

Valvular Heart Disease

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

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

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Care Path Overview

Care Path Clinical Discussion

Valvular Heart Disease refers to defects of the heart valves caused by aging, injury, inflammation, or infection. Additionally, congenital heart disease is often associated with valvular heart disease. Cardiomyopathies, particularly dilated cardiomyopathies, often lead to mitral valve and/or tricuspid valve disease. Functional problems of any of the four valves are either stenosis (a restriction to the forward flow of blood) or regurgitation (a valve is structurally weak, allowing the backward flow of blood).

Transthoracic echocardiography (TTE) is the standard diagnostic test for evaluating patients with known or suspected valvular heart disease. If there is a discrepancy between history and physical exam findings and the results of TTE, then additional testing, such as stress testing, transesophageal echocardiogram (TEE), computed tomography (CT), cardiac magnetic resonance imaging (MRI), or cardiac catheterization, may be indicated.¹

The physician should consider the presence of symptoms and physical findings to determine the imaging value to diagnose and develop a treatment plan. The goal is to determine which valve or valves are abnormal and the severity of the abnormality. A treatment plan can be developed, ranging from monitoring, initiation of medication therapy to percutaneous or open surgical intervention. The purpose of valvular intervention is to improve symptoms, prolong survival, and minimize complications, including atrial fibrillation, stroke, hospital admission for heart failure, irreversible ventricular dysfunction, and pulmonary hypertension.¹ The American College of Cardiology recommends that patients with severe valvular heart disease who may need intervention be evaluated by a Multidisciplinary Heart Valve Team.¹

Aortic stenosis is one common type of Valvular Heart Disease. Treatment of aortic stenosis should consider symptoms, echocardiography findings, and in some cases, further advanced imaging modalities. Reduced ventricular function and valvular cross-sectional area measurements are critical indicators. If there are symptoms, concerning results on exercise testing, abnormal biomarkers, rapid progression, or severe stenosis indicators, consider valve replacement.¹ Options for intervention for patients with aortic stenosis are surgical aortic valve replacement (SAVR) or transcatheter aortic valve replacement (TAVR).¹

When intervention is warranted, choose the intervention based on shared decision-making that considers the risks and benefits of the type of valve

(mechanical versus bioprosthetic) and the approach (transcatheter versus surgical).¹ A mechanical valve requires long-term anticoagulation, but a bioprosthetic valve typically does not last as long as a mechanical valve. Therefore, the appropriateness of anticoagulation and the patient's age are key factors in deciding which valve is optimal.¹

The most common complication of surgical valve replacement is atrial fibrillation. Other complications are stroke, pericarditis, heart block requiring temporary or permanent pacing, vascular and bleeding complications, renal dysfunction, and infection. The most common complications after transcatheter intervention include stroke, the need for permanent pacing, paravalvular leak, vascular complications, bleeding, and residual valve dysfunction.¹

Aortic regurgitation is a less common form of valvular heart disease. It is seen in patients with connective tissue disorders, bicuspid valve disease, rheumatic heart disease, long standing hypertension, aortic dissection or aneurysm or as a consequence of aortic valve endocarditis. Echocardiography is important in the diagnosis and follow-up of patients with aortic regurgitation. Treatment is indicated when patients develop symptoms or, if asymptomatic, demonstrate evidence of systolic dysfunction or excessive ventricular dilatation. Currently, open surgical valve replacement is the optimal treatment; currently available transcatheter approaches are not designed for treatment of pure aortic regurgitation and should only be carefully considered if there is adequate calcification of the aortic valve to allow proper anchoring of the transcatheter device. This may be seen in patients with mixed aortic stenosis and regurgitation.

Mitral stenosis is another common form of Valvular Heart Disease. Mitral stenosis is a potentially disabling disease that was traditionally most commonly due to rheumatic heart disease but is increasingly seen due to mitral annular calcification or from prior chest irradiation. Mitral stenosis can lead to serious consequences, including pulmonary edema, pulmonary hypertension, and systemic embolization. Rheumatic mitral stenosis is a post-infection inflammatory condition that progresses gradually over two or three decades and tends to be more common in women. With the broad availability of penicillin and similar antibiotics, rheumatic fever and mitral stenosis are rarely seen in the Western world but are still common among patients from underdeveloped countries. Percutaneous balloon mitral valvotomy (PBMV) is a minimally invasive therapy that is the preferred treatment modality for patients with moderate to severe mitral stenosis (MVA less than 1.5 cm²), evidence of pulmonary hypertension, valve anatomy suitable for PBMV, and without significant mitral regurgitation. Consider surgical mitral valve replacement if the valve apparatus is heavily calcified, if there is moderate or severe mitral regurgitation, or if there are other cardiac

surgery indications (i.e., CABG). The complications after transcatheter or surgical intervention for mitral stenosis include stroke, paravalvular leak, vascular complications, bleeding, and residual valve dysfunction.¹

Mitral Regurgitation, another common form of Valvular Heart Disease, has a wide range of different etiologies. Mitral regurgitation is classified as "primary mitral regurgitation" when the regurgitation is due to disease of the mitral leaflets or chordae tendinea and is classified as "secondary mitral regurgitation" when the leaflets and chordae are normal and the regurgitation is due to disease of the left ventricle or left atrium. Primary mitral regurgitation is also called "degenerative mitral regurgitation" and secondary mitral regurgitation is also known as "functional mitral regurgitation. Common causes of primary or degenerative mitral regurgitation include mitral valve prolapse, rheumatic heart disease, inflammatory injury from collagen vascular diseases, and endocarditis. Common causes of secondary or functional mitral regurgitation include ischemic heart disease, and any dilated cardiomyopathy. Treatment varies based on symptoms, the severity of regurgitation, and etiology. For patients with primary or degenerative etiologies, moderate to severe regurgitation and symptoms, valve repair is usually indicated and this may be accomplished by open surgical repair or replacement or, in high surgical risk patients, with a minimally invasive transcatheter repair (TMVR).

Currently, the MitraClip is the only FDA-approved device for TMVR. The procedure is performed in the cardiac catheterization laboratory via the femoral vein and transseptal puncture utilizing transesophageal echo guidance (TEE) and general anesthesia. Dual antiplatelet therapy with aspirin and clopidogrel is required for 3-6 months following the procedure. Select patients with severe, primary mitral regurgitation and no symptoms may also benefit from surgical repair. For patients with secondary or functional mitral regurgitation, optimal medical therapy directed at treatment of heart failure is the first line therapy. Patients with ongoing symptoms and moderate to severe degrees of functional mitral regurgitation may also benefit from TMVR with the MitraClip. Surgical repair or replacement may also be considered for this subset but is not commonly performed unless the patient is also undergoing heart surgery for another indication such as aortic valve replacement or coronary artery bypass surgery.

Tricuspid regurgitation is another form of valvular disease. Similar to mitral regurgitation, it is classified as "primary" when it is due to disease of the tricuspid leaflets and "secondary" or "functional" when it is due to dilation of the tricuspid annulus from disease of the right atrium or right ventricle. Primary tricuspid regurgitation is less common and can be due to congenital heart disease, rheumatic heart disease, myxomatous degeneration, radiation, endocarditis or carcinoid. Secondary or functional tricuspid regurgitation is a more common cause and is seen in patients with chronic systolic heart failure, aortic or mitral valve disease, long standing atrial fibrillation, permanent pacemakers and pulmonary hypertension. Symptoms of tricuspid regurgitation include fatigue and right heart failure such as edema and ascites. Medical treatment with diuretics and optimization of the underlying heart condition leading to tricuspid regurgitation represents first line therapy. Surgery may be considered when medical therapy fails or if the patient is undergoing heart surgery for another reason. Less invasive, percutaneous methods of treating tricuspid regurgitation are being investigated but are currently not approved therapies.

For all patients who have had a valve intervention, a transthoracic echo is recommended one to three months after the procedure to establish a baseline measurement of valve function and the ventricles' status. If the patient develops new symptoms or a change in the physical examination, a repeat TTE is appropriate. The timing of periodic follow-up imaging varies by valve intervention type.¹ In addition to monitoring the prosthetic valve or repair, patients with valvular heart disease require associated medical therapy, management of concurrent cardiac conditions, and monitoring for persistent symptoms or functional limitation.¹

Most patients with LV dysfunction and severe Valvular Heart Disease are candidates for valve replacement or repair. If the patient declines intervention or the risk of intervention is extremely high, continue standard medication therapy to promote cardiac performance and mitigate stroke risk.

For patients with rheumatic mitral stenosis or a mechanical prosthesis and atrial fibrillation, oral anticoagulation with a vitamin K antagonist is indicated. For patients with AF and native valve heart disease (except rheumatic mitral stenosis [MS]) or who received a bioprosthetic valve >3 months prior, a non-vitamin K oral anticoagulant (NOAC) is an effective alternative to VKA anticoagulation and should be administered on the basis of the patient's CHA₂DS₂-VASc score in a shared decision-making process.¹

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

- Patients with valvular heart disease may present with symptoms, a heart murmur, or incidental findings of valvular abnormalities on noninvasive testing.¹
- The prevalence of valvular heart disease in industrialized countries is approximately 2.5%. Valvular disease is significantly more common in patients older than 65 years. In the United States, aortic stenosis and mitral regurgitation account for 3 in 4 cases of valvular disease.²
- Transthoracic echocardiography is the standard diagnostic test for evaluating patients with known or suspected valvular heart disease.
- If there is a discrepancy between the physical examination and transesophageal echo, the physician should consider further testing, such as transesophageal echocardiography, cardiac CT scan, cardiac magnetic resonance imaging (MRI), stress testing, or cardiac catheterization.¹
- When intervention is warranted, the choice of intervention should be made with shared decision-making that considers the risks and benefits of the type of valve (mechanical versus bioprosthetic) and approach (transcatheter versus surgical).¹

Definitions

- **Systolic Murmurs:** heart murmurs occurring during the squeezing phase of the cardiac cycle.
- **Diastolic murmurs:** heart murmurs heard during the relaxing phase of the cardiac cycle.
- **Innocent heart murmurs:** often occur in children and are sounds produced by high blood flow and disappear with maturity. In adults, anemia, hyperthyroidism, and pregnancy can cause murmurs not associated with heart disease.
- **Abnormal heart murmurs:** These occur with congenital heart disease in children; in adulthood these murmurs, or are usually due to acquired valvular heart disease.
- Aortic Valve: Valve connecting the left ventricle to the aorta/systemic circulation.
- Mitral Valve: Valve connecting the left atrium to the left ventricle.
- **Tricuspid Valve:** Valve connecting the right atrium and the right ventricle.

- **Pulmonic Valve:** Valve connecting the right ventricle with pulmonary circulation.
- Transcatheter Aortic Valve Replacement (TAVR): Insertion of a new aortic valve via cardiac catheterization to repair or replace the original valve.
- Surgical Aortic Valve Replacement/Repair (SAVR): Open surgical procedure under general anesthesia to repair or replace a damaged aortic valve.
- **MitraClip:** Used in the transcatheter repair to repair a leaking mitral valve.
- CHA₂DS₂-VASc Score: A composite score of clinical factors to predict future stroke risk in patients with atrial fibrillation. Points are assigned for the presence of comorbidities like Congestive Heart Failure (+1), Hypertension (+1), Age greater than or equal to 75y (+2), Diabetes (+1), Stroke history, TIA, or thromboembolism (+2), Vascular disease, e.g., prior MI, PVD, aortic plaque (+1), Age 65-74y (+1), and Sex category (Female +1). This scoring system is likely more specific for identifying patients at low risk for stroke.
- CHADS₂ Score: An earlier scoring system for predicting stroke risk, which did not include age stratification, sex-based risk, or prior vascular disease.
- HAS-BLED Score: A calculation incorporating multiple risk factors to predict the incidence of major bleeding events for patients on oral anticoagulation. A HAS-BLED score ≥3 merits caution before prescribing anticoagulants, with consideration of a mitigation strategy.
- New York Heart Association (NYHA) Classification³: A common measure of heart failure.
 - Class I : Patient has cardiac disease that does not limit physical activity.
 - Class II (Mild): Patient has cardiac disease, causing slight limitations in physical activity. Comfortable at rest.
 - Class III (Moderate): Patient has cardiac disease that noticeably limits physical activity. Comfortable at rest.
 - Class IV (Severe): Patient has cardiac disease that prevents them from physical activity. Experiences symptoms and discomfort at rest.
- **Pre-Test Probability:** Pre-test 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. $^{\!\!\!4}$

Valvular Heart Disease

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. **Non-Surgical Surgical**

		Management	Management
Workup and	Labs, ECG and/or Chest X-ray	•	
Monitoring	External Wearable Device ^{PA}		
	Transthoracic Echocardiography (TTE) PA*		
	Transesophageal Echocardiogram (TEE)PA		
	Stress Echocardiogram ^{PA}		Non
	Magnetic Resonance Angiogram (MRA), Chest		-Sur
Non-Invasivo	Myocardial Perfusion Imaging Single Photon Emission Computed Tomography (MPI-SPECT) ^{PA}	● ^{DR}	gical I
Testing	Coronary Computed Tomography Angiography (CCTA) ^{PA}	AND	Manag
	Fractional Flow Reserve (CT-FFR)		Ieme
	Computed Tomography Angiography (CTA), Cardiac PA		ent
	Computed Tomography (CT), Chest, Abdomen, and Pelvis (TAVR CT)		
	Magnetic Resonance Imaging (MRI)PA	•	
	Medical Therapy (e.g., beta-blockers, ACE inhibitors)		
Non-Surgical Management	Lifestyle Changes (e.g., healthy diet and exercise)		
J. J	Tobacco Cessation		
	Cardiac Catheterization ^{PA}		
	Percutaneous Coronary Intervention (PCI) ^{PA} or Bypass Revascularization		
Surgical or	Transcatheter Aortic Valve Replacement (TAVR)PA		R -
Interventional Management	Surgical Left Atrial Appendage Exclusion		
	Surgical Maze Procedure ^{PA}		
	Transcatheter Mitral Valve Repair ^{PA}		
	Surgical Mitral Valve Repair ^{PA}		

Кеу

- 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

Valvular Heart Disease

ICD-10 Codes Associated with Classification

ICD-10 Code	Code Description/Definition
105.0	Rheumatic mitral stenosis
105.1	Rheumatic mitral insufficiency
105.2	Rheumatic mitral stenosis with insufficiency
105.8	Other rheumatic mitral valve diseases
105.9	Rheumatic mitral valve disease, unspecified
106	Rheumatic aortic valve diseases
106.0	Rheumatic aortic stenosis
106.1	Rheumatic aortic insufficiency
106.2	Rheumatic aortic stenosis with insufficiency
106.8	Other rheumatic aortic valve diseases
106.9	Rheumatic aortic valve disease, unspecified
107	Rheumatic tricuspid valve diseases
107.0	Rheumatic tricuspid stenosis
107.1	Rheumatic tricuspid insufficiency
107.2	Rheumatic tricuspid stenosis and insufficiency
107.8	Other rheumatic tricuspid valve diseases
107.9	Rheumatic tricuspid valve disease, unspecified
108	Multiple valve diseases
108.0	Rheumatic disorders of both mitral and aortic valves
108.1	Rheumatic disorders of both mitral and tricuspid valves
108.2	Rheumatic disorders of both aortic and tricuspid valves
108.3	Combined rheumatic disorders of mitral, aortic and

	tricuspid valves
108.8	Other rheumatic multiple valve diseases
108.9	Rheumatic multiple valve disease, unspecified
109	Other rheumatic heart diseases
109.0	Rheumatic myocarditis
109.1	Rheumatic diseases of endocardium, valve unspecified
109.2	Chronic rheumatic pericarditis
109.8	Other specified rheumatic heart diseases
109.81	Rheumatic heart failure
109.89	Other specified rheumatic heart diseases
109.9	Rheumatic heart disease, unspecified
133	Acute and subacute endocarditis
133.0	Acute and subacute infective endocarditis
133.9	Acute and subacute endocarditis, unspecified
134	Nonrheumatic mitral valve disorders
134.0	Nonrheumatic mitral (valve) insufficiency
134.1	Nonrheumatic mitral (valve) prolapse
134.2	Nonrheumatic mitral (valve) stenosis
134.81	Nonrheumatic mitral (valve) annulus calcification
134.89	Other nonrheumatic mitral valve disorders
134.9	Nonrheumatic mitral valve disorder, unspecified
135	Nonrheumatic aortic valve disorders
135.0	Nonrheumatic aortic (valve) stenosis
135.1	Nonrheumatic aortic (valve) insufficiency
135.2	Nonrheumatic aortic (valve) stenosis with insufficiency
135.8	Other nonrheumatic aortic valve disorders
135.9	Nonrheumatic aortic valve disorder, unspecified
136	Nonrheumatic tricuspid valve disorders
136.0	Nonrheumatic tricuspid (valve) stenosis

136.1	Nonrheumatic tricuspid (valve) insufficiency
136.2	Nonrheumatic tricuspid (valve) stenosis with insufficiency
136.8	Other nonrheumatic tricuspid valve disorders
136.9	Nonrheumatic tricuspid valve disorder, unspecified
137	Nonrheumatic pulmonary valve disorders
137.0	Nonrheumatic pulmonary valve stenosis
137.1	Nonrheumatic pulmonary valve insufficiency
137.2	Nonrheumatic pulmonary valve stenosis with insufficiency
137.8	Other nonrheumatic pulmonary valve disorders
137.9	Nonrheumatic pulmonary valve disorder, unspecified
138	Endocarditis, valve unspecified
151.1	Rupture of chordae tendineae, not elsewhere classified
Q22.0	Pulmonary valve atresia
Q22.1	Congenital pulmonary valve stenosis
Q22.2	Congenital pulmonary valve insufficiency
Q22.4	Congenital tricuspid stenosis
Q228	Other congenital malformations of tricuspid valve
Q230	Congenital stenosis of aortic valve
Q231	Congenital insufficiency of aortic valve
Q232	Congenital mitral stenosis
Q233	Congenital mitral insufficiency
Q238	Other congenital malformations of aortic and mitral valves
Q239	Congenital malformation of aortic and mitral valves, unspecified
Q244	Congenital subaortic stenosis
Q248	Other specified congenital malformations of heart
Q249	Congenital malformation of heart, unspecified
Q253	Supravalvular aortic stenosis
Q87410	Marfan's syndrome with aortic dilation
Q87418	Marfan's syndrome with other cardiovascular

	manifestations
T8201XA	Breakdown (mechanical) of heart valve prosthesis, initial encounter
T8201XD	Breakdown (mechanical) of heart valve prosthesis, subsequent encounter
T8203XA	Leakage of heart valve prosthesis, initial encounter
T8203XD	Leakage of heart valve prosthesis, subsequent encounter
T8209XA	Other mechanical complication of heart valve prosthesis, initial encounter
T82223A	Leakage of biological heart valve graft, initial encounter
T826XXA	Infection and inflammatory reaction due to cardiac valve prosthesis, initial encounter
T82817A	Embolism due to cardiac prosthetic devices, implants and grafts, initial encounter
T82857A	Stenosis of other cardiac prosthetic devices, implants and grafts, initial encounter
T82897A	Other specified complication of cardiac prosthetic devices, implants and grafts, initial encounter
T82897D	Other specified complication of cardiac prosthetic devices, implants and grafts, subsequent encounter
Z95.2	Presence of prosthetic heart valve
Z95.3	Presence of xenogenic heart valve
Z95.4	Presence of other heart-valve replacement

Presentation and Etiology

Causes and Risk Factors⁵

Valvular heart disease can result from medical illnesses, inflammation, infection, or injuries including:

- Hypertension.
- Myocardial infarction.
- Heart failure.
- Prior Chest Irradiation
- Rheumatic fever.

- Infective endocarditis.
- Autoimmune diseases (e.g., systemic lupus erythematosus, rheumatoid arthritis).
- Sarcoidosis and other cardiomyopathies.
- Congenital heart disease such as Marfan's Syndrome or ventricular septal defect.
- Medication.

Clinical Presentation 1.5

Patients with valvular heart disease may or may not have symptoms. A heart murmur may be detected on physical examination, or valvular heart disease may be found incidentally with noninvasive testing.

History

A thorough history includes the presence or absence of cardiac symptoms, including chest pain, dyspnea, orthopnea, palpitations, syncope, edema, fatigue, decreased exercise tolerance, and weight change. Patients with infective endocarditis may experience fever, anorexia, back pain, and weight loss. The physician should obtain a thorough past medical history, family history, and social history. If infective endocarditis is suspected, the physician should inquire about any recent procedures, especially dental procedures and recreational drug use.

Typical Physical Exam Findings

A detailed physical examination should be performed to diagnose and assess the severity of valve lesions.¹ Essential exam components include vital signs, as well as a thorough lung and cardiovascular assessment. The physician should look for signs of heart failure and other cardiac comorbidities. Many valvular heart disorders have characteristic murmurs. These include:

Systolic Murmurs

Aortic stenosis

- Harsh systolic ejection murmur.
- Begins shortly after S1, peaks toward mid-systole, and ends before S2 (crescendo-decrescendo).
- Best heard in the second right intercostal space and radiates into the carotid arteries.
- Delayed carotid upstroke, soft aortic valve closure sound, and paradoxical split of S2 may be heard.⁶

• The intensity of the murmur increases with squatting and decreases with the Valsalva maneuver.

Mitral Valve Prolapse

- Mid-systolic click.
- May be accompanied by a late systolic murmur.²
- The intensity of the murmur increases with the Valsalva maneuver and decreases with squatting or hand grip.

Mitral regurgitation

- Blowing holosystolic murmur.
- Best heard at the apex and radiates to axilla.⁶
- If mitral valve prolapse is present, the physician might hear a mid-systolic click.⁶
- Intensity of the murmur increases with squatting or handgrip and decreases with the Valsalva maneuver.
- An S3 indicates severe disease but does not always indicate heart failure.²

Pulmonary stenosis

- Crescendo-decrescendo systolic ejection murmur.
- Louder with inspiration.
- Heard best at the second left intercostal space.⁶

Tricuspid regurgitation

- Holosystolic murmur.
- Louder with inspiration.
- Best heard at the lower left sternal border.⁶

Diastolic Murmurs

Aortic regurgitation

- Blowing decrescendo diastolic murmur.
- Best heard at the aortic area with the diaphragm of the stethoscope, after deep expiration, while the patient is sitting and leaning forward.
- Intensity of the murmur is increased by squatting or handgrip and decreased with standing or the Valsalva maneuver.⁵

Mitral stenosis

- Opening snap followed by a low-pitched diastolic rumble.
- Best heard at the apex, with the bell of the stethoscope, while the patient is in the left lateral decubitus position.⁵
- Intensity of the murmur increases with squatting and decreases with the Valsalva maneuver.
- A loud P2 component may be present if there is significant pulmonary hypertension.

Pulmonary regurgitation

- Decrescendo diastolic murmur.
- Louder with inspiration.
- Best heard at the second left intercostal space.⁶

Tricuspid stenosis

- Opening snap and a low-pitched rumbling diastolic murmur
- Best heard during inspiration at the left sternal border.⁶

Typical Evaluation and Diagnostic Findings

After a thorough history and physical exam, perform an electrocardiogram (ECG) and chest x-ray. A transthoracic echocardiogram (TTE) is crucial for the diagnosis of valvular heart disease.¹

Asymptomatic patients with Valvular Heart Disease require periodic follow-up to prevent irreversible consequences of severe valvular disease, which may occur in the absence of symptoms. Annual history and physical examination are necessary. The frequency of repeat cardiac echocardiography differs based on the type and severity of the valve lesion, the known rate of progression of the valve lesion, and the valve lesion's effect on the affected ventricle. In addition to routine monitoring, a repeat TTE is appropriate if new symptoms arise or there is a change in the physical examination.¹ If there is a discrepancy between the physical examination and transthoracic echo, the physician should consider further testing, such as computed tomography, cardiac magnetic resonance imaging, stress testing, transesophageal echocardiography, or cardiac catheterization.¹

Care Path Services & Medical Necessity Criteria

Workup and Symptom Monitoring

Service: External Wearable Devices

General Guidelines

- Units, Frequency, & Duration: Noninvasive external cardiac monitoring may be conducted using external wearable devices for 24 hours to 30 days, depending on symptom frequency.
- Criteria for Subsequent Requests: Subsequent requests may be considered for device malfunction, high burden of poor quality data/artifact, or inability to capture a recording of patient symptoms. The latter would be pertinent if the initial monitor chosen were of shorter duration or solely dependent on patient-activated data.
- **Recommended Clinical Approach:** An external wearable cardiac monitor may be indicated to evaluate palpitations or abnormal heart rhythms in the workup of valvular heart disease. The type of monitor should be selected based on patient symptom frequency and duration of the episodes. Daily symptoms or ongoing rhythm abnormalities (e.g., frequent premature ventricular contractions) may be addressed with a 24-48 hour Holter monitor. Less frequent, episodic palpitations are more likely to be captured with longer monitoring, either a 30-day loop recorder, cardiac mobile telemetry, or an extended-wear patch device. Consideration of a patient's ability to trigger a device effectively may also guide device selection in favor of those with more passive event recording capability.¹⁸
- 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 TRUE⁹:
 - The patient has known or suspected valvular heart disease and ANY of the following:
 - Palpitations.
 - Syncope.
 - Paroxysmal atrial fibrillation.

- The presence of arrhythmia should reasonably be expected to have occurred within 21 days.
- 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 that would acquire similar clinical information regarding the patient's symptoms.
- In considering mobile cardiac telemetry, the patient has worn an event monitor for at least 21 days without any diagnostic findings.
- 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 TRUE⁹:
 - The patient has symptoms suggestive of angina or clinically significant coronary artery obstruction, and monitoring would delay other needed testing or intervention.
 - The patient has an implantable cardiac device capable of acquiring clinical data of a similar or equivalent quality to an external cardiac monitor.
 - In consideration of mobile cardiac telemetry, the patient has not yet worn an event monitor or has not completed at least 21 days of monitoring.

Site of Service Criteria

Outpatient, in-office.

HCPCS Code	Code Description/Definition
93224	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation by a physician or other qualified healthcare professional
93225	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; recording (includes connection, recording, and disconnection)
93226	External electrocardiographic recording up to 48 hours by

Procedure Codes (HCPCS/CPT)

	continuous rhythm recording and storage; scanning analysis with report
93227	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; review and interpretation by a physician or other qualified healthcare professional
0295T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation
0296T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; recording (includes connection and initial recording)
0297T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; scanning analysis with report
0298T	External electrocardiographic recording for more than 48 hours up to 21 days by continuous rhythm recording and storage; review and interpretation
93268	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; includes transmission, review and interpretation by a physician or other qualified healthcare professional
93270	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; recording (includes connection, recording, and disconnection)
93271	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; transmission and analysis

93272	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; review and interpretation by a physician or other qualified healthcare professional
93228 (Mobile cardiac telemetry)	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible 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; review and interpretation with report by a physician or other qualified healthcare professional
93229	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible 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; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified healthcare professional

Service: Computed Tomography Angiography (CTA), Cardiac

General Guidelines

- Units, Frequency, & Duration: None.
- Criteria for Subsequent Requests: None.
- **Recommended Clinical Approach:** Cardiac CTA is a noninvasive imaging modality that can evaluate the anatomy and pathology of the heart valves, pericardium, cardiac chambers, central great vessels, and the function of the heart.¹⁰ Cardiac CTA scan does not have a first line major role in evaluating valvular heart disease. However, it does have an important role in providing important vascular anatomic information in the planning of surgical and interventional procedures. Gated CTA Scan of the heart is indicated for the evaluation and planning of patients being considered for transcatheter aortic valve replacement to assess the size of the aortic valve annulus, dimensions of the sinuses, distribution of calcium and height of the coronary arteries. CTA Scan of the chest, abdomen, and pelvis is routinely performed as part of the preprocedural evaluation of patients being considered for tassess the aortic and iliofemoral vessels anatomy.
- Exclusions: None.

Medical Necessity Criteria

Indications

- → Cardiac CTA is considered appropriate if ANY of the following is TRUE:
 - The patient has **ANY** positive findings:
 - Known or suspected native cardiac valve dysfunction when echocardiographic imaging is inconclusive or discordant with clinical findings.
 - Severe aortic stenosis under consideration for transcatheter aortic valve replacement
 - Bicuspid aortic valve when any of the following are true¹:
 - Echocardiography is inconclusive or discordant with clinical findings.
 - Presence of severe stenosis with Heart Team approach considering transcatheter aortic valve replacement
 - The diameter of the aortic sinuses or ascending aorta is greater than or equal to 4.0 cm.

- Prosthetic valve replacement or prior valve repair and suspected valve dysfunction.¹
- Known of suspected paravalvular infections when echocardiography is inconclusive or discordant with clinical findings.¹
- Suspected low-flow, low-gradient severe aortic stenosis with normal or reduced LVEF for quantitation of aortic valve calcium by CT imaging.¹
- Known or suspected pulmonary outflow tract obstruction.
- Known or suspected congenital heart disease if any of the following are true:
 - Echocardiography is inconclusive or discordant with clinical findings.
 - Before an intervention for valve repair or replacement.
- Known or suspected cardiac mass, tumor, thrombus, or potential cardiac source of emboli.

Non-Indications

- → Cardiac CTA may not be considered appropriate if ANY of the following is TRUE:
 - The patient has contrast dye hypersensitivity and cannot be pre-medicated to prevent contrast allergy.¹⁰
 - In pregnant patients.
 - The patient has severely impaired renal function (creatinine clearance <30 cc/min) and is not already on dialysis because angiographic contrast is utilized for the study. Non-contrast CT may be considered for calcium scoring of the aortic valve or for assessment of iliofemoral vessels.</p>
 - The patient uses metformin and it cannot be held for 48 hours after contrast exposure.
 - The patient has poorly controlled heart rates in atrial fibrillation (heart rates > 100 bpm).

Site of Service Criteria

None.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
75572	Computed tomography (CT) of heart with contrast material for evaluation of cardiac structure and morphology, including 3-dimensional (3D) image

	postprocessing, assessment of cardiac function, and evaluation of venous structures
75573	Computed tomography (CT) of heart with contrast material for evaluation of cardiac structure and morphology in congenital heart disease

Service: Computed Tomography (CT), Chest, Abdomen, and Pelvis (TAVR CT)

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:** CT scan of the chest, abdomen, and pelvis is an integral part of the Pre-TAVR evaluation to evaluate the aorta and iliofemoral arteries and their suitability to permit delivery and deployment of the stent-graft safely.¹¹
- **Exclusions:** Potential exclusions include renal insufficiency (eGFR less than 30ml/min and not already on dialysis), history of allergic reaction to iodinated contrast agents and not pre-medicated to prevent contrast allergy, and inability to cooperate with breath-holding and other technical requirements.

Medical Necessity Criteria

Indications

- → CT, Chest, Abdomen, and Pelvis (TAVR CT) is considered appropriate if ANY of the following is TRUE¹²⁻¹³:
 - The patient has severe aortic stenosis that is being evaluated for transcatheter aortic valve replacement (TAVR) from the iliofemoral approach.

Non-Indications

- → CT, Chest, Abdomen, and Pelvis (TAVR CT) may not be appropriate if ANY of the following is TRUE¹²⁻¹⁴:
 - In a patient with poor-rate control (i.e., rapid with heart rate > 100 bpm) while in atrial fibrillation or other tachyarrhythmias.
 - In a patient with renal failure if angiographic contrast is needed (eGFR less than 30ml/min) unless patient is already on dialysis
 - In a patient with contrast dye allergy who cannot be pre-medicated for contrast allergy prevention.
 - In a patient unable to cooperate with breath-holding.
 - The patient uses metformin and this cannot be held for 48 hours post contrast exposure.
 - In pregnant patients.

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)
74150	Computed tomography (CT) of abdomen without contrast material
74160	Computed tomography (CT) of abdomen with contrast material
74170	Computed tomography (CT) of abdomen without contrast material, followed by contrast material and further sections
72192	Computed tomography (CT) of pelvis without contrast material
72193	Computed tomography (CT) of pelvis with contrast material
72194	Computed tomography (CT) of pelvis without contrast material, followed by contrast material and further sections

Service: Coronary Computed Tomography Angiogram (CCTA)

General Guidelines

- Units, Frequency, & Duration: None.
- **Criteria for Subsequent Requests:** Clinical reason and judgment according to college and clinical practice guidelines and usage of the ACR Appropriateness Criteria.
- **Recommended Clinical Approach:** Coronary CTA is a non-invasive test used predominantly to evaluate the presence and extent of underlying CAD. It may be a useful adjunct in evaluating patients with valvular heart disease who are being considered for surgical or interventional procedures.
- **Exclusions:** None.

Medical Necessity Criteria

Indications

- \rightarrow CCTA is considered appropriate if ANY of the following is TRUE ¹¹⁵:
 - Preoperative assessment of the coronary arteries before valve surgery if low to intermediate risk of CAD.
 - Preoperative assessment of the coronary arteries prior to transcatheter aortic valve replacement (TAVR) in patients with a low pretest probability for CAD.
 - Moderate to severe chronic secondary mitral regurgitation that may be due to ischemia.

Non-Indications

- → CCTA may not be considered appropriate if ANY of the following is TRUE¹⁶:
 - Normal coronary angiogram or CCTA with no stenosis or plaque within the last two years.
 - The patient has poor-rate control while in atrial fibrillation (heart rate > 100 bpm).
 - The patient has a known or suspected allergy to contrast media and cannot be pre-medicated to prevent contrast allergy.
 - The patient has a known or suspected renal insufficiency with creatine clearance <30 cc/min and is not on dialysis.</p>
 - In pregnant patients.
 - The patient takes metformin and this cannot be held for 48 hours after contrast exposure.

Site of Service Criteria

Outpatient.

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 must be ordered in conjunction with Coronary 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 anatomy on imaging.^{1Z,18}
- Exclusions: None.

Medical Necessity Criteria

Indications

- → FFR*** is considered appropriate if ANY of the following is TRUE¹⁹:
 - For functional evaluation of coronary CTA lesions with 40-90% stenosis in a proximal to a middle coronary segment on CCTA.
 - For evaluation of multivessel disease to identify culprit lesions causing symptoms.
 - For evaluation of multiple lesions in a single vessel to evaluate physiologic severity.^{17,20}

***FFR can only be requested with a CCTA or after a recently performed CCTA

Non-Indications

- → **FFR** is NOT appropriate if **ANY** of the following conditions are **TRUE**²:
 - 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 to be studied.¹⁸
 - Coronary anatomy that is low risk (is less than 40% stenosed).
 - In complex congenital heart disease.

<u>Site of Service Criteria</u>

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: Magnetic Resonance Imaging (MRI), Cardiac

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:** While echocardiography is the primary imaging modality for evaluating valvular heart disease, Cardiac Magnetic Resonance (CMR) can play a complementary role when echocardiography is inconclusive or discordant with clinical findings.²² CMR is particularly useful in quantifying the severity of valvular regurgitation and stenosis and in evaluating right and left ventricular size and function. CMR is also useful in evaluating diseases of the aorta, including aortic aneurysms and dissection, and diseases of the pericardium, including noncalcified constrictive pericarditis.²³⁻²⁴
- **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 m²) if gadolinium is requested.

Medical Necessity Criteria

Indications

- \rightarrow MRI is considered appropriate if ANY of the following is TRUE²³⁻²⁴:
 - The patient has moderate or severe aortic regurgitation when TTE is inconclusive or discordant with clinical findings.¹
 - The patient has a bicuspid aortic valve when TTE is inconclusive or discordant with clinical findings.¹
 - Patient with the bicuspid aortic valve if the diameter of the aortic sinuses or ascending aorta is greater than or equal to 4.0 cm.¹
 - TTE or TEE is inconclusive or discordant with clinical findings.^{1,25}
 - The patient is being considered for permanent pacemaker or AICD implantation.

Non-Indications

- \rightarrow MRI is not considered appropriate if ANY of the following is TRUE^{23-24.25}:
 - Non-compatible implanted devices.
 - Metallic intraocular foreign bodies.
 - Claustrophobia.
 - There is a potential for adverse reactions to contrast media.
A patient with severe renal impairment (GFR less than 30 ml/min per 1.73 m²) should not receive gadolinium given the risk of nephrogenic systemic fibrosis.

Site of Service Criteria

Inpatient or Outpatient.

Procedure	Codes	(HCPCS	/CPT)
		-	

HCPCS Code	Code Description/Definition
75557	Cardiac magnetic resonance imaging (MRI) without contrast material, for evaluation of morphology and function
75559	Cardiac magnetic resonance imaging (MRI) with stress imaging, without contrast material, for evaluation of morphology and function
75561	Cardiac magnetic resonance imaging (MRI) without contrast material, followed by contrast material and further sequences, for evaluation of morphology and function
75563	Cardiac magnetic resonance imaging (MRI) with stress imaging, without contrast material, followed by contrast material and further sequences, for evaluation of morphology and function
C9762	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with strain imaging
C9763	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with stress imaging
S8042	MRI Low Field

Service: Magnetic Resonance Angiogram (MRA), Chest

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:** Chest MRA (with or without gadolinium contrast) is useful for assessing the aorta, its branch vessels, and the pulmonary vasculature.
- **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 m²) if gadolinium is requested.

Medical Necessity Criteria

Indications

- → MRA is considered appropriate if ANY of the following is TRUE²³⁻²⁴:
 - Prior to valve intervention (i.e., TAVR or MitraCLip).
 - The patient has known or suspected complications following valve intervention.
 - The patient has known or suspected congenital heart disease when an echo is inconclusive or discordant with clinical findings.^{26,27}

Non-Indications

- \rightarrow MRA is not considered appropriate if ANY of the following is TRUE^{23-24,27}:
 - Non-compatible implanted devices.
 - Metallic intraocular foreign bodies.
 - Claustrophobia.
 - There is a potential for adverse reactions to contrast media.
 - A patient with severe renal impairment (GFR less than 30 ml/min per 1.73 m²) should not receive gadolinium given the risk of nephrogenic systemic fibrosis.

<u>Site of Service Criteria</u>

Outpatient.

HCPCS Code	Code Description/Definition
71555	Magnetic resonance angiography (MRA) of chest with contrast material
C8909	Mra w/cont, chest
C8911	Mra w/o fol w/cont, chest
C8910	Mra w/o cont, chest

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

<u>General Guidelines</u>

- Units, Frequency, & Duration: None.
- Criteria for Subsequent Requests: None.
- **Recommended Clinical Approach:** MPI-SPECT may be considered for patients with valvular heart disease and ongoing symptoms suggestive of CAD on guideline-directed medical therapy and an intermediate or high pre-test probability of CAD.⁴²⁸
 - If the patient is unable to exercise or has ECG abnormalities that interfere with an ECG interpretation during exercise, then MPI-SPECT or stress echo should be considered.
 - Limitations of MPI-SPECT include cost and radiation. In addition, interpretation of MPI-SPECT 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).¹⁹
- Exclusions: None.

Medical Necessity Criteria

- → 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, including²⁹:
 - 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 conditions³⁰:
 - 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 with no stenosis or plaque within the last 2 years
 - Normal stress test within the last year
 - The patient is pregnant.
 - The patient is clinically stable with no known cardiac disease.
 - 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.
 - An active cardiac condition that has not been stabilized (e.g., uncontrolled hypertension, uncontrolled arrhythmias, undiagnosed chest pain).
 - An active pulmonary condition that has not been stabilized (e.g., difficulty breathing, the possibility of pulmonary embolism).

Site of Service Criteria

Outpatient.

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	Planar cardiac blood pool imaging, gated equilibrium study at rest
78473	Planar cardiac blood pool imaging, gated equilibrium studies at rest

Service: Stress Echocardiogram

General Guidelines

- Units, Frequency, & Duration: None.
- Criteria for Subsequent Requests: None.
- **Recommended Clinical Approach:** In patients with valvular heart disease, stress echocardiography is a useful modality to assess a patient's functional capacity, ventricular function, and severity of valve dysfunction during exercise. This information may be useful in determining the need for and timing of surgical or interventional treatments. In addition, stress echo can help to clarify the presence and severity of CAD. It can be accomplished using either exercise or pharmacologic agents (predominantly dobutamine) as the stress mechanism. Low dose dobutamine stress echo is the initial test of choice to assess low flow low gradient aortic stenosis (LFLGAS) to differentiate severe aortic stenosis from pseudo severe aortic stenosis. 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 (valves, ascending aorta, pericardial space). The test is less technically demanding than MPI-SPECT.
- Exclusions: None.

Medical Necessity Criteria

- → Stress echo is considered appropriate if ANY of the folland owing is TRUE³⁶:
 - Low-dose dobutamine stress echocardiography (DSE) is appropriate for patients with low-flow, low-gradient aortic stenosis to differentiate severe aortic stenosis from pseudo severe aortic stenosis due to primary myocardial dysfunction.
 - The patient has moderate or asymptomatic severe AS (stages B and C), for measurement of changes in valve hemodynamics with exercise or pharmacological stress.²⁶
 - The patient has asymptomatic moderate or severe chronic primary MR.¹²⁶
 - The patient has mitral valve disease and a discrepancy between clinical symptoms and resting echocardiogram findings.²⁶
 - The patient has moderate or severe aortic regurgitation for assessment of symptoms and functional capacity.²⁶
 - Discordance between clinical assessment and TTE about the severity of AR.

 Female patient with severe valve disease who is considering pregnancy.¹

Non-Indications

- → Stress echo may not be considered appropriate if ANY of the following is TRUE³¹⁻³⁶:
 - Acute pericarditis/Myocarditis.
 - Severe symptomatic valvular aortic stenosis.
 - Uncontrolled arrhythmias causing symptoms or instability.
 - Symptomatic congestive heart failure.
 - Severe hypertension (greater than 180/100 mm Hg).
 - Technical limitations that would limit the quality of diagnostic Stress Echo (e.g., obesity, severely underweight, chest wall deformity, the patient cannot be in the appropriate position).

Site of Service Criteria

Outpatient.

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: Transesophageal Echocardiogram (TEE)

General Guidelines

- Units, Frequency, & Duration: None.
- Criteria for Subsequent Requests: None.
- Recommended Clinical Approach: Transesophageal echocardiography (TEE) can be useful for valvular disease patients when transthoracic echocardiography results are inconclusive or discordant with history and physical exam. TEE is particularly useful in patients with mitral regurgitation to assess mitral leaflet anatomy when considering the mitral leaflet repair or MitraClip procedure feasibility. TEE is also useful in assessing the presence of infective endocarditis and/or left atrial thrombus. TEE is an integral part of minimally invasive valve interventions, including TAVR and MitraCLip procedures.
- Exclusions: None.

Medical Necessity Criteria

- → TEE is considered appropriate if ANY of the following is TRUE 126:
 - Known or suspected valvular heart disease when TTE provides insufficient or discordant information.
 - Further cardiac imaging is needed before mitral valve intervention.
 - Further cardiac imaging is needed before TAVR intervention.
 - Need for re-evaluation of suspected prosthetic valve dysfunction when it would help guide therapy.
 - Within three days of a mitral valve repair, TEE is appropriate to exclude the presence of intracardiac mass, thrombus, or vegetation.
 - Patients with prior valve replacement or repair and clinical symptoms or signs suggest prosthetic valve dysfunction, even when TTE does not show valve dysfunction.
 - Intraprocedural guidance for ANY of the following valve interventions:
 - Valve surgery for Infectious Endocarditis.
 - Transcatheter Aortic Valve Replacement (TAVR).
 - Mitral valve intervention, MitraClip.
 - In patients with known or suspected Infectious Endocarditis and ANY of the following:
 - Nondiagnostic TTE results.
 - Intracardiac device leads are present.

- Change in clinical signs or symptoms (e.g., new murmur, embolism, persistent fever, HF, abscess, or atrioventricular heart block).
- High-risk of complications (e.g., extensive infected tissue, large vegetation on initial echocardiogram, or staphylococcal, enterococcal, or fungal infections).
- Being considered for an early change to oral antibiotic therapy for stable IE treatment, a baseline TEE before switching to oral therapy, and a repeat TEE 1 to 3 days before completing the oral antibiotic regimen should be performed.
- Prosthetic valve in the presence of persistent fever without bacteremia or a new murmur.
- In patients with suspected cardiac mass, tumor, thrombus, or cardiac source of embolus.
- In patients with Staphylococcus aureus bacteremia with or without a known source.
- In patients with a mechanical prosthetic valve and signs or symptoms of prosthetic valve obstruction or an embolic event.

Non-Indications

- \rightarrow TEE may not be considered appropriate if **ANY** of the following is **TRUE**³⁷:
 - The patient has a history of undiagnosed dysphagia.
 - The patient has a history of esophageal stricture, malignancy, recent surgery of the esophagus, active GI bleeding, esophageal varices (relative), or prior surgery (relative).

Site of Service Criteria

None.

HCPCS Code	Code Description/Definition
93312	Real time transesophageal echocardiography with 2-dimensional (2D) image documentation, M-mode recording, probe placement, image acquisition, interpretation, and report
93313	Real time transesophageal echocardiography with 2-dimensional (2D) image documentation and placement of transesophageal probe only
93314	Interpretation and report only of real time transesophageal echocardiography with 2-dimensional (2D) image

	documentation and image acquisition
93315	Transesophageal echocardiography (TEE) with probe placement, image acquisition, interpretation, and report
93316	Transesophageal echocardiography (TEE) for placement of transesophageal probe only
93317	Interpretation and report only of transesophageal echocardiography (TEE) with image acquisition
93318	Real time transesophageal echocardiography (TEE) with probe placement, 2-dimensional (2D) image acquisition and interpretation
93355	Transesophageal echocardiography (TEE) for guidance of transcatheter closure of left atrial appendage, with quantitative measurements, probe manipulation, interpretation and report
C8925	2d tee w or w/o fol w/con,in
C8926	Tee w or w/o fol w/cont,cong

Service: Transthoracic Echocardiogram (TTE)

General Guidelines

- Units, Frequency, & Duration: Single procedures performed as needed for defined criteria
- Criteria for Subsequent Requests:
 - Repeat TTEs are appropriate for:
 - Evaluating significant changes in signs or symptoms since the patient's prior TTE.
 - Providing objective evidence of left ventricular functional response to medical therapy.
 - A repeat TTE is appropriate for patients at various intervals with a history of:
 - Significant valve dysfunction or deformity (e.g., severe stenosis, mitral valve prolapse) with the frequency of repeat echocardiograms based on the type and severity of the valve lesion, the known rate of progression of the specific valve lesion, and the effect of the valve lesion on the affected ventricle.¹
 - Annual repeat TTEs are **NOT** appropriate for clinically stable or asymptomatic patients with mild valvular disease or mild pulmonary hypertension.
- **Recommended Clinical Approach:** Transthoracic echocardiography is the standard diagnostic imaging modality of choice for evaluating patients with known or suspected valvular heart disease.
- **Exclusions:** None.

Medical Necessity Criteria

- → TTE is considered appropriate if ANY of the following is TRUE:
 - The patient has suspected valvular heart disease.
 - The patient has suspected cardiac mass, tumor, thrombus, or cardiac source of embolus.²⁶
 - The patient has known valvular heart disease and a change in clinical status or cardiac examination.
 - Before a planned valve intervention.
 - The patient has asymptomatic mild valvular heart disease and no TTE within the past three to five years.¹
 - The patient has asymptomatic moderate valvular heart disease and no echo within the past one to two years.¹

- The patient has asymptomatic severe valvular heart disease and no echo within the past 6-12 months.¹
- After controlling systemic hypertension in patients with an initial diagnosis of low-flow low-gradient severe aortic stenosis with normal Left Ventricular Ejection Fraction (LVEF).
- Bicuspid aortic valve (AV) and aortic diameter greater than 4.5 cm; or aortic diameter greater than 4.0 cm with a rapid rate of change in the aortic diameter or family history of aortic dissection and no echo within the past year.
- Patient with a bicuspid aortic valve who has undergone aortic valve repair, the diameter of the aortic sinuses or ascending aorta is greater than or equal to 4.0 cm, and no TTE within the past year.
- Within three months after valve intervention for a new baseline.¹
- Patient with history of valve intervention with suspicion of valve dysfunction
- In patients with a bioprosthetic surgical valve, TTE at 5 and 10 years and then annually after implantation is reasonable, even in the absence of a change in clinical status.¹
- Mechanical valve with no TTE in the past three years.
- After valve replacement, female patient planning pregnancy and no TTE within the past year.
- Patient with bioprosthetic TAVR and no TTE within the past year.¹
- Patient with known or suspected infective endocarditis.¹

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 ultrasound waves penetration.^{26,38}

Site of Service Criteria

Inpatient, outpatient, or observation status may apply.

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: 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.³⁹
- 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.^{39,40} Referral to CR is recommended within 12 months after a myocardial infarction (MI), percutaneous coronary intervention, or coronary artery bypass araft surgery or in the setting of stable angina or symptomatic peripheral arterial disease (i.e., intermittent claudication).³⁹ Referral to CR is also recommended after heart valve surgery or intervention (including TAVR or MitraClip) cardiac transplantation or in the setting of chronic heart failure (NYHA Class I-III) with reduced ejection fraction (HFrEF).39 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. 15,41,42 Medicare coverage may not be available for these diagnoses.
- Exclusions: None.

Medical Necessity Criteria

- → Cardiac Rehabilitation is considered appropriate if ANY of the following is TRUE (within 1 year):^{15,42,43}
 - 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 or percutaneous valve intervention
- 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 are present⁴³:
 - 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.

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: None.
- **Recommended Clinical Approach:** If noninvasive testing is inconclusive, a hemodynamic cardiac catheterization can provide the physician with direct measurements of intracardiac and pulmonary artery pressures, transvalvular pressure gradients, and cardiac output measurements. Aortic and ventricular angiography may provide information on LV function and the extent of valvular regurgitation. Coronary angiography may provide information regarding the presence and extent of underlying CAD, which may influence the timing and type of intervention decisions.¹
- Exclusions: None.

Medical Necessity Criteria

Indications

- → Cardiac catheterization is considered appropriate if ANY of the following is TRUE¹:
 - The patient has suspected or known valvular heart disease when noninvasive tests are inconclusive or discordant with clinical assessment.
 - The patient has chronic severe secondary mitral regurgitation.
 - Before valve interventions to assess coronary anatomy and ANY of the following:
 - Symptoms of angina.
 - Objective evidence of ischemia.
 - Decreased ventricular systolic function.
 - Coronary artery disease (CAD).
 - Coronary risk factors (including men greater than 40 years of age and postmenopausal women).

Non-Indications

- → Cardiac catheterization may not be considered appropriate if ANY of the following is TRUE⁴⁴⁻⁴⁵:
 - Acute kidney injury or unstable kidney disease.
 - Uncontrolled severe coagulopathy or thrombocytopenia with platelets < 30,000).

- Fever or systemic infection.
- Uncontrolled arrhythmia.
- Uncontrolled hypertension.
- Acute decompensated heart failure unless catheterization is indicated to diagnose or treat the cause of heart failure.
- Severe contrast agent allergy that cannot be premedicated prior to contrast exposure.
- The patient is pregnant.

Site of Service Criteria

Inpatient or outpatient.

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:** This procedure is done during a heart catheterization for symptomatic, significant stenosis, or blockage refractory to optimal medical therapy.
- Exclusions: None.

Medical Necessity Criteria

Indications

- → PCI is considered appropriate if ANY of the following is TRUE:
 - Patient undergoing transcatheter aortic valve replacement (TAVR) with significant left main or proximal CAD with or without angina.¹
 - Patients undergoing transcatheter aortic valve replacement (TAVR) with significant stenosis in any of the three major coronary arteries

Non-Indications

- → PCI may not be considered appropriate if ANY of the following is TRUE:
 - PCI is not indicated if a coronary lesion is not angiographically or hemodynamically significant and there is no clinical indication for revascularization.

Site of Service Criteria

Inpatient, outpatient, or observation status may apply.

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
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

Service: Transcatheter Aortic Valve Replacement (TAVR)

General Guidelines

- Units, Frequency, & Duration: None.
- Criteria for Subsequent Requests: Dysfunction of previous TAVR.
- Recommended Clinical Approach: TAVR is an effective catheter-based procedure for the treatment of aortic stenosis. Patients considered for TAVR now include all risk cohorts (low- to high-risk). Compared to surgical aortic valve replacement (SAVR), TAVR has a lower risk of stroke, major bleeding, and atrial fibrillation and a shorter hospital length of stay and shorter recovery.^{114,46-49}
- **Exclusions:** Life expectancy less than 1 year even with a successful procedure or those with a chance of "survival with benefit" of less than 25% at 2 years.¹

Medical Necessity Criteria

Indications

- \rightarrow TAVR is considered appropriate if ANY of the following is TRUE^{1/14,46-49}:
 - For patients with symptomatic severe aortic stenosis.
 - For asymptomatic patients with severe aortic stenosis and left ventricular dysfunction (LVEF less than 50%).
 - For patients with asymptomatic severe aortic stenosis and low surgical risk when an exercise test demonstrates decreased exercise tolerance (normalized for age and sex) or a fall in systolic blood pressure of greater than or equal to 10 mm Hg from baseline to peak exercise.
 - For asymptomatic patients with very severe AS (defined as an aortic velocity of greater than or equal to 5 m/s) and low surgical risk.
 - For patients with symptomatic aortic stenosis with low-flow/low-gradient severe aortic stenosis
 - For valve-in-valve procedures for failed prior bioprosthetic valves as defined in the guidelines.¹⁴⁶⁻⁴⁹

Non-Indications

- → TAVR may not be considered appropriate if ANY of the following is TRUE
 - Life expectancy less than 12 months owing to a non-cardiac cause
 - Myocardial infarction within the last thirty days

- Congenital unicuspid, or noncalcified valve or a bicuspid valve with unsuitable anatomy for TAVR.
- Hypertrophic obstructive cardiomyopathy
- A short distance between the annulus and coronary ostium for an artery unprotected by a bypass graft and concern that TAVR may result in coronary obstruction that cannot be protected.
- ◆ Left ventricular ejection fraction less than 20%
- Severe pulmonary hypertension with right ventricular dysfunction determined to be not due to severe aortic stenosis and/or determined to be unlikely to improve after TAVR.
- Echocardiographic evidence of intracardiac mass, thrombus, or vegetation(unless completely healed).
- Severe primary mitral regurgitation without a plan to perform a transcatheter MitraClip procedure after TAVR.
- Severe functional mitral regurgitation determined unlikely to improve after TAVR or without a plan to perform a transcatheter MitraClip procedure after TAVR.
- MRI confirmed stroke or Transient Ischemic Attack (TIA) within the last six months unless Heart Team determines that the risk of delaying treatment of aortic stenosis exceeds potential benefit from delaying TAVR
- Mixed aortic valve disease (concomitant aortic regurgitation) if there is determined to be inadequate valve calcification to allow TAVR.
- A significant aortoiliac disease that would interfere with delivery and deployment of the stent-valve without alternative access approach available (transcarotid, transaxillary, transapical or transcaval).⁴⁶⁻⁴⁹

Site of Service Criteria

Inpatient, outpatient, or observation status may apply.

HCPCS Code	Code Description/Definition
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve using percutaneous femoral artery approach
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with

	prosthetic valve by open femoral artery approach
33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve by open axillary artery approach
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve by open iliac artery approach
33365	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve by median mediastinotomy
33366	Transcatheter aortic valve replacement (TAVR/TAVI) using prosthetic valve with transapical exposure

Service: Surgical Left Atrial Appendage Exclusion

<u>General Guidelines</u>

- Units, Frequency, & Duration: Single procedure as indicated by clinical criteria.
- Criteria for Subsequent Requests: None.
- Recommended Clinical Approach: A surgical approach to left atrial appendage exclusion is a possible therapy for atrial fibrillation patients at high-risk for stroke undergoing cardiac surgery for other indications. Initially, methods like internal sutures or a non-cutting stapler were used, with poor results due to the LAA's recanalization. While these methods are available, there are only small studies of these techniques to assess stroke risk reduction.⁵⁰ There is a risk of procedural complications with the implants, including peri-device leakage, perforation, pericardial tamponade, thrombosis, stroke, and even death. Current consensus guidelines still favor continued oral anticoagulation therapy before and after surgical LAA exclusion. However, surgical LAA excision or exclusion in conjunction with surgical ablation to prevent thromboembolic complications of atrial fibrillation received a Class IIa (Level of evidence: C; "limited data") recommendation in the 2017 Society of Thoracic Surgeons clinical practice guidelines.⁵⁰ There is currently no data to support prophylactic LAA excision or exclusion in cardiac surgery patients who may be at increased risk for postoperative atrial fibrillation. However, the ATLAS trial studying the AtriClip for this purpose is currently ongoing.⁵¹
- Exclusions: None.

Medical Necessity Criteria

Indications

- → Surgical Left Atrial Appendage Exclusion is considered appropriate if ANY of the following is TRUE:
 - The patient is scheduled for cardiac surgery and has preoperative atrial fibrillation and CHA2DS2-VASC score greater than or equal to 2 and HAS-BLED greater than or equal to 2.

Non-Indications

- → Surgical Left Atrial Appendage Exclusion is not considered appropriate if ANY of the following is TRUE:
 - The patient has a CHA₂DS₂-VASc score less than 2 or HAS-BLED score of less than 2.

- The patient has no indication of undergoing a cardiac surgical procedure.
- The patient has no history of preoperative atrial fibrillation.

Site of Service Criteria

Inpatient status.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
33999	Unlisted procedure-cardiac surgery

*Atrial appendage ligation, plication, or AtriClip is included in mitral valve and Maze procedures and should not be reported separately when performed in the same session as these procedures

Service: Surgical Maze Procedure

General Guidelines

- Units, Frequency, & Duration: Single procedure as indicated by clinical criteria.
- Criteria for Subsequent Requests: None.
- Recommended Clinical Approach: Surgical management of atrial fibrillation is typically approached with a Maze procedure, electrically segmenting the left atrium with radiofrequency ablation.
 For symptomatic patients with paroxysmal or persistent AF undergoing valvular surgery, the maze procedure can reduce symptoms and prevent recurrent arrhythmias.¹
- Exclusions: None.

Medical Necessity Criteria

Indications

- → Surgical maze procedure is considered appropriate if ANY of the following is TRUE:
 - In a patient with atrial fibrillation or atrial flutter undergoing valve surgery.¹⁵⁰

Non-Indications

- → Surgical maze procedure is not considered appropriate if ANY of the following is TRUE:
 - In a patient with symptomatic atrial fibrillation where no cardiac surgery is planned, and percutaneous catheter ablation is a feasible treatment option.

Site of Service Criteria

Inpatient status.

HCPCS Code	Code Description/Definition
33254	Operative tissue ablation and reconstruction of atria, limited (e.g., modified Maze procedure)
33255	Operative tissue ablation and reconstruction of atria, extensive (e.g., Maze procedure); without cardiopulmonary bypass

33256	Operative tissue ablation and reconstruction of atria, extensive (e.g., Maze procedure); with cardiopulmonary bypass
33257	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), limited (e.g., modified Maze procedure)
33258	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (e.g., Maze procedure); without cardiopulmonary bypass
33259	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (e.g., Maze procedure); with cardiopulmonary bypass
33265	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, limited (e.g., modified Maze procedure); without cardiopulmonary bypass
33266	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, extensive (e.g., Maze procedure); without cardiopulmonary bypass

Service: Transcatheter Mitral Valve Repair

General Guidelines

- Units, Frequency, & Duration: None.
- **Criteria for Subsequent Requests:** Revision of Mitral Valve repair is rarely required for subsequent valve leak or dysfunction.
- Recommended Clinical Approach: Percutaneous or transcatheter Mitral Valve repair (MitraClip device) is approved for patients with moderate to severe primary Mitral Regurgitation (MR) (3-4+) and NYHA Class III-IV heart failure symptoms and considered high or prohibitive surgical risk for open surgical valve repair. Primary mitral valve disease includes degenerative valve disease, mitral valve prolapse, and flail mitral leaflet but does not include MR due to CAD or prior MI. MitraClip is also approved for symptomatic patients with secondary or functional mitral regurgitation and moderate to severe regurgitation on optimal medical therapy for heart failure, including resynchronization therapy if indicated regardless of surgical risk. TEE is routinely performed before the MitraClip procedure to identify suitable patients with the appropriate anatomy for repair. The procedure is performed in the cardiac catheterization laboratory via a femoral vein approach and a transseptal puncture. The MitraClip procedure requires TEE guidance and, as such, is performed under general anesthesia. Patients require anticoagulation with heparin during the procedure and six months of antiplatelet therapy afterward. Patients are usually hospitalized overnight and discharged the next day. Percutaneous Mitral valve repair with the MitraClip avoids the need for more extensive surgical valve repair or replacement with significantly less morbidity and mortality. Risks of transcatheter mitral valve repair include bleeding from the access site, tamponade during the septal puncture, and the rare occurrence of device embolization or partial displacement, usually requiring surgery.⁵³

• Exclusions:

- Mitral Valve is felt to be unsuitable for percutaneous, edge to edge repair based on the preprocedural TEE or TTE.
- Cannot tolerate anticoagulation or antiplatelet therapy post-procedure.
- Active endocarditis of the mitral valve.
- Rheumatic or other cause of mitral stenosis.
- Extensive chordal fusion or calcification.
- Papillary muscle rupture.
- Presence of thrombus in the femoral vein, inferior vena cava, or within a cardiac chamber, especially the left atrium.

Medical Necessity Criteria

Indications

- → Transcatheter mitral valve repair is considered appropriate if ANY of the following are TRUE¹⁵³⁻⁵⁴:
 - In severely symptomatic patients (NYHA class III or IV) being considered for transcatheter edge-to-edge repair (TEER) and ALL of the following:
 - Primary severe MR and
 - High or prohibitive surgical risk
 - mitral valve anatomy is favorable for the repair procedure
 - Patient life expectancy is at least 1 year.
 - In patients with chronic severe secondary MR related to LV systolic dysfunction (LVEF <50%) and ALL of the following:
 - Persistent symptoms (NYHA class II, III, or IV) while on
 - Optimal medical therapy in patients with
 - Appropriate anatomy as defined on TEE and ALL of the following:
 - LVEF between 20% and 50%,
 - LVESD less than or equal to 70 mm
 - pulmonary artery systolic pressure less than or equal to 70 mm Hg.

Non-Indications

- → Transcatheter mitral valve repair is not considered appropriate if ANY of the following is TRUE¹⁵³⁻⁵⁴:
 - In patients that require heart surgery for another form of cardiac disease such as CAD requiring CABG.
 - In patients that cannot tolerate anticoagulation or antiplatelet therapy post-procedure.
 - Active endocarditis of the mitral valve.
 - Extensive chordal fusion or calcification/rheumatic mitral valve disease.
 - Papillary muscle rupture.
 - Presence of thrombus in the femoral vein, inferior vena cava, or within a cardiac chamber especially the left atrium.

<u>Site of Service Criteria</u>

Inpatient status.

Procedure Codes (HCPCS/CPT)

HCPCS Code Code Description/Definition

33418	Transcatheter mitral valve repair with initial prosthetic valve by percutaneous approach
0345T	Transcatheter mitral valve repair percutaneous approach via the coronary sinus

Service: Surgical Mitral Valve Repair

General Guidelines

- Units, Frequency, & Duration: None.
- **Criteria for Subsequent Requests:** If a patient has had a mitral valve repair and needs further intervention, a mitral valve replacement is typically indicated.
- **Recommended Clinical Approach:** Mitral valve repair is recommended for patients with severe primary mitral regurgitation due to degenerative disease or mitral valve prolapse, especially posterior leaflet prolapse. TEE is performed before the procedure to assess suitable anatomy for repair. However, the final decision for repair vs. replacement is made at the time of surgery.¹ Mitral valve repair has lower perioperative mortality than mitral valve replacement. It has improved long-term left ventricular function due to preserving the papillary muscles and avoiding a prosthetic valve's complications. Mitral valve repair should be performed at a Comprehensive Valve Center when possible.
- Exclusions: None.

Medical Necessity Criteria

- → Surgical mitral valve repair is considered appropriate if ANY of the following is TRUE¹:
 - In symptomatic patients with severe primary mitral regurgitation.
 - In asymptomatic patients with severe primary mitral regurgitation and ANY of the following:
 - Left Ventricular dysfunction (LVEF less than or equal to 60% or LVESD greater than or equal to 40 mm).
 - Normal Left Ventricular function (LVEF > 60% and LVESD < 40 mm) with low expected surgical mortality risk and a high likelihood of a successful repair.
 - Normal LV function but deterioration of Left Ventricular function on serial imaging studies.
 - In patients with severe secondary MR and ANY of the following:
 - The patient is undergoing CABG.
 - The patient has atrial annular dilation with preserved LV systolic function (LVEF greater than or equal to 50%) and severe persistent symptoms (NYHA class III or IV) despite optimal medical therapy.

 In asymptomatic women with severe MR and a valve suitable for repair who are considering pregnancy.

Non-Indications

- → Surgical mitral valve repair may not be appropriate if ANY of the following is TRUE:
 - Severe Left Ventricular dysfunction (LVEF less than 20%).
 - Severe emphysema.
 - Severe restrictive lung disease.
 - The patient has severe and irreversible pulmonary hypertension

Site of Service Criteria

Inpatient.

HCPCS Code	Code Description/Definition
	Valvuloplasty, mitral valve, with cardiopulmonary bypass;
33426	with prosthetic ring

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.⁵⁵ 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).^{56,57} 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).58,59-60
- Exclusions: None.

Medical Necessity Criteria

- → Ventricular Assist Device is considered appropriate if ANY of the following are TRUE: 56,61
 - 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 true⁶¹:
 - 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:
 - LVEF less than 25% and unable to exercise for Heart Failure or, if able to perform cardiopulmonary exercise testing, with peak VO2 less than 12 mL/kg/min and/or less than 50% predicted value.
 - >3 Heart Failure hospitalizations in the previous 12 months without an obvious precipitating cause.
 - 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:
 - If the patient is being considered for a short-term or temporary device, and ANY of the following are true:
 - Uncontrolled sepsis.
 - Bleeding diathesis.
 - Severe aortic or PAD.
 - If the patient is being considered for a long-term device and ANY of the following is true⁶¹:
 - 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).

<u>Site of Service Criteria</u> Inpatient

HCPCS Code	Code Description/Definition
33990	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, arterial access only
33991	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only
0451T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; complete system (counterpulsation device, vascular graft, implantable vascular hemostatic seal, mechano-electrical skin interface and subcutaneous electrodes)
0452T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; complete system (counterpulsation device, vascular graft, implantable vascular hemostatic seal, mechano-electrical skin interface and subcutaneous electrodes); aortic counterpulsation device and vascular hemostatic seal
0453T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; complete system (counterpulsation device, vascular graft, implantable vascular hemostatic seal, mechano-electrical skin interface and subcutaneous electrodes); mechano-electrical skin interface
0454T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular
	approach, and programming of sensing and therapeutic parameters; complete system (counterpulsation device, vascular graft, implantable vascular hemostatic seal, mechano-electrical skin interface and subcutaneous electrodes); subcutaneous electrode
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0455T	Removal of permanently implantable aortic counterpulsation ventricular assist system; complete system (aortic counterpulsation device, vascular hemostatic seal, mechano-electrical skin interface and electrodes)
0456T	Removal of permanently implantable aortic counterpulsation ventricular assist system; complete system (aortic counterpulsation device, vascular hemostatic seal, mechano-electrical skin interface and electrodes); aortic counterpulsation device and vascular hemostatic seal
0457T	Removal of permanently implantable aortic counterpulsation ventricular assist system; complete system (aortic counterpulsation device, vascular hemostatic seal, mechano-electrical skin interface and electrodes); mechano-electrical skin interface
0458T	Removal of permanently implantable aortic counterpulsation ventricular assist system; complete system (aortic counterpulsation device, vascular hemostatic seal, mechano-electrical skin interface and electrodes); subcutaneous electrode
0459T	Relocation of skin pocket with replacement of implanted aortic counterpulsation ventricular assist device, mechano-electrical skin interface and electrodes
0460T	Repositioning of previously implanted aortic counterpulsation ventricular assist device; subcutaneous electrode
0461T	Repositioning of previously implanted aortic counterpulsation ventricular assist device; subcutaneous electrode; aortic counterpulsation device
0462T	Programming device evaluation (in person) with iterative adjustment of the implantable mechano-electrical skin interface and/or external driver to test the function of the device and select optimal permanent programmed values with analysis, including review and report, implantable aortic counterpulsation ventricular assist system, per day
0463T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, implantable aortic

	counterpulsation ventricular assist system, per day		
Q0477	Pwr module pt cable Ivad 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
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	ВМІ 30	BMI 40	
3- Intermediate Risk	Anemia	hemoglobin <11 (females), <12 (males)		Workup to identify etiology
3- Intermediate Risk	ніv	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-brachi al pressure index (ABPI) <0.9		Preoperative consultation with vascular surgeon

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	ВМІ 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	Renal insufficiency	serum creatinine >1.5 mg/dL or creatinine clearance <100 mL/min		

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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