulmonary arteries.[2]
- **Exclusions:** Exclusions include contraindications of MRI (e.g., retained metal, incompatible width to bore size, claustrophobia), incompatibility with following directions (i.e., breath-hold), and renal insufficiency (eGFR less than 30 mL/min per 1.73 m^2) if gadolinium contrast is requested.

Indications

➔ **MRI/MRA** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ The patient has a known or suspected cardiomyopathy (e.g., hypertrophic cardiomyopathy (HCM), amyloidosis, sarcoidosis), and MRI/MRA is needed for **ANY** of the following[2]:
  - Assessing ventricular function and valve abnormalities incompletely characterized by a TTE.
  - In HCM, assessing wall thickness, LVOT gradient or systolic anterior motion of the mitral valve incompletely characterized by a TTE.
  - In HCM, anticipating alcohol septal ablation to assess mitral valve and papillary muscles.

- Assessing the extent of myocardial scar and risk of ventricular arrhythmias and sudden cardiac death.
- Determining myocardial viability for consideration of myocardial revascularization.
- Differentiating between restrictive cardiomyopathy from constrictive pericarditis.[34]

Non-Indications

➔ **MRI/MRA** may not be considered appropriate if **ANY** of the following is **TRUE**[35]:

- ◆ The patient has non-compatible implanted devices.
- ◆ The patient has metallic intraocular foreign bodies.
- ◆ There is a potential for adverse reactions to contrast media.
- ◆ The patient has severe claustrophobia.
- ◆ If the patient has renal insufficiency (eGFR less than 30 mL/min per 1.73 m^2) and if gadolinium contrast is requested, an MRI/MRA may not be considered appropriate.

Site of Service Criteria

None.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
71550	Magnetic resonance imaging (MRI) of chest without contrast material
71551	Magnetic resonance imaging (MRI) of chest with contrast material
71552	Magnetic resonance imaging (MRI) of chest with contrast material, including noncontrast images and image postprocessing, for evaluation of hilar and mediastinal lymphadenopathy
71555	Magnetic resonance angiography (MRA) of chest with contrast material
C8909	Mra w/cont, chest
C8910	Mra w/o cont, chest
C8911	Mra w/o fol w/cont, chest

Service: Stress Echocardiogram

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** Stress echocardiography is appropriate for patients with cardiomyopathies who have an increased risk of exercise induced ventricular arrhythmias or sudden cardiac death (SCD). It is also applicable for patients with cardiomyopathies and chest pain who may have CAD. Physicians can use either exercise or pharmacologic agents (i.e., dobutamine) as the stress mechanism.[36] Dobutamine stress echo may be particularly helpful in evaluating myocardial viability before coronary revascularization (either CABG or PCI). This test results in no radiation exposure and is typically lower cost than MPI-SPECT. Other advantages of stress echo compared to MPI-SPECT include shorter patient time commitment, additional information on cardiac structures (LV chamber dimensions, wall motion abnormalities and wall thickness, valve function, ascending aorta, pericardial space), and the test is technically less demanding than MPI-SPECT. The diagnostic accuracy of stress echocardiography is reduced in patients with limited acoustic windows.[28,37]
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Stress echo** is considered appropriate if **ANY** of the following is **TRUE**:
- ◆ In a patient with hypertrophic cardiomyopathy where a mild dynamic left ventricular outflow obstruction requires exercise provocation.
- ◆ To assess for cardiac ischemia, **ALL** of the following are **TRUE**:
  - The patient has chest pain (or an ischemic equivalent), and **ANY** of the following[29]:
    - No known CAD with an intermediate or high pretest probability of CAD
    - History of CAD with symptoms on optimal guideline-directed medical therapy (GDMT) or documented intolerance to GDMT.
  - The patient has **ANY** of the following[38]:
    - ECG abnormalities that interfere with the ECG diagnosis of ischemia, including **ANY** of the following:

- An inability to achieve the target heart rate with a standard exercise treadmill test (greater than or equal to 85% of age-predicted maximal HR).
- Ventricular preexcitation (Wolff-Parkinson-White)
- Ventricular paced rhythm
- Left bundle branch block (LBBB)
- Greater than 1 mm ST depression at rest
- Left ventricular hypertrophy with ST-T abnormalities
- The patient takes digoxin.

- **ANY** of the following conditions[33]:
  - Severe chronic obstructive pulmonary disease (COPD)
  - Congestive heart failure (CHF)
  - Prior thoracotomy (e.g., CABG)
  - An inability to exercise or exercises submaximally that requires pharmacological stress
  - Segmental wall motion abnormalities at rest

Non-Indications

➔ **Stress echo** is not considered appropriate if **ANY** of the following are **TRUE**[39]:

- Normal coronary angiogram or CCTA within the last two years and with no stenosis or plaque (if the assessment is for cardiac ischemia).
- Normal stress test (given adequate stress) within the last year (if the assessment is for cardiac ischemia).
- The patient has a high-priority clinical illness to address before stress testing, such as[36]:
  - Acute coronary syndrome (STEMI, NSTEMI, unstable angina),
  - Acute pericarditis/myocarditis.
  - Severe aortic stenosis.
  - Uncontrolled arrhythmias.
  - Symptomatic congestive heart failure.
  - Known left main coronary artery stenosis.
  - Severe hypertension (greater than 180/100 mmHg).
  - An inability to exercise sufficiently or to tolerate a pharmacologic agent to simulate exercise.

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
93350	Real time transthoracic echocardiography with 2-dimensional (2D) image documentation during rest and cardiovascular stress test using treadmill and pharmacologically induced stress, with interpretation and report
93351	Real time transthoracic echocardiography with 2-dimensional (2D) image documentation during rest and cardiovascular stress test using treadmill, bicycle exercise and pharmacologically induced stress, with interpretation and report, including performance of continuous electrocardiographic monitoring, with physician supervision
C8928	Tte w or w/o fol w/con,stres
C8930	Tte w or w/o contr, cont ecg

Service: Myocardial Perfusion Imaging Single Photon Emission Computed Tomography (MPI-SPECT)

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** Myocardial perfusion imaging single-photon emission computed tomography (MPI-SPECT) may be an appropriate test for patients with known or suspected cardiomyopathy and chest pain or patients at increased risk for exercise-induced ventricular arrhythmias or sudden cardiac death (SCD). An exercise stress test is appropriate if the patient can exercise to a satisfactory workload. If the patient is unable to exercise or has ECG abnormalities that interfere with the interpretation of an ECG during exercise, then MPI-SPECT or stress echo should be considered. Limitations of MPI-SPECT include cost and radiation. MPI-SPECT interpretation can be affected by attenuation artifacts related to soft tissue overlying the heart or extracardiac radioisotope (e.g., liver or gastrointestinal uptake, which may be adjacent to the heart). MPI-SPECT may also be appropriate for evaluating stress-induced symptoms or stress-induced ventricular tachycardia in patients with a diagnosis of hypertrophic cardiomyopathy (HCM), sarcoidosis, or other cardiomyopathies.[2]
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **MPI-SPECT** is considered appropriate if **ALL** of the following are **TRUE**:
- ◆ The patient has chest pain (or an ischemic equivalent) and **ANY** of the following:
  - No known CAD and has an intermediate or high pretest probability of CAD.
  - History of CAD with symptoms on optimal guideline-directed medical therapy (GDMT) or documented intolerance to GDMT.
- ◆ The patient has **ANY** of the following:
  - ECG abnormalities that interfere with the ECG diagnosis of ischemia, including[40]:
    - An inability to achieve the target heart rate with a standard exercise treadmill test (greater than or equal to 85% of age-predicted maximal heart rate).

    - Ventricular preexcitation (Wolff-Parkinson-White pattern).
    - Ventricular-paced rhythm.
    - Left bundle branch block (LBBB).
    - Greater than 1 mm ST depression at rest.
    - Left ventricular hypertrophy with ST-T abnormalities.
    - The patient takes digoxin.
- Previous stress echocardiography had inadequate results, technical difficulties with interpretation, or results discordant with clinical data.
- **ANY** of the following conditions[41]:
    - Severe chronic obstructive pulmonary disease (COPD)
    - Congestive heart failure (CHF)
    - Inability to get an echo window for imaging
    - Prior thoracotomy (e.g., CABG)
    - An inability to exercise OR exercises submaximally which requires pharmacological stress
    - Segmental wall motion abnormalities at rest

Non-Indications

➔ **MPI-SPECT** may not be considered appropriate if **ANY** of the following is true:

- Normal coronary angiogram or CCTA within the last two years and with no stenosis or plaque
- Normal stress test (given adequate stress) within the last year
- There was a recent myocardial infarction or unstable angina unless the condition has been stabilized.
- The patient is pregnant.
- Vasodilators (i.e., adenosine, regadenoson, and dipyridamole) are contraindicated in patients with hypotension, sinus node dysfunction, high-degree atrioventricular (AV) block (in the absence of back up pacemaker capability), and reactive airway disease.
- The patient has a high-priority clinical illness to address before stress testing, such as **ANY** of the following:
    - Acute pericarditis/myocarditis.
    - Severe aortic stenosis.
    - Uncontrolled arrhythmias.
    - Symptomatic congestive heart failure.
    - Known left main coronary artery stenosis.
    - Severe hypertension (greater than 180/100 mmHg).

- An inability to exercise sufficiently or to tolerate a pharmacologic agent to simulate exercise.

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
78451	Single-photon emission computed tomography (SPECT) myocardial perfusion imaging study with stress
78452	Multiple single-photon emission computed tomography (SPECT) myocardial perfusion imaging studies with stress
78472	Single Planar cardiac blood pool imaging, gated equilibrium study at rest
78473	Multiple Planar cardiac blood pool imaging, gated equilibrium studies at rest and stress

Service: Transthoracic Echocardiogram (TTE)

General Guidelines

- **Units, Frequency, & Duration:** Single procedure.
- **Criteria for Subsequent Requests:** Repeat transthoracic echocardiography may be necessary for worsening symptoms, to assess the effects of medical therapy, or when automatic implantable cardioverter-defibrillator (AICD) placement is in consideration.
- **Recommended Clinical Approach:** Transthoracic echocardiography is an important diagnostic imaging modality for patients with known or suspected cardiomyopathy, heart failure, or with symptoms of dyspnea, peripheral edema, syncope, near syncope, palpitations, and unexplained fatigue. It provides an assessment of left and right ventricular function, valve function, and the presence of myocardial and pericardial disease.[42]
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **TTE** is considered appropriate if **ANY** of the following is **TRUE**[42]:

- ◆ The patient did not have a prior TTE, and this test is intended to confirm the clinical suspicion of cardiomyopathy.
- ◆ The patient has confirmed cardiomyopathy and is presenting with worsening symptoms or new signs or symptoms.
- ◆ Prior testing (e.g., chest x-ray, ECG, or cardiac biomarkers) suggested but did not confirm a cardiomyopathy diagnosis.
- ◆ The patient has a cardiac arrhythmia suspected to result from a cardiomyopathy
- ◆ For initial screening of 1st-degree relatives of an index case of hypertrophic cardiomyopathy.
- ◆ For follow up screening every 3-5 years for genotype positive, phenotype negative hypertrophic cardiomyopathy in adults.[2]
- ◆ For follow-up testing for dilated cardiomyopathy (ischemic or nonischemic) patients to track LVEF for **ANY** of the following:
  - To guide medical therapy
  - Recommendations for cardiac resynchronization therapy
  - Listing for transplant.

Non-Indications

- ➔ **TTE** is not considered appropriate if **ANY** of the following is **TRUE**:
  - ◆ Echocardiography has no contraindications. Echocardiography may have limited benefit in patients at the extremes of adult body weight because a thick chest wall (in markedly obese patients) or overcrowded ribs (in severely underweight patients) may limit the penetration of ultrasound waves.[33,42-43]

Site of Service Criteria

Inpatient, outpatient, or observation status.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
93303	Complete transthoracic echocardiography for congenital cardiac anomalies
93304	Follow-up transthoracic echocardiography for congenital cardiac anomalies
93306	Real time transthoracic echocardiography with 2-dimensional (2D) image documentation, M-mode recording with spectral Doppler echocardiography, and color flow Doppler echocardiography
93307	Complete real time transthoracic echocardiography with 2-dimensional (2D) image documentation
93308	Follow-up real time transthoracic echocardiography with 2-dimensional (2D) image documentation
C8921	Tte w or w/o fol w/cont, com
C8922	Tte w or w/o fol w/cont, f/u
C8923	2d tte w or w/o fol w/con,co
C8924	2d tte w or w/o fol w/con,fu
C8929	Tte w or wo fol wcon,doppler

Service: Tc-pyrophosphate Scan

General Guidelines

- **Units, Frequency, & Duration:** Once.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** Technetium-99m pyrophosphate scanning (also referred to as bone tracer cardiac scintigraphy) is an essential test for identifying and differentiating ATTR from AL amyloidosis. This test may be sufficient to diagnose the cardiomyopathy without a tissue biopsy.[44-45]
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Tc-pyrophosphate scan** is considered appropriate if **ANY** of the following is **TRUE**[44]:
- ◆ Unexplained left ventricular hypertrophy (LVH).
- ◆ Aortic stenosis and features of cardiac amyloidosis.
- ◆ Other signs or symptoms typical of amyloidosis.
- ◆ There is suspicion of cardiac ATTR amyloidosis, and the patient has a contraindication to magnetic resonance (e.g., renal insufficiency, presence of a pacemaker).

Non-Indications

➔ **Tc-pyrophosphate scan** is not considered appropriate if the following is **TRUE**:
- ◆ Monoclonal protein identified by serum or urine protein electrophoresis.

Site of Service Criteria

Inpatient, outpatient, or observation status.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
78802	Amyloid Planar spot view and SPECT
78803	Amyloid planar spot view and whole body

Non-Surgical Management

Service: Cardiac Rehabilitation

General Guidelines

- **Units, Frequency, & Duration:** Cardiac rehabilitation is generally appropriate for 36 sessions, 60 minutes each, typically over 12 - 18 weeks. Additional sessions can be requested.[46]
- **Criteria for Subsequent Requests:** Current guidelines do not support the need for repeat cardiac rehabilitation in the absence of a new cardiac event.
- **Recommended Clinical Approach:** Cardiac rehabilitation (CR) is an evidence-based intervention that uses patient education, health behavior modification, and exercise training to improve secondary prevention outcomes and is recognized as an integral component of care for patients with cardiovascular disease.[46-47] Referral to CR is recommended within 12 months after an myocardial infarction (MI), percutaneous coronary intervention, or coronary artery bypass graft surgery or in the setting of stable angina or symptomatic peripheral arterial disease (i.e., intermittent claudication).[46] Referral to CR is also recommended after heart valve surgery or cardiac transplantation, or in the setting of chronic heart failure (NYHA Class I-III) with reduced ejection fraction (HFrEF).[46] The effects of cardiac rehabilitation on mortality, cardiovascular events, hospitalizations, or health-related quality of life are less certain in patients with atrial fibrillation, Adult Congenital Heart Disease, and after permanent pacemaker/ICD implantation but are described as useful by various National and International specialty societies.[48-50]
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Cardiac Rehabilitation** is considered appropriate if **ANY** of the following are **TRUE** (within a one year period)[49-51]:

- Acute myocardial infarction
- Acute coronary artery syndrome
- Chronic stable angina
- Chronic congestive heart failure (NYHA Class I-III, including with LV assist devices)
- After coronary artery bypass surgery
- After a percutaneous coronary intervention

- After valvular surgery
- Cardiac transplantation
- Symptomatic peripheral arterial disease
- Atrial fibrillation
- Adult Congenital Heart Disease
- After permanent pacemaker/ICD implantation

Non-Indications

➔ **Cardiac Rehabilitation** may not be considered appropriate if **ANY** of the following is present[51]:

- Active unstable angina
- Decompensated cardiac failure
- Active dangerous or complex arrhythmias
- Dissecting aneurysm
- Myocarditis
- Acute pericarditis
- Severe obstruction of the left ventricular outflow tract
- Severe hypertension
- Exertional hypotension or syncope
- Severe orthopedic limitations
- Recent systemic or pulmonary embolus)
- Severe or symptomatic aortic stenosis
- Previous cardiac rehabilitation in the absence of a new cardiac event.

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
S9472	Cardiac rehabilitation program, nonphysician provider, per diem
93798	Physician or other qualified healthcare professional services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)

Surgical or Interventional Management

Service: Cardiac Catheterization

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** Repeat cardiac catheterization may rarely be required to reassess intracardiac and pulmonary artery hemodynamics as a guide to pharmacologic therapy.
- **Recommended Clinical Approach:** Cardiac catheterization may be indicated for evaluating patients with known or suspected cardiomyopathies to assess intracardiac and pulmonary artery hemodynamics. It can also evaluate left ventricular (LV) function and wall motion. Finally, it can determine the presence and severity of coronary artery disease (CAD). Endomyocardial biopsy may be performed during cardiac catheterization to determine the etiology of cardiomyopathy.[2]
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Cardiac catheterization** is considered appropriate if **ANY** of the following is **TRUE**[2]:

- ◆ Symptoms of coronary artery disease (chest pain or ischemic equivalent), which may exist comorbidly with or cause the underlying cardiomyopathy.
- ◆ Known or suspected cardiomyopathy where assessing intracardiac hemodynamics and coronary anatomy may be beneficial in subsequent management (e.g., transplant listing, left ventricular assist device).
- ◆ Suspected infiltrative cardiomyopathy (sarcoidosis, amyloidosis), where endomyocardial biopsy is necessary for a definitive diagnosis that will substantially impact therapy.
- ◆ Ventricular fibrillation or sustained ventricular tachycardia with or without symptoms.
- ◆ Survived sudden cardiac death or potentially life-threatening ventricular arrhythmia.
- ◆ Suspected or clinical uncertainty between constrictive vs. restrictive physiology.
- ◆ Suspected cardiomyopathy (LV ejection fraction (LVEF) less than 40%) of unknown etiology with symptoms.[52]

Non-Indications

➔ **Cardiac catheterization** may not be considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Acute or chronic kidney disease.
- ◆ Coagulopathy.
- ◆ Fever or a systemic infection.
- ◆ Uncontrolled arrhythmia.
- ◆ Uncontrolled hypertension.
- ◆ Decompensated heart failure.
- ◆ Severe contrast agent allergy.
- ◆ The patient is pregnant.

Site of Service Criteria

Inpatient, outpatient, or observation status.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
93451	Right heart catheterization
93452	Left heart catheterization with intraprocedural injection for left ventriculography
93453	Combined right and left heart catheterization with intraprocedural injection for left ventriculography
93454	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation
93455	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with catheter placement in bypass graft, with intraprocedural injections for bypass graft angiography
93456	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with right heart catheterization
93457	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary

	angiography, imaging supervision, and interpretation, with catheter placement in bypass graft, with intraprocedural injection for bypass graft angiography and right heart catheterization
93458	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with left heart catheterization, with intraprocedural injection for left ventriculography
93459	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision and interpretation, with left heart catheterization, catheter placement in bypass graft, with bypass graft angiography
93460	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with right and left heart catheterization
93461	Catheter placement in coronary artery for coronary angiography, with intraprocedural injection for coronary angiography, imaging supervision, and interpretation, with right and left heart catheterization, catheter placement in bypass graft, with bypass graft angiography

Service: Percutaneous Coronary Intervention (PCI)/Angioplasty/Stent

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** For patients with cardiomyopathy and chest pain, percutaneous coronary intervention (**PCI**) is appropriate for quality-of-life-limiting anginal chest pain. It is also appropriate in the presence of flow-limiting coronary stenoses where intervention will substantially improve cardiac function or symptoms. Myocardial revascularization with PCI may be appropriate for patients with significant myocardial viability, even in the absence of symptoms.[53]
- **Exclusions:** PCI is not indicated for patients with stable and infrequent angina or non-flow-limiting (less than 70% or FFR greater than 0.8) coronary stenosis.

Medical Necessity Criteria

Indications

➔ **PCI** is considered appropriate if **ANY** of the following is **TRUE**[53]:
- The patient has Ventricular fibrillation
- The patient has Polymorphic ventricular tachycardia (VT)
- The patient survived cardiac arrest
- Acute ST-elevation myocardial infarction (STEMI)
- Non–ST-elevation acute coronary syndrome (NSTE-ACS)
- Unstable angina
- Refractory angina (or ischemic equivalent) and **ALL** of the following:
  - Symptoms despite medical therapy
  - Significant coronary artery stenoses as shown by **ANY** of the following:
    - Significant anatomic stenosis greater than or equal to 50% left main
    - Significant anatomic stenosis greater than or equal to 70% non–left main CAD
    - Significant physiological stenosis: fractional flow reserve (FFR) less than or equal to 0.80
- Stable Ischemic Heart Disease (SIHD) and **ALL** of the following[53]:
  - Significant left main stenosis (greater than or equal to 50%)
  - PCI is expected to provide equivalent revascularization to a CABG
- Stable Ischemic Heart Disease (SIHD) and multivessel CAD.

Non-Indications

➔ **PCI** is not considered appropriate if **ALL** of the following is **TRUE**[53]**:**
- ◆ The patient has an unprotected left main CAD with unfavorable anatomy for PCI.
- ◆ The patient is a good candidate for CABG.

Site of Service Criteria

Inpatient, outpatient, or observation status.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
92920	Percutaneous transluminal coronary angioplasty into single major coronary artery
92928	Percutaneous transcatheter insertion of stent into single major coronary artery
92937	Percutaneous transluminal revascularization of a single coronary artery bypass graft with angioplasty
92943	Percutaneous transluminal revascularization of chronic total occlusion of a single coronary artery branch with atherectomy, angioplasty, and insertion of stent
C9600	Perc drug-el cor stent sing
C9604	Perc d-e cor revasc t cabg s
C9607	Perc d-e cor revasc chro sin

Service: Cardiac Implantable Device (Permanent Pacemaker)

General Guidelines

- **Units, Frequency, & Duration:** One instance, as needed per inclusion criteria.
- **Criteria for Subsequent Requests:** Subsequent requests may be considered for device replacement due to battery end of life (EOL) or elective replacement interval (ERI), replacement after infection, a clinical need for different pacing modes, or replacement after manufacturer recall.
- **Recommended Clinical Approach:** Permanent pacemaker (PPM) implantation is indicated for various cardiac conduction system abnormalities associated with different cardiomyopathies. Cardiac pacemaker implantation is appropriate in patients with symptomatic high-grade AV block.
    - Cardiac resynchronization therapy (CRT) with biventricular pacing may be necessary for worsening heart failure symptoms when the QRS duration is greater than or equal to 150 ms.[4]
    - For patients who are also at increased risk of ventricular arrhythmias and sudden cardiac death or who have a left ventricular ejection fraction (LVEF) less than or equal to 35%, a combined pacemaker ICD should be implanted (see next service section).
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Permanent pacemakers** are considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Permanent pacemaker for a patient with symptomatic heart block or symptomatic bradycardia.[54-55]
- ◆ CRT is indicated for patients with LVEF 35% or less, sinus rhythm, and **ANY** of the following[4,54-56]:
    - LBBB with a QRS 150 ms or greater, and NYHA class II, III, or ambulatory IV symptoms on GDMT (Class I indication).
    - LBBB with a QRS 120 to 149 ms, and NYHA class II, III, or ambulatory IV symptoms on GDMT (Class IIa indication)
    - Non-LBBB pattern with QRS 150 ms or greater, and NYHA class III/ambulatory class IV symptoms on GDMT (Class IIa indication).
- ◆ CRT may be considered for patients with LVEF 35% or less, sinus rhythm, and **ANY** of the following[4,54-56]:

- Non-LBBB pattern with QRS 150 ms or greater, and NYHA class II symptoms on GDMT (Class IIb indication)
- Non-LBBB with a QRS 120 to 149 ms, and NYHA class III, or ambulatory IV symptoms on GDMT (Class IIb indication)

◆ CRT for patients with LVEF 30% or less, sinus rhythm and **ALL** of the following[4,56]:
- Ischemic etiology of heart failure
- LBBB with QRS 150 ms or greater
- NYHA class I symptoms on GDMT (Class IIb indication).

◆ CRT for patients with AF and LVEF 35% and **ALL** of the following:
- Currently on GDMT
- Requires ventricular pacing or otherwise meets CRT criteria
- AV nodal ablation or rate control allows near 100% ventricular pacing with CRT

◆ CRT for patients who have LVEF 35% and **ALL** of the following:
- Currently on GDMT
- Undergoing new or replacement device implantation with anticipated ventricular pacing (>40%)

Non-Indications

➔ **Permanent pacemakers** are not considered appropriate if **ANY** of the following is **TRUE**:

◆ CRT biventricular pacemakers are not indicated in a patient whose expected remaining lifespan is less than 12 months.[56]

Site of Service Criteria

Inpatient or observation status.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
33206	Insertion of permanent atrial pacemaker with transvenous electrode
33207	Insertion of permanent ventricular pacemaker with transvenous electrode
33208	Insertion of permanent atrial and ventricular pacemaker with transvenous electrode
33212	Insertion of pacemaker pulse generator with connection to existing single lead
33213	Insertion of pacemaker pulse generator with connection to existing dual leads

33214	Conversion of single chamber implanted pacemaker system to dual chamber system
33216	Insertion of transvenous electrode of permanent pacemaker
33221	Insertion of pacemaker pulse generator with existing multiple leads
33224	Transvenous insertion of pacing electrode for left ventricular pacing, with connection to existing pacemaker
33274	Transcatheter insertion of permanent leadless right ventricular pacemaker
C1779	Lead, pmkr, transvenous vdd
C1785	Pmkr, dual, rate-resp
C1786	Pmkr, single, rate-resp
C1898	Lead, pmkr, other than trans
C1900	Lead, coronary venous
C2619	Pmkr, dual, non rate-resp
C2620	Pmkr, single, non rate-resp
C2621	Pmkr, other than sing/dual

Service: Cardiac Implantable Device (Defibrillator)

General Guidelines

- **Units, Frequency, & Duration:** Once, as needed per inclusion criteria.
- **Criteria for Subsequent Requests:** Subsequent requests may be appropriate for device replacement due to battery end of life (EOL) or elective replacement interval (ERI), replacement after infection, a clinical need for different pacing modes, or replacement after manufacturer recall.
- **Recommended Clinical Approach:** Implantable cardiac defibrillator (ICD) device implantation is indicated for cardiomyopathy patients at risk of ventricular tachycardia and sudden cardiac death with a left ventricular ejection fraction (LVEF) less than or equal to 35%. It is also appropriate in patients who have survived cardiac arrest or have syncope due to ventricular arrhythmias, even if LVEF is greater than 35%.[2]
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Defibrillators** are considered appropriate if **ANY** of the following is **TRUE**:
- ◆ In patients with ischemic heart disease with **ANY** of the following[2,57]:
  - Who either survive sudden cardiac arrest (SCA) due to ventricular tachycardia/ventricular fibrillation (VT/VF) or experience hemodynamically unstable VT or stable sustained VT not due to reversible causes.
  - Unexplained syncope who have inducible sustained monomorphic VT on electrophysiological (EP) study.
  - In patients with LVEF of 35% or less who are at least 40 days post-myocardial infarction (MI) and **ALL** of the following:
    - At least 90 days post-revascularization (if performed)
    - NYHA class II or III heart failure (HF) despite guideline-directed medical therapy (GDMT)
  - In patients with left ventricular ejection fraction (LVEF) of 30% or less and **ALL** of the following:
    - At least 40 days post-MI
    - At least 90 days post-revascularization (if performed)

        - NYHA class I HF despite GDMT.
    - In patients with non-sustained ventricular tachycardia (NSVT) due to prior MI and **ALL** of the following:
        - LVEF of 40% or less
        - Inducible sustained VT or VF at electrophysiological study.
- In non-hospitalized patients with NYHA class IV symptoms who are candidates for cardiac transplantation or a left ventricular assist device (LVAD).
- In patients with non-ischemic cardiomyopathy (NICM) with **ANY** of the following:
    - Who either survive SCA due to VT/VF or experience hemodynamically unstable VT or stable sustained VT not due to reversible causes.
    - Syncope presumed to be due to VA and who do not meet indications for a primary prevention ICD, an ICD or an electrophysiological study for risk stratification for sudden cardiac death (SCD) can be beneficial.
    - Heart failure (HF) with NYHA class II–III symptoms and an LVEF of 35% or less, despite GDMT.
    - Due to a Lamin A/C mutation who have 2 or more risk factors (NSVT, LVEF <45%, non-missense mutation, and male sex).
    - In patients with heart failure with NYHA class I symptoms and an LVEF of 35% or less, despite GDMT, an implantable cardioverter-defibrillator (ICD) may be considered.
- In patients with arrhythmogenic right ventricular cardiomyopathy and **ANY** of the following:
    - An additional marker of increased risk of SCD (resuscitated SCA, sustained VT, significant ventricular dysfunction with RVEF or LVEF less than or equal to 35%).
    - Syncope presumed due to ventricular arrhythmias (VA)
- In patients with hypertrophic cardiomyopathy (HCM) with **ANY** of the following:
    - Survived an SCA due to VT or VF, or have spontaneous sustained VT causing syncope or hemodynamic compromise.
    - With 1 or more of the following risk factors, an ICD is reasonable if ANY of the following are present:

        - Maximum LV wall thickness greater than or equal to 30 mm.
        - SCD in 1 or more first-degree relatives presumably caused by HCM.
        - One or more episodes of unexplained syncope within the preceding 6 months.
    - Spontaneous NSVT or an abnormal blood pressure response with exercise, who also have additional SCD risk modifiers or high-risk features, an ICD is reasonable.
    - Nonsustained ventricular tachycardia (NSVT) or an abnormal blood pressure response with exercise but do not have any other SCD risk modifiers, an ICD may be considered, but its benefit is uncertain.
- In patients with giant cell myocarditis with VF or hemodynamically unstable VT treated according to GDMT, an ICD and/or an antiarrhythmic medication may be considered.
- In patients with cardiac sarcoidosis who have sustained VT or are survivors of SCA or have an LVEF of 35% or less, an ICD is recommended.
- In patients with HFrEF who are awaiting a heart transplant and who otherwise would not qualify for an ICD (e.g., NYHA class IV and/or use of inotropes) with a plan to discharge home, an ICD is reasonable.

Non-Indications

➔ **Defibrillators** are not considered appropriate if **ANY** of the following is **TRUE**:

- Patient with normal or low normal LVEF (greater than 45%) in the absence of documented ventricular tachycardia.
- In a patient whose expected remaining lifespan is less than 12 months.
- In patients with VT that is amenable to catheter ablation.

Site of Service Criteria

Inpatient or observation status.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
0577T	Electrophysiologic evaluation of implantable

	cardioverter-defibrillator system with substernal electrode (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)
33217	Insertion of 2 transvenous electrodes of permanent cardioverter-defibrillator
33249	Insertion of dual chamber permanent pacing cardioverter-defibrillator system with transvenous lead
33240	Insertion of pacing cardioverter-defibrillator pulse generator with connection to existing single lead
33241	Removal of pacing cardioverter-defibrillator pulse generator
33230	Insertion of pacing cardioverter-defibrillator pulse generator with connection to existing dual leads
33216	Insertion of transvenous electrode of permanent pacemaker

Service: Myocardial Resection

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** A left ventricular (LV) aneurysm after a myocardial infarction can contribute to symptoms associated with heart failure (HF), ventricular arrhythmias, or thrombus formation. In cases refractory to conservative treatment, removal of the involved myocardial tissue may be beneficial. Indications for LV aneurysm resection after myocardial infarction complicated by refractory CHF or ventricular arrhythmias are published in various guidelines.[57-58] Surgical reverse-ventricular remodeling (ventricular reconstruction, Batista procedure, SAVER procedure, Dor procedure) does not appear to be of benefit but may be considered in carefully selected patients with heart failure reduced ejection fraction (HFrEF) for specified indications, including refractory HF or refractory ventricular arrhythmias.[4,59] Many insurance carriers consider such procedures as investigational due to an apparent lack of clinical benefit. Medicare does not consider the procedure as reasonable and necessary and thus does not provide coverage.[60]
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Myocardial Resection** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ If the patient is being considered for an LV aneurysm resection, and **ANY** of the following are true[57-58]:
  - Refractory heart failure or angina.
  - Ventricular arrhythmias not amenable to drugs or radiofrequency ablation.
  - Recurrent thromboembolism despite appropriate anticoagulant therapy.
- ◆ If the patient is being considered for a Surgical reverse-ventricular remodeling (ventricular reconstruction, Batista procedure, SAVER procedure, Dor procedure) and **ALL** of the following are true:
  - Patients with HFrEF (symptomatic HF with LVEF less than or equal to 40%) and **ANY** of the following:

- Refractory HF.
- Refractory ventricular arrhythmias.[4,59]

Non-Indications

➔ **Myocardial Resection** may not be considered appropriate if **ANY** of the following is **TRUE**:

- Surgical reverse-ventricular remodeling (ventricular reconstruction, Batista procedure, SAVER procedure, Dor procedure) is not indicated for patients with **ALL** of the following:
  - Without documented refractory HF or ventricular arrhythmias.[4,59]

Site of Service Criteria

Inpatient

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
33542	Myocardial resection (e.g., ventricular aneurysmectomy)
33548	Surgical ventricular restoration procedure, includes prosthetic patch, when performed (e.g., ventricular remodeling, SVR, SAVER, Dor procedures)

Service: Wearable Defibrillator (e.g., LifeVest)

General Guidelines

- **Units, Frequency, & Duration:** One instance, as needed per inclusion criteria.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** A wearable cardioverter-defibrillator (WCD) is an external device worn as a garment capable of automatic detection and treatment of ventricular tachycardia (VT) or ventricular fibrillation (VF). There are patients at high risk for ventricular arrhythmias and sudden cardiac death who may not be ideal candidates for an implanted device for the following reasons[61]:
    - Susceptibility to life-threatening ventricular arrhythmias may be short-lived (e.g., after recovery from acute MI or myocarditis)
    - An implanted device may interfere with future interventions (e.g., cardiac transplantation)
    - When a systemic infection prevents insertion of an ICD
- **Exclusions:** Should not be requested if an implantable cardioverter-defibrillator is in place and functional.

Medical Necessity Criteria

Indications

➔ **Wearable Defibrillators** are considered appropriate if **ANY** of the following is **TRUE**[61]:

- ◆ In patients with aborted SCA when an ICD is inaccessible or transiently contraindicated (eg. systemic infection).
- ◆ LVEF less than or equal to 35% after recent MI during the 40 day ICD waiting period.
- ◆ After coronary artery bypass surgery (CABG) or percutaneous coronary intervention with LVEF less than or equal to 35% during the 90 day ICD waiting period.
- ◆ Listed for cardiac transplant
- ◆ Recently diagnosed nonischemic cardiomyopathy with LVEF less than or equal to 35% during the 3 month waiting period.[57,62]
- ◆ During an interval when an ICD requires removal (e.g., device pocket infection, endocarditis).

Non-Indications

- ➔ **Wearable Defibrillators** are **NOT** considered appropriate if **ANY** of the following is **TRUE**[61]:
  - ◆ In a patient who is a candidate for an implantable cardioverter-defibrillator (ICD).
  - ◆ VT that is amenable to catheter ablation.
  - ◆ Terminal disease with a life expectancy of less than 1 year.

Site of Service Criteria

Outpatient or Inpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type
K0607	Replacement battery for automated external defibrillator, garment type only, each
K0608	Replacement garment for use with automated external defibrillator, each
K0609	Replacement electrodes for use with automated external defibrillator, garment type only, each
93292	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified healthcare professional, includes connection, recording and disconnection per patient encounter; wearable defibrillator system
93745	Initial set-up and programming by a physician or other qualified healthcare professional of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problems or events

Service: Ventricular Assist Device

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** Mechanical Circulatory Support (MCS) may be appropriate to support patients with advanced heart failure with reduced ejection fraction (HFrEF). Technology has progressed to allow MCS to be utilized in a variety of clinical situations involving critically ill patients or high-risk procedures.[63] MCS is characterized in a variety of ways, including expected length of use [short-term (temporary, non-implanted), intermediate to long term (destination, implanted)], ventricle assisted (left, right, both), or physical location of the pumping device (intracorporeal vs extracorporeal). Short-term devices include the intra-aortic balloon pump (IABP), other percutaneous devices (Impella or TandemHeart), extracorporeal mechanical oxygenation (ECMO), and centrifugal pumps used for coronary artery bypass surgery (CABG).[4,64] Contraindications to short-term MCS can vary between devices. Intermediate to long term devices include the HeartMate II, HeartMate 3, the HeartWare (HVAD) system (which was pulled by the parent company (Medtronic) in mid-2021 over safety concerns), and the SynCardia Total Artificial Heart (TAH).[65]
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Ventricular Assist Device** is considered appropriate if **ANY** of the following is **TRUE**:[64,66-68]

◆ If the patient is being considered for a short-term or temporary device, and **ANY** of the following are true:

- Adjunct for high-risk percutaneous coronary interventions
- Cardiogenic shock (LV, RV, or both)
- Ischemic mitral regurgitation
- Acute reversible cardiomyopathies (myocarditis, stress cardiomyopathy, peripartum cardiomyopathy)
- Primary cardiac transplant allograft failure due to rejection
- Post-transplant RV failure
- Patients slow to wean from cardiopulmonary bypass following heart surgery
- Refractory arrhythmias

- ◆ If the patient is being considered for a long-term device and **ALL** of the following are true[67-68]:
  - Patients with HFrEF and persistence of severe (Stage D) symptoms despite optimal medical and device therapy
  - Patients without severe right ventricular dysfunction and/or severe tricuspid regurgitation
  - The patient has **ANY** of the following:
    - Dependence on I.V. inotropic therapy or temporary MCS.
    - Progressive end-organ dysfunction (worsening renal or hepatic function, type II pulmonary hypertension, cardiac cachexia) due to reduced perfusion and not to inadequately low ventricular filling pressure (PCWP greater than 20 mmHg and SBP less than 90 mmHg or cardiac index less than 2 L/min/m2).

Non-Indications

- ➔ **Ventricular Assist Device** may not be considered appropriate if **ANY** of the following is **TRUE**[68]:
  - ◆ If the patient is being considered for a short-term or temporary device, and **ANY** of the following are true[63]:
    - Uncontrolled sepsis.
    - Bleeding diathesis.
    - Severe aortic or PAD.
  - ◆ If the patient is being considered for a long-term device and **ANY** of the following are true[67]:
    - A stable psychosocial background is **NOT** present. (Stable psychosocial background includes demonstrated understanding of the technology, and there is a caregiver in the same household that will help the patient.
    - Major contraindication is present (contraindication to long-term oral anticoagulation, infection, severe renal dysfunction, ventricular arrhythmias).

Site of Service Criteria

Inpatient

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only

Q0477	Pwr module pt cable lvad rpl
Q0480	Driver pneumatic vad, rep
Q0481	Microprcsr cu elec vad, rep
Q0482	Microprcsr cu combo vad, rep
Q0483	Monitor elec vad, rep
Q0484	Monitor elec or comb vad rep
Q0485	Monitor cable elec vad, rep
Q0486	Mon cable elec/pneum vad rep
Q0487	Leads any type vad, rep only
Q0488	Pwr pack base elec vad, rep
Q0489	Pwr pck base combo vad, rep
Q0490	Emr pwr source elec vad, rep
Q0491	Emr pwr source combo vad rep
Q0492	Emr pwr cbl elec vad, rep
Q0493	Emr pwr cbl combo vad, rep
Q0494	Emr hd pmp elec/combo, rep
Q0495	Charger elec/combo vad, rep
Q0496	Battery elec/combo vad, rep
Q0497	Bat clps elec/comb vad, rep
Q0498	Holster elec/combo vad, rep
Q0499	Belt/vest elec/combo vad rep
Q0500	Filters elec/combo vad, rep
Q0501	Shwr cov elec/combo vad, rep
Q0502	Mobility cart pneum vad, rep
Q0503	Battery pneum vad replacemnt
Q0504	Pwr adpt pneum vad, rep veh
Q0505	#N/A
Q0506	Lith-ion batt elec/pneum vad
Q0507	Misc sup/acc ext vad
Q0508	Mis sup/acc imp vad
Q0509	Mis sup/ac imp vad nopay med
33975	Insertion of extracorporeal single ventricle ventricular assist device

33976	Insertion of extracorporeal biventricular assist device
33977	Removal of extracorporeal single ventricle ventricular assist device
33978	Removal of extracorporeal biventricular assist device
33979	Insertion of implantable intracorporeal single ventricle ventricular assist device
33980	Removal of implantable intracorporeal single ventricle ventricular assist device
33981	Replacement of pump of extracorporeal biventricular assist device
33982	Replacement of pump of implantable intracorporeal single-ventricle ventricular assist device
33983	Replacement of pump of implantable intracorporeal single ventricle ventricular assist device with cardiopulmonary bypass
33990	Insertion of percutaneous arterial ventricular assist device by arterial access only
33991	Insertion of percutaneous arterial ventricular assist device by arterial and venous access, with transseptal puncture, with radiological supervision and interpretation
33992	Removal of percutaneous ventricular assist device at separate and distinct session from insertion

Surgical Risk Factors

Patient Medical Risk Stratification

Patient Risk Score	Patient Characteristic	Min Range	Max Range	Guidance
1- Very Low Risk	No known medical problems			
2- Low Risk	Hypertension		180/110 mm Hg	
2- Low Risk	Asthma	peak flow >80% of predicted or personal best value		
2- Low Risk	Prior history of alcohol abuse			Screen for liver disease and malnutrition
2- Low Risk	Prior history of tobacco use			
3- Intermediate Risk	Asthma	peak flow <80% of predicted or personal best value		
3- Intermediate Risk	Active alcohol abuse			
3- Intermediate Risk	Age	65	75	
3- Intermediate Risk	History of treated, stable coronary artery disease (CAD)			
3- Intermediate Risk	Stable atrial fibrillation			
3- Intermediate Risk	Diabetes mellitus	HbA1C >7%		
3- Intermediate Risk	Morbid obesity	BMI 30	BMI 40	
3- Intermediate Risk	Anemia	hemoglobin <11 (females), <12 (males)		Workup to identify etiology
3- Intermediate Risk	HIV	CD4 <200 cells/mm3		Get clearance from HIV specialist
3- Intermediate Risk	Rheumatologic disease			Preoperative consultation with rheumatologist re: perioperative medication management
3- Intermediate Risk	Peripheral vascular disease or history of peripheral vascular bypass	ankle-brachial pressure index (ABPI)		Preoperative consultation with vascular surgeon

		<0.9		
3- Intermediate Risk	History of venous thromboembolism (VTE)			
3- Intermediate Risk	Well-controlled obstructive sleep apnea			
3- Intermediate Risk	Malnutrition	transferrin <200 mg/dL albumin <3.5 g/dL prealbumin <22.5 mg/dL total lymphocyte count <1200-1500 cell/mm3 BMI <18		Preoperative consultation with nutritionist
3- Intermediate Risk	Active tobacco Use			Enroll patient in smoking cessation program
3- Intermediate Risk	Known allergy or hypersensitivity to medication needed for procedure			
4- High Risk	Advanced Renal Disease (Creatinine > 2)			
4- High Risk	Diabetes mellitus with complications	HbA1c >8%		
4- High Risk	Age	76	85	
4- High Risk	Oxygen dependent pulmonary disease			
4- High Risk	Sickle cell anemia			
4- High Risk	Obesity	BMI 40		
4- High Risk	Cirrhosis, history of hepatic decompensation or variceal bleeding			
4- High Risk	Impaired cognition; dementia			
4- High Risk	Compensated CHF			
4- High Risk	Cerebrovascular disease			
4- High Risk	Uncontrolled or suspected obstructive sleep apnea (OSA)			
4- High Risk	Opioid dependence			
5- Very High Risk	Percutaneous Coronary Intervention (PCI) within 1 month			

5- Very High Risk	Cardiovascular: unstable angina, recent myocardial infarction (60 days), uncontrolled atrial fibrillation or other high-grade abnormal rhythm, severe valvular disease, decompensated heart failure			
5- Very High Risk	Primary pulmonary hypertension			Preoperative consultation with pulmonologist warranted
5- Very High Risk	Cirrhosis or severe liver disease, history of hepatic decompensation or variceal bleeding			
5- Very High Risk	Severe frailty, dependence for ADLs, or history of 3 or more falls in last 6 mos			
5- Very High Risk	Obesity		BMI >50	
5- Very High Risk	Age		>85	
5- Very High Risk	History of VTE with CI to anticoagulation, failure of anticoagulation, cessation of anticoagulation therapy secondary to bleeding			Preoperative consultation with hematologist or internist
5- Very High Risk	Renal failure requiring dialysis			
5- Very High Risk	Immunosuppression			
5- Very High Risk	Chronic Pain			

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