Sinus Node Dysfunction

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Other Notices:

Guideline Information:

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

Physician author: Alisa Niksch, MD (Pediatric Cardiologist/Electrophysiologist), Mary Krebs, MD (Primary Care Physician)
Peer reviewed by: Carter Newton, MD FACC (Cardiologist), Russell Rotondo, MD FACC (Cardiologist), Ania Garlitski, MD (Cardiologist)
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Table of Contents

Care Path Overview

Care Path Clinical Discussion

Sinus node dysfunction is an electrical condition where the sinus node of the heart does not depolarize appropriately. While resting sinus bradycardia (HR less than 50 BPM) can be a shared feature of this phenomenon with more benign conditions, sinus node dysfunction has broader manifestations that produce symptoms of poor cardiac output. These can include prolonged pauses in sinus node depolarization for greater than 3 seconds, chronotropic incompetence (failure of HR to respond appropriately to exertion or other physical demands), and tachy-brady syndrome. This can cause functional symptoms such as dizziness, fatigue, shortness of breath, syncope, cognitive difficulties, and even palpitations if tachy-brady syndrome is present.

Sinus node dysfunction usually develops very gradually over decades due to a process of progressive fibrosis. It is initially asymptomatic but may become much more commonly symptomatic in the elderly population. Depression of sinus node function can occur as a side effect of many antiarrhythmic and psychiatric medications that affect ion channel function or after cardiac surgery due to direct damage or chronic fibrosis. Other infiltrative diseases like sarcoidosis, amyloidosis, or hemochromatosis can also produce abnormal sinus node function. Suppression of sinus node function can also be a reversible effect of obstructive sleep apnea. Autonomic derangement after a myocardial infarction can also manifest as sinus node dysfunction/arrest (as well as heart block).

While the following rhythms may be seen in the context of sinus node dysfunction, any manifestation which causes symptoms merits treatment. While some causes of sinus node dysfunction are reversible, others are not, and permanent pacing is indicated. There is no established minimum heart rate or pause duration in sinus node dysfunction where permanent pacing is recommended. It is the relationship of bradycardia to symptoms that are the driver of clinical decision-making.

Junctional rhythm is an automatic rhythm that occurs either: (1) when the sinus node impulses are slower than the intrinsic pacemaker in or around the AV node; or (2) when there is an AV block present and the junctional pacemaker becomes the predominant heart rhythm. This escape, or “back up” rhythm, typically occurs at a rate of 40-60 BPM. Unless there is an additional disruption to the conduction system, junctional rhythm is usually associated with a narrow QRS morphology.

Junctional rhythm with normal sinus node function is extremely common in the young and athletes, especially during sleep. However, it can be associated with sinus node disease causing significant symptoms and functional limitations which merit cardiac pacing. Junctional rhythm is found in cases of digoxin toxicity, ischemia of the AV node (most commonly via posterior descending artery obstruction), or inflammatory processes such as Lyme disease or rheumatic fever.[1]

Symptoms of junctional rhythm are variable; patients with an adequate junctional rate may be asymptomatic. However, junctional rhythm may be associated with ventriculoatrial dissociation, which can cause chest discomfort, shortness of breath, fatigue, or a feeling of fullness. A slow junctional rhythm associated with an initial diagnostic workup is similar to the approach to sinus node dysfunction. A comprehensive history and physical and an initial 12-lead ECG should be done to identify any reversible causes of junctional rhythm as a manifestation of other conduction diseases. Junctional rhythm is often seen on extended ambulatory ECG monitoring.

Asymptomatic junctional rhythm in a young person does not require any medical interventions. Junctional rhythm resulting from sinus node dysfunction should be approached according to the symptoms and pathology associated with the sinus node disease (see the previous section). This includes indications for permanent pacing. A junctional rhythm related to digoxin toxicity is usually seen in the acute care setting; it can be treated with atropine and digoxin immune fab (Digibind).

Idioventricular rhythm is a slow, regular, wide complex rhythm that typically presents with a heart rate at or slightly under 40 BPM. This rhythm is also another back up “pacemaker” in the heart when the sinus node is diseased or suppressed. There are usually no P waves seen during this rhythm. Idioventricular rhythm can also be a benign finding in a young person with no other signs of sinus node dysfunction or AV block; however, it can present in the context of high-grade AV block, electrolyte abnormalities, digoxin toxicity, or exposure to inhalational anesthetics. An accelerated form of idioventricular rhythm can occur during reperfusion after myocardial infarction.[2]

While some of the same underlying conditions can cause both junctional and idioventricular rhythm, the ECG appearance can be quite different. In addition to a wide complex QRS, the rhythm can have a variable appearance depending on the site of origin of the rhythm. Idioventricular rhythms can originate in either the right or left bundle branches, in either fascicle of the left bundle branch, or more distally in the Purkinje fibers.

A finding of idioventricular rhythm by itself does not have significant prognostic value. Again, this may result from true sinus node disease or

suppression due to increased vagal tone. When the idioventricular rhythm is not tolerated because of AV dyssynchrony, atropine can be used in the acute setting as a temporary treatment until the underlying cause is identified and corrected.

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

- ➢ Sinus node dysfunction occurs in approximately 1 out of every 600 patients over the age of 65.[3] It can present as an incidental, asymptomatic finding with a variety of manifestations on ECG, including a slower ectopic atrial or junctional rhythm. Sinus node dysfunction can also be quite symptomatic with functional limitation of cardiac output.
    - Ambulatory cardiac monitoring can assist in matching symptoms to periods of bradycardia; monitors which can be used for a 21 or 30-day period have a higher yield in capturing clinically important events. For exercise-induced symptoms, stress testing can be a feasible alternative for diagnosis.
    - As structural heart disease is commonly associated with sinus node dysfunction, initial imaging with transthoracic echocardiography is recommended. However, advanced imaging (MRI, CT) may be needed to look at anatomical features in greater detail.
    - A focus of treating symptomatic sinus node dysfunction is the removal of potential triggers, including medications, electrolyte abnormalities, or obstructive sleep apnea.
    - Pacing is the definitive treatment for sinus node dysfunction. While atrial pacing may be sufficient initially, a significant risk of future AV block makes the implant of a dual-chamber system reasonable.
- ➢ Junctional rhythm is a typical back up rhythm found in the setting of sinus node dysfunction. The typical heart rate of a junctional rhythm is between 40-60 bpm.[1,4]
    - Many patients can be asymptomatic in this rhythm, but this can create symptoms as described for sinus node dysfunction if the rate is inadequate.
    - The most distinctive exam finding is an abnormal pulsation of the jugular veins when a slow atrial impulse causes atrial contraction against a closed tricuspid valve.
    - Evaluation and treatment of symptomatic junctional rhythm are aligned with that of sinus node dysfunction in general (see subsequent sections). Asymptomatic junctional rhythm found incidentally does not require extensive monitoring or imaging.
- ➢ Idioventricular rhythm is usually a slow, wide complex rhythm that occurs intermittently at rates at or slightly below 40 bpm.
    - Idioventricular rhythm is usually asymptomatic and captured on ambulatory cardiac monitoring. Rarely, especially when associated with other conduction disorders or heart failure, palpitations, fatigue, dizziness, and syncope.[2]

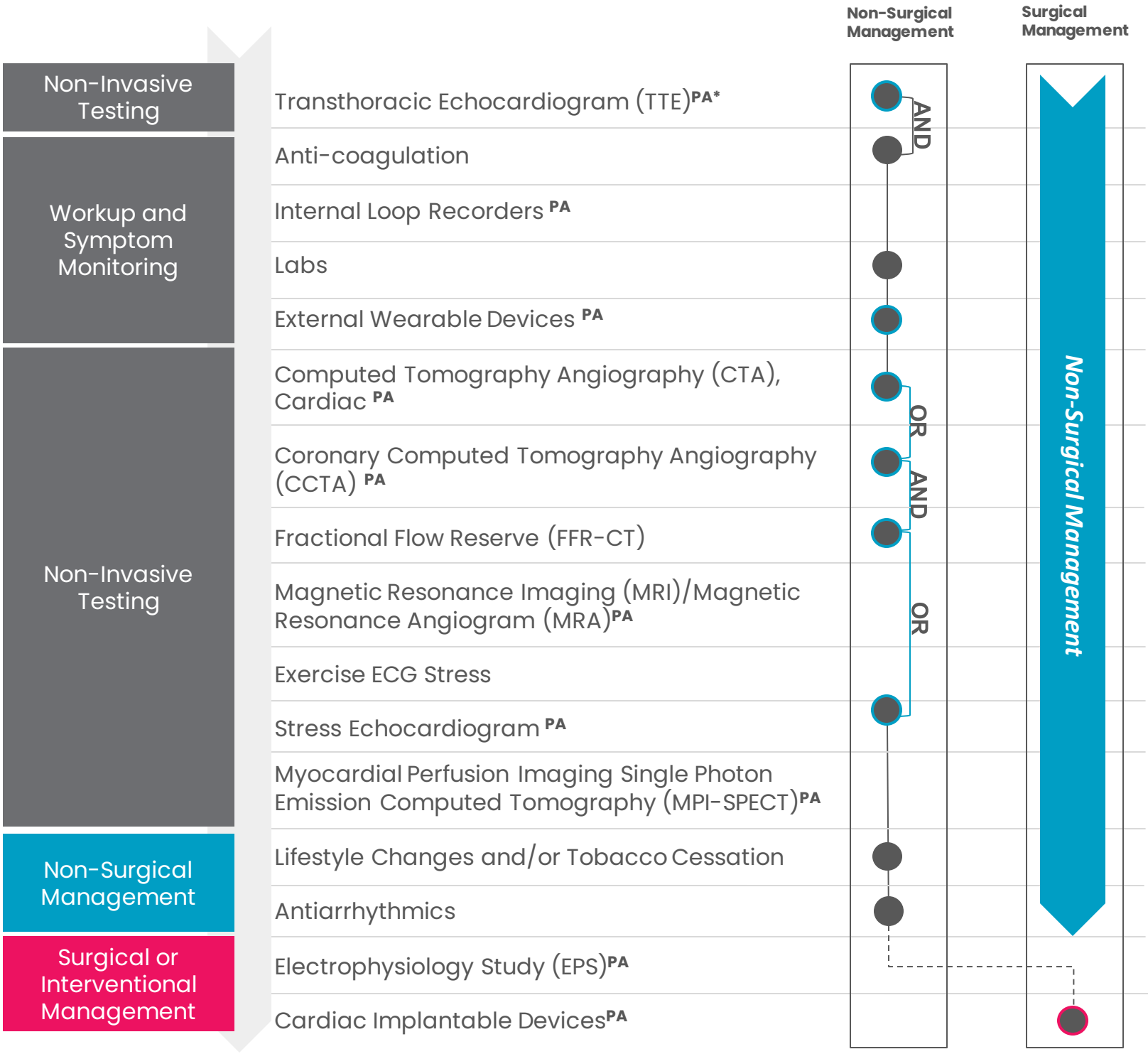
- Idioventricular rhythm can originate from the left or right bundle branches or the Purkinje system and may not look the same in every patient. This does not affect the prognosis.
- Treatment of idioventricular rhythm is based on any associated conduction disorders, whether an underlying sinus node dysfunction (see above) or high-grade atrioventricular block.[2]

Definitions

- **Sinus Pause (or arrest):** An episode of greater than 3 seconds without atrial activity on ECG monitoring. A back up ectopic atrial or junctional rhythm usually provides electrical activity during these periods.
- **Brady-Tachy Syndrome:** Bradycardia alternating with paroxysmal supraventricular arrhythmias, most frequently atrial fibrillation. This occurs in 50% of patients affected by sinus node dysfunction.
- **Chronotropic Incompetence:** The lack of capacity of the heart rate to achieve at least 80% of the maximal predicted heart rate based on age (220-age=maximum predicted HR) in the absence of medications known to blunt the heart rate response to exercise. This marks the failure of the heart rate to rise to a level that is physiologically appropriate for the exercise being performed.
- **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.[5,42]

Sinus Node Dysfunction

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



Key

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

= Rate Control management prior authorization group of services
= Rhythm Control management prior authorization group of services
= Subsequent service
= Management path moves to a different management path

Care Path Diagnostic Criteria

Disease Classification

Arrhythmias, Sinus Node Dysfunction

ICD-10 Codes Associated with Classification

ICD-10 Code	Code Description/Definition
I45.9	Conduction disorder, unspecified
R00.1	Bradycardia, unspecified
I49.5	Sick sinus syndrome
I49.8	Other specified cardiac arrhythmias
T82.110A	Breakdown (mechanical) of cardiac electrode, initial encounter
T82.110D	Breakdown (mechanical) of cardiac electrode, subsequent encounter
T82.111A	Breakdown (mechanical) of cardiac pulse generator (battery), initial encounter
T82.118D	Breakdown (mechanical) of other cardiac electronic device, subsequent encounter
T82.119A	Breakdown (mechanical) of unspecified cardiac electronic device, initial encounter
T82.120A	Displacement of cardiac electrode, initial encounter
T82.121A	Displacement of cardiac pulse generator (battery), initial encounter
T82.128A	Displacement of other cardiac electronic device, initial encounter
T82.190A	Other mechanical complication of cardiac electrode, initial encounter
T82.191A	Other mechanical complication of cardiac pulse generator (battery), initial encounter
T82.198A	Other mechanical complication of other cardiac electronic

	device, initial encounter
T82.198S	Other mechanical complication of other cardiac electronic device, sequela
T82.199A	Other mechanical complication of unspecified cardiac device, initial encounter
T82.518A	Breakdown (mechanical) of other cardiac and vascular devices and implants, initial encounter
T82.598A	Other mechanical complication of other cardiac and vascular devices and implants, initial encounter
T82.598D	Other mechanical complication of other cardiac and vascular devices and implants, subsequent encounter
T82.7XXA	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, initial encounter
T82.7XXD	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, subsequent encounter
T82.837A	Hemorrhage due to cardiac prosthetic devices, implants and grafts, initial encounter
T82.867D	Thrombosis due to cardiac prosthetic devices, implants and grafts, subsequent encounter
T82.897A	Other specified complication of cardiac prosthetic devices, implants and grafts, initial encounter
T82.897S	Other specified complication of cardiac prosthetic devices, implants and grafts, sequela
T85.698A	Other mechanical complication of other specified internal prosthetic devices, implants and grafts, initial encounter
Z45.010	Encounter for checking and testing of cardiac pacemaker pulse generator [battery]
Z45.018	Encounter for adjustment and management of other part of cardiac pacemaker

Presentation and Etiology

Causes and Risk Factors

Sinus node dysfunction is a gradual loss of efficiency of the sinus node to generate or propagate electrical signals to the rest of the heart. Many extrinsic physiologic factors can affect sinus node function, including inputs from the vagal nerve, which can be asymptomatic and benign in young, healthy individuals. However, in many patients, sinus node function can deteriorate gradually due to fibrosis and tissue remodeling from the following conditions:

- Heart failure.
- Past cardiac surgeries.
- Cardiac infiltrative disease (e.g., sarcoidosis, amyloidosis, hemochromatosis).
- Metastatic cancer.

Sinus node function can also be affected by the presence of:

- Hypoxia during obstructive sleep apnea.
- Electrolyte abnormalities.
- Hypothyroidism.
- Medications (primarily antiarrhythmics and psychoactive agents).

Treatment of sinus node dysfunction relies on the presence of clinical symptoms associated with bradyarrhythmia, with permanent pacing often required when reversible causes have been exhausted.[4]

Clinical Presentation

As previously stated, the presentation of sinus node dysfunction can vary. Sinus pauses or arrest can be asymptomatic with an adequate back up rhythm like an ectopic atrial or junctional rhythm. However, with a less stable conduction system or additional comorbidities, there can be:

- Fatigue.
- Dizziness.
- Shortness of breath.
- Chest discomfort
- Syncope,
- Hemodynamic collapse.

A comprehensive history of a patient suspected of having sinus node suppression or dysfunction should examine the frequency, duration, severity, longevity, circumstances, triggers, and alleviating factors of symptoms suspicious of bradycardia or conduction disorders. These factors can include temporal relationships to:

- Medications.
- Meals.
- Illnesses or medical interventions.
- Emotional distress.
- Physical exertion.
- Positional changes.
- Other orthostatic or vagal precipitating factors (e.g., urination, defecation, cough, prolonged standing, shaving, tight collars, and head-turning).

Because of the propensity of some commonly prescribed medications (and nutraceuticals) to elicit or exacerbate bradyarrhythmias, a thorough review of both prescription and over-the-counter medications is essential.[4]

Any conduction system disorder can be the first indication of a systemic disease process or deterioration of a pre-existing cardiac condition, like heart failure or sarcoidosis, among others. Evaluating a patient with bradycardia should include past cardiovascular history and risk factors, family history, a thorough review of systems, and travel history.

Typical Physical Exam Findings

- Vital signs showing low heart rate
- Low blood pressure
- A decline in blood pressure on standing
- Cool or pale extremities
- Generalized listless effect or signs of mental confusion
- Irregular size or rate of jugular venous pulsations
- Palpable liver enlargement
- Bibasilar rales on lung auscultation
- Physical findings suggestive of structural heart disease (e.g., heart murmurs, displaced PMI)

When there are escape rhythms originating at or below the AV node (e.g., junctional rhythm), jugular venous pulsations can be exaggerated and irregular. Examining the lungs for crackles and assessing liver size can help identify left or right heart failure. Vagal-mediated sinus node suppression can be evaluated with orthostatic provocation, head-turning, and carotid massage (when carotid stenosis can be safely excluded). Findings of a rash, joint symptoms, and fever can indicate the presence of systemic rheumatologic disease.[6]

Typical Diagnostic Findings

- 12-lead ECG
- Ambulatory cardiac monitoring
- Transthoracic echocardiogram
- Cardiac MRI
- Cardiac CT
- Stress testing with or without imaging

Initial diagnostic workup should begin with a 12-lead ECG. The 12-lead ECG should also be examined for signs of other cardiac pathology, including ischemic changes.

With suspicion of sinus node disease, extended ambulatory electrocardiographic monitoring is beneficial; one can often see the total absence of P waves with or without an ectopic atrial rhythm, ventricular depolarization occurring at a faster rate than atrial depolarization, or periods of bradycardia alternating with atrial flutter or fibrillation.

With a history of prior cardiac disease or cardiac surgery/intervention, evaluation with cardiac imaging is appropriate.[4]

- Transthoracic echocardiography can better assess cardiac function and define anatomic abnormalities which could impact rhythm stability.
- Cardiac MRI can define structural heart disease and myocardial fibrosis/infiltrative disease, contributing to the progression of sinus node dysfunction.
- Cardiac CT imaging can also be useful for cardiac anatomy definition after cardiac surgery, and coronary CTA can add value to the assessment of coronary patency[7,8]; however, it is less sensitive for evaluating diseases of the myocardium.

With exercise-related symptoms, stress testing is recommended, with particular attention to the HR response to exertion. Chronotropic incompetence is a sign of progressive sinus node disease where the heart rate cannot reach beyond 80% of the maximal predicted heart rate for age.[4] When risk factors for coronary artery disease are present, additional imaging with echocardiography or radionuclide scanning is appropriate.

Treatment of sinus node dysfunction is focused on:

1. Managing reversible causes of the bradycardia
2. Providing an adequate physiologic heart rate response and restoring AV synchrony

Initial interventions may include:

- Removing any medications which would have direct effects on slowing cardiac conduction
- Treatment of underlying systemic conditions
- Supporting heart rate in patients who are at-risk of becoming unstable
- Performing laboratory studies evaluating electrolytes, thyroid function, blood gas, and pH to detect conditions that can acutely be corrected.

Patients who have evidence of bradycardia and suspicion of sinus node dysfunction with risk factors of obstructive sleep apnea (OSA) should be screened with polysomnography. Data is available showing an unusually high prevalence of OSA in paced individuals.[9] However, many causes of sinus node dysfunction are irreversible or progressive, and pacemaker implantation is necessary to prevent symptoms related to bradycardia and prevent ectopy or atrial development arrhythmias.[10] While atrial pacing is preferred, inserting a ventricular lead may be prudent due to the increased risk of AV block in a significant percentage of these patients.[3,4]

Care Path Services & Medical Necessity Criteria

Workup and Symptom Monitoring

Service: Internal Loop Recorders (ILRs)

General Guidelines

- **Units, Frequency, & Duration:** When medical necessity criteria are met in the absence of exclusionary criteria, referral to a cardiac electrophysiologist or trained cardiologist for the implant of an internal loop recorder (ILR) can be indicated. A single outpatient procedure is anticipated. The duration of the implant can be up to 4 years, depending on the device's battery life. Periodic recordings are actively or passively transmitted for interpretation by a physician.
- **Criteria for Subsequent Requests:** Subsequent requests are only accepted with documentation of device malfunction, an infection that required removal of the initial device, or incorrect placement resulting in poor sensing.
- **Recommended Clinical Approach:** Noninvasive ambulatory ECG monitoring is recommended in patients with symptoms suggestive of bradycardia due to sinus node dysfunction or arrest before this intervention, if possible. Poor diagnostic yield of noninvasive monitoring in the setting of continued symptoms may lead a physician to recommend an ILR for their patient.[11] This is particularly true for patients with unexplained syncope, which is often due to a bradyarrhythmic event.[10,12] This procedure is performed by a trained cardiologist or cardiac electrophysiologist, and referral to a center that supports this service is required.
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Internal Loop Recorder** is considered appropriate if **ALL** of the following is **TRUE**:

- ◆ The patient has **ANY** of the following findings:
  - Fatigue.
  - Dizziness.
  - Shortness of breath.

- Chest discomfort, syncope.
- Hemodynamic collapse.
- Vital signs showing low heart rate or blood pressure.
- A decline in blood pressure on standing.
- Cool or pale extremities.
- Generalized listless effect or signs of mental confusion.
- Irregular size or rate of jugular venous pulsations.
- Palpable liver enlargement.
- Bibasilar rales on lung auscultation.
- Physical findings suggestive of structural heart disease (e.g., heart murmurs, displaced PMI).

◆ No diagnostic conclusions have been achieved with noninvasive monitoring methods, such as an external loop recorder or mobile cardiac telemetry.[4,10]

◆ The patient has no other implantable cardiac devices which can detect, record, and transmit data to a physician/cardiologist.

Non-Indications

➔ **Internal Loop Recorder** is not considered appropriate if **ANY** of the following is **TRUE**:

◆ The patient does not have any positive clinical risk factors, presentation or history findings, or physical exam findings pertinent to remote ECG monitoring.

◆ The patient has a culprit arrhythmic diagnosis identified on noninvasive monitoring.

◆ The patient has an active infection or an irreversible bleeding disorder.

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
33285	Insertion and programming of subcutaneous cardiac rhythm monitor
33286	Removal of subcutaneous cardiac rhythm monitor

Service: External Wearable Devices

General Guidelines

- **Units, Frequency, & Duration:** When medical necessity is met based on described clinical criteria and exclusionary criteria are absent, noninvasive external cardiac monitoring may be conducted using external wearable devices for 24 hours to 30 days, depending on symptom frequency.
- **Criteria for Subsequent Requests:** Subsequent requests are appropriate for follow-up monitoring of a chronic or progressive cardiac rhythm abnormality. They may also be considered for device malfunction, high burden of poor quality data/artifact, or inability to record patient symptoms.
- **Recommended Clinical Approach:** With symptoms suggestive of bradycardia based on clinical history, physical exam, and 12-lead ECG, the most appropriate external wearable monitor should be selected based on patient symptom frequency and suspected duration of the episodes. Daily symptoms may be addressable with a 24-48 hour Holter monitor. However, in patients with syncope of uncertain origin, Holter monitoring only yielded a significant bradyarrhythmia in 11% of studies.[13] Less frequent or asymptomatic events are more likely to be captured with longer duration monitoring, either a 30-day loop recorder, cardiac mobile telemetry, or an extended-wear patch device. Consideration of patient ability to trigger a device effectively may also guide device selection in favor of those with more passive event recording capability.[4,13,14,15]
- **Exclusions:** Two types of monitors cannot be ordered simultaneously.

Medical Necessity Criteria

Indications

➔ **External Wearable Device** is considered appropriate if **ALL** of the following is **TRUE**[16,17]:

- ◆ The frequency of symptoms suspected to be due to sinus node dysfunction or circumstances that may provoke sinus node dysfunction should reasonably be expected to have a frequency of occurring within three weeks.
- ◆ For diagnostic surveillance of sinus node dysfunction.
- ◆ 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 Device** is not considered appropriate if **ANY** of the following is **TRUE**:
  - ◆ When bradycardia is associated with symptoms suggestive of angina or clinically significant coronary artery obstruction, and monitoring would delay other needed testing or intervention.[18]
  - ◆ The patient has an existing pacemaker or internal loop recorder capable of acquiring clinical data of a similar or equivalent quality to an external cardiac monitor.

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

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

Non-Invasive Testing

Service: Computed Tomography Angiography (CTA)/Computed Tomography with Contrast, Cardiac

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:** Cardiac CTA is useful in the setting of structural abnormalities and assessment of acquired or congenital anatomic factors which may impact management strategy, including factors that may influence the approach to implantation of a pacemaker or defibrillator. Angiography as an adjunct imaging protocol is also useful in understanding anatomic features, especially vascular anatomy.[19] However, cardiac CTA is not a sensitive imaging modality for assessing myocardial disease, often associated with sinus node dysfunction. In the case of myocarditis, fibrosis quantification related to hypertrophic cardiomyopathy, infiltrative disease, surgical scarring, or assessment of prior infarct, MRI/MRA is a much more valuable technique.[4]
- **Exclusions:** Cardiac CTA for evaluation for cardiac anatomic evaluations may not include other study protocols, e.g., calcium scoring (CAS) or CCTA, which may require a different diagnostic indication.

Medical Necessity Criteria

Indications

➔ **Cardiac CTA** is considered appropriate if **ALL** of the following is **TRUE**:
- ◆ As an imaging modality in a patient with sinus node dysfunction and suspected structural heart disease where other imaging modalities have not defined anatomical structures successfully.
- ◆ For pre-procedural evaluation of cardiac anatomy for appropriate planning of pacing system implantation.[4,19]

Non-Indications

➔ **Cardiac CTA** may not be considered appropriate if **ANY** of the following is **TRUE**[4,19]:
- ◆ When an MRI has recently been requested for the same indications.
- ◆ In a patient with non-rate controlled atrial fibrillation.

- The patient has impaired renal function because angiographic contrast is utilized for the study.
- In a patient with contrast dye hypersensitivity.
- The patient uses metformin.
- In pregnant patients.[20]

Site of Service Criteria

Outpatient.

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: Coronary Computed Tomography Angiography (CCTA)

General Guidelines

- **Units, Frequency, & Duration:** Single instance as guided by medical necessity criteria.
- **Criteria for Subsequent Requests:** For periodic surveillance of coronary artery lesions or new clinical indications.
- **Recommended Clinical Approach:** Coronary computed tomography angiography is a specific anatomic evaluation for coronary artery anatomy and quantification of coronary obstructive lesions. It is a test that has high sensitivity in the identification of plaques. It also has a high negative predictive value for screening patients at lower to moderate risk of CAD. This is a test that is increasingly performed for screening patients in the outpatient setting for CAD. It can be a complimentary evaluation with stress testing and can serve as an alternative diagnostic tool in equivocal or uninterpretable stress testing results. The use of noninvasive fractional flow reserve (FFR) following a positive CCTA may be considered medically necessary to guide decisions about the use of invasive coronary angiography in patients with intermediate to high-risk coronary lesions on imaging.[7,8,14]
  Exclusions: As sinus node dysfunction is not directly related to atherosclerotic disease (the sinus nodal artery is not prone to ischemia), CCTA is not a typical study in the workup of sinus node dysfunction.

Medical Necessity Criteria

Indications

➔ **CCTA** is considered appropriate if **ANY** of the following is **TRUE**:
- ◆ The patient is symptomatic for CAD with an intermediate to high pre-test probability.[5,42]
- ◆ For preoperative assessment for planned non-coronary cardiac surgeries, including valvular heart disease, congenital heart disease, and pericardial disease, in lieu of cardiac catheterization.
- ◆ For evaluation of coronary anatomy for coronary anomalies.

Non-Indications

➔ **CCTA** may not be considered appropriate if **ANY** of the following is **TRUE**:
- ◆ The patient has non-rate controlled atrial fibrillation.

- The patient has impaired renal function because angiographic contrast is utilized for the study.
- The patient has contrast dye hypersensitivity.
- The patient uses metformin.
- In pregnant patients.[20]
- Normal coronary angiogram or CCTA with no stenosis or plaque within the last two years.
- Normal stress test (given adequate stress) within the last year.

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
75574	Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed.

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 lesions on imaging.[7,21]
- **Exclusions:** As sinus node dysfunction is not directly related to atherosclerotic disease (the sinus nodal artery is not prone to ischemia), noninvasive fractional flow reserve (CT-FFR) is not a typical study in the workup of sinus node dysfunction.

Medical Necessity Criteria

Indications

➔ **FFR***** is considered appropriate if **ANY** of the following is **TRUE**:
- ◆ For functional evaluation of coronary CTA lesions which are 40-90% stenosed in a proximal to a middle coronary segment on CCTA.[7,22,23]
- ◆ For evaluation of multivessel disease to identify culprit lesions causing symptoms.
- ◆ For evaluation of multiple lesions in a single vessel to evaluate physiologic severity.[7,8,15]

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

Non-Indications

➔ **FFR** is not appropriate if **ANY** of the following conditions are **TRUE**[24]:
- ◆ 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.[7]
- ◆ Coronary anatomy that is low risk (less than 30% stenosis).
- ◆ In complex congenital heart disease.

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

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

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

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** Considerations of additional phase, dynamic sequences, positioning of the patient, and use of markers at the discretion of the protocoling radiologist.
- **Recommended Clinical Approach:** Cardiac MRI is useful in the setting of acquired or congenital structural abnormalities and assessment of anatomic factors which may impact the clinical course and prognosis of significant sinus node dysfunction. As an adjunct imaging protocol, angiography is also useful in understanding anatomic features that may impact the strategy for implantation of a pacemaker or defibrillator.[25] Cardiac MRI with late gadolinium enhancement is particularly useful for studying fibrosis within the myocardium, the extent of which can impact the cardiac conduction system. This is useful in patients with a past history of surgery in the atria, infiltrative diseases like sarcoidosis or hemochromatosis, lymphoma, or past infarction.[4]
- **Exclusions:** Exclusions include contraindications of MRI (e.g., retained metal, incompatible width to bore size, claustrophobia), incompatibility with following directions (i.e., breath-hold), and renal insufficiency (eGFR less than 30 mL/min per 1.73 m^2) if gadolinium is requested.

Medical Necessity Criteria

Indications

➔ **MRI/MRA** is considered appropriate if **ANY** of the following is **TRUE**[26,27]:
- ◆ As a second-line imaging modality in a patient with sinus node dysfunction and suspected structural heart disease where echocardiography cannot define anatomical structures fully.
- ◆ For pre-procedural evaluation of cardiac anatomy for appropriate planning of pacing system implantation.

Non-Indications

➔ **MRI/MRA** may not be considered appropriate if **ANY** of the following is **TRUE**[20]:
- ◆ Simultaneous or recent cardiac CT scan for the same indication.
- ◆ Non-compatible implanted devices.
- ◆ Metallic intraocular foreign bodies.
- ◆ There is a potential for adverse reactions to contrast media.

- Claustrophobia.
- If the patient has renal insufficiency (eGFR less than 30 mL/min per 1.73 m^2) and if gadolinium contrast is requested, an MRI/MRA may not be considered appropriate.

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

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

Service: Exercise ECG Stress

General Guidelines

- **Units, Frequency, & Duration:** Single instance when medical criteria are met.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** In select patients where symptoms suggest inadequate heart rate response during exercise (fatigue, shortness of breath, dizziness, syncope), ECG exercise testing can be helpful as a provocative test to determine if chronotropic incompetence is the cause of symptoms. If the possibility of CAD exists, routine exercise testing may expose this diagnosis as well. These tests should be performed per standard protocols for known exertional workloads.[4]
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Exercise ECG Stress** is considered appropriate if **ANY** of the following is **TRUE**[4]:

- ◆ The patient has exercise-related symptoms suspected to be due to chronotropic incompetence.
- ◆ Chronotropic incompetence has not been already demonstrated by other testing like Holter monitoring.

Non-Indications

➔ **Exercise ECG Stress** is not considered appropriate if **ANY** of the following is **TRUE**[4]:

- ◆ If the patient is unable to complete a stress test due to physical limitations.
- ◆ In a patient with sinus node dysfunction who has already met the criteria for pacing.

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition

93015	Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; with supervision, interpretation and report
93016	Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; supervision only, without interpretation and report
93017	Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; tracing only, without interpretation and report
93018	Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; interpretation and report only

Service: Stress Echocardiogram

General Guidelines

- **Units, Frequency, & Duration:** Single instance when medical criteria are met.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** An ECG stress test performed for evaluation of chronotropic incompetence can be accompanied by imaging when there are risk factors of reversible ischemia present. Patients with episodes of sinus bradycardia or sinus pauses with additional comorbidities like hypertension, diabetes, or hyperlipidemia are candidates for stress testing with imaging. A stress echocardiogram can be accomplished using either exercise or pharmacologic agents (predominantly dobutamine) as the stress mechanism.[28]
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Stress echo** is considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Patients who have symptoms and clinical history suggesting an intermediate or high pre-test likelihood of CAD.[5,29]
- ◆ Patients who have clinical suspicion for inducible conduction abnormalities related to ischemia.

Non-Indications

➔ **Stress echo** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Normal coronary angiogram or CCTA with no stenosis or plaque within the last two years.
- ◆ Normal stress test (given adequate stress) within the last year.
- ◆ The patient has 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.

Procedure Codes (HCPCS/CPT)

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

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

General Guidelines

- **Units, Frequency, & Duration:** Single instance when medical criteria are met.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** An ECG stress test that is being performed for evaluation of chronotropic incompetence can be accompanied by imaging when there are risk factors of reversible ischemia present. Patients with episodes of sinus bradycardia or sinus pauses with additional comorbidities like hypertension, diabetes, or hyperlipidemia are candidates for stress testing with imaging. An MPI-SPECT can be accomplished using either exercise or pharmacologic agents to simulate the effects of exercise.[30]
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **MPI-SPECT** is considered appropriate if **ALL** of the following are **TRUE**:
- ◆ The patient has symptoms and clinical history suggesting an intermediate or high pre-test likelihood of CAD.[5,29]
- ◆ The patient has clinical suspicion for inducible conduction abnormalities related to ischemia.

Non-Indications

➔ **MPI-SPECT** is not considered appropriate if **ANY** of the following is **TRUE**[31]:
- ◆ Normal coronary angiogram or CCTA with no stenosis or plaque within the last two years.
- ◆ Normal stress test (given adequate stress) within the last year.
- ◆ The patient has an active cardiac condition that has not been stabilized (e.g., uncontrolled hypertension, uncontrolled arrhythmias, undiagnosed chest pain).
- ◆ The patient has an active pulmonary condition that has not been stabilized (e.g., difficulty breathing, the possibility of pulmonary embolism).
- ◆ Vasodilators (i.e., adenosine, regadenoson, and dipyridamole) are contraindicated in patients with hypotension, sinus node dysfunction, high-degree atrioventricular (AV) block[22] (in the

absence of back up pacemaker capability), and reactive airway disease.

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
78451	Single-photon emission computed tomography (SPECT) myocardial perfusion imaging study with stress
78452	Multiple single-photon emission computed tomography (SPECT) myocardial perfusion imaging studies with stress
78453	Single planar myocardial perfusion imaging study at rest
78454	Multiple planar myocardial perfusion imaging studies with stress
78469	Planar and single photon emission computed tomography (SPECT) myocardial imaging
78481	Single planar cardiac blood pool imaging study by first pass technique with exercise and pharmacological stress, wall motion study plus ejection fraction, with quantification
78483	Multiple planar cardiac blood pool imaging studies by first pass technique with exercise and pharmacological stress, wall motion study plus ejection fraction

Service: Transthoracic Echocardiogram (TTE)

General Guidelines

- **Units, Frequency, & Duration:** Single procedures, performed as needed for defined criteria**.**
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** Bradycardia or conduction disorders can be present in a wide variety of cardiovascular and systemic diseases and can be one of the first signs of these conditions. As the prognosis and treatment of documented bradyarrhythmias are heavily influenced by underlying structural heart disease, assessment of cardiac structure and function is often clinically indicated. Transthoracic echocardiography is a safe and easily accessible imaging modality to gain insight into the etiology and implications of sinus node dysfunction.[4]
- **Exclusions:** None.

Medical Necessity Criteria

Indications

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

- ◆ Patients with sinus node dysfunction and clinical evidence of valvular, pericardial, or primary myocardial disease.[4]
- ◆ Patients with sinus node dysfunction who have a documented history or a suspicion of left ventricular dysfunction for follow-up evaluation after treatment.
- ◆ Patients with sinus node dysfunction and a history of a congenital heart lesion.
- ◆ Patients with sinus arrest or sinus pauses and an additional sign or symptom, including chest pain, shortness of breath, syncope, abnormal ECG, palpitations, TIA, stroke, or peripheral embolic event.

Non-Indications

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

- ◆ Echocardiography has no contraindications. Echocardiography may have limited benefit in patients at the extremes of adult body weight because a thick chest wall (in markedly obese patients) or overcrowded ribs (in severely underweight patients) may limit the penetration of ultrasound waves.[31,32]

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

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

Non-Surgical Management

Service: Cardiac Rehabilitation

General Guidelines

- **Units, Frequency, & Duration:** Cardiac rehabilitation is generally appropriate for 36 sessions, 60 minutes each, typically over 12 - 18 weeks. Additional sessions can be requested.[33]
- **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.[33,34] Referral to CR is recommended within 12 months after a myocardial infarction (MI), percutaneous coronary intervention, or coronary artery bypass graft surgery, or in the setting of stable angina or symptomatic peripheral arterial disease (i.e., intermittent claudication). Referral to CR is also recommended after heart valve surgery or cardiac transplantation, or in the setting of chronic heart failure (NYHA Class I-III) with reduced ejection fraction (HFrEF).[33] 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.[35-37] Medicare coverage may not be available for these diagnoses.
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Cardiac Rehabilitation** is considered appropriate if **ANY** of the following are **TRUE** (within a one year period):[36-38]

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

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

Non-Indications

➔ **Cardiac Rehabilitation** may not be considered appropriate if **ANY** of the following are present:[38]

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

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

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

Surgical or Interventional Management

Service: Electrophysiology Study (EPS)

General Guidelines

- **Units, Frequency, & Duration:** One instance, as indicated by clinical guidelines.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** There is no specific indication for performing electrophysiology testing to evaluate sinus node dysfunction. With a class IIb (weak level of evidence) recommendation by AHA/ACC/HRS consensus, there may be consideration of EPS when there is suspicion of conduction disease and noninvasive testing does not reveal any AV block.[4] While there are maneuvers during an electrophysiology study that can evaluate sinus node recovery, this is usually done as part of a comprehensive EPS for other arrhythmias. These arrhythmias can include atrial fibrillation or flutter, both of which can be associated with sinus node dysfunction in brady-tachy syndrome.
- **Exclusions:** Invasive evaluation of sinus node function is included in billing codes for most other comprehensive EP studies.

Medical Necessity Criteria

Indications

➔ **EPS** is considered appropriate if **ALL** of the following is **TRUE**:
- ◆ In a patient with symptoms of significant bradycardia.
- ◆ All noninvasive evaluations have been inconclusive, including extended ECG monitoring and stress testing, but a high suspicion of sinus node dysfunction remains. (Electrophysiologic evaluation of sinus node function is not typically done as a separate procedure without another appropriate indication. Sinus node function evaluations are usually incorporated into diagnostics performed in advance of other ablation procedures.)[4]

Non-Indications

➔ **EPS** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Symptomatic sinus bradycardia/arrest has been correlated with patient symptoms on other outpatient testing.

Site of Service Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
93600	Bundle of His recording
93602	Intra-atrial recording
93603	Right ventricular recording
93610	Intra-atrial pacing
93612	Intraventricular pacing
93618	Induction of arrhythmia by electrical pacing
93619	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, with right atrial pacing and recording, right ventricular pacing and recording, and His bundle recording
93620	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, with attempted induction of arrhythmia, with right atrial pacing and recording, right ventricular pacing and recording, and His bundle recording
93624	Electrophysiologic follow-up study with pacing and recording to test effectiveness of therapy with attempted induction of arrhythmia
93631	Intra-operative epicardial and endocardial pacing and mapping to localize the site of tachycardia or zone of slow conduction for surgical correction

Service: Cardiac Implantable Device

General Guidelines

- **Units, Frequency, & Duration:** One instance, as needed per inclusion criteria.
- **Criteria for Subsequent Requests:** Subsequent requests may be considered for device replacement due to battery end of life (EOL) or elective replacement interval (ERI), replacement after infection, the clinical need for different pacing modes, or replacement after manufacturer recall.
- **Recommended Clinical Approach:** Pacing may assist patients with sick sinus syndrome to relieve clinically symptomatic bradycardia, restore physiologic heart rate response, and control brady-tachy syndrome. Many antiarrhythmics used to control atrial fibrillation can exacerbate sick sinus syndrome, which may require pacing to prevent symptomatic bradycardia if no alternative treatments are feasible.[39-41] Single chamber atrial pacing can be adequate in patients who have intact AV nodal function and no evidence of bundle branch block. However, the rate of developing AV block in patients initially presenting with sinus node dysfunction ranges between 3%-35%. Depending on comorbidities and other findings on ECG monitoring, the implant of a ventricular lead may be prudent.[10,40,41] Adequate atrial pacing may reduce the frequency of atrial tachyarrhythmic events; however, pacemaker functions that attempt to actively treat episodes of atrial flutter have not shown consistent effectiveness.
- **Exclusions:** Sinus node dysfunction is an appropriate diagnosis for pacemaker requests; additional clinical information is needed for defibrillator implant requests.

Medical Necessity Criteria

Indications

➔ **Cardiac implantable device** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ The patient has sinus node dysfunction and symptoms that are directly or highly suspicious to be attributable to the arrhythmia.[4,39-41]
- ◆ The patient has symptomatic sinus node dysfunction where the rhythm is caused by standard of care treatments (e.g., pharmacologic treatments) where there is no alternative management or alternative management strategies have been exhausted.

- The patient has chronotropic incompetence due to bradycardia.
- In a patient with brady-tachy syndrome for symptom improvement.[39-41]

Non-Indications

➔ **Cardiac implantable device** is not considered appropriate if **ANY** of the following is **TRUE**:

- The patient has asymptomatic sinus bradycardia or sinus pauses due to physiologically elevated parasympathetic (vagal) tone.
- In sleep-related sinus bradycardia or sinus pauses.
- Syncope of undetermined etiology.

Site of Service Criteria

Outpatient or Observation.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
33206	Insertion of permanent atrial pacemaker with transvenous electrode
33207	Insertion of permanent ventricular pacemaker with transvenous electrode
33208	Insertion of permanent atrial and ventricular pacemaker with transvenous electrode
33212	Insertion of pacemaker pulse generator with connection to existing single lead
33213	Insertion of pacemaker pulse generator with connection to existing dual leads
33214	Conversion of single chamber implanted pacemaker system to dual chamber system
33216	Insertion of transvenous electrode of permanent pacemaker
33217	Insertion of 2 transvenous electrodes of permanent cardioverter-defibrillator
33221	Insertion of pacemaker pulse generator with existing multiple leads
33224	Transvenous insertion of pacing electrode for left ventricular pacing, with connection to existing pacemaker
33227	Removal and replacement of permanent pacemaker pulse

	generator in single lead system
33228	Removal and replacement of permanent pacemaker pulse generator in dual lead system
33229	Removal and replacement of permanent pacemaker pulse generator in multiple lead system
33233	Removal of permanent pacemaker pulse generator
33274	Transcatheter insertion of permanent leadless right ventricular pacemaker
C1779	Lead, pmkr, transvenous vdd
C1785	Pmkr, dual, rate-resp
C1786	Pmkr, single, rate-resp
C1898	Lead, pmkr, other than trans
C1899	Lead, pmkr/aicd combination
C1900	Lead, coronary venous
C2619	Pmkr, dual, non rate-resp
C2620	Pmkr, single, non rate-resp
C2621	Pmkr, other than sing/dual

Surgical Risk Factors

Patient Medical Risk Stratification

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

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Review History	
February 4, 2022 (V.1)	**Physician author:** Alisa Niksch, MD (Pediatric Cardiologist/ Electrophysiologist), Mary Krebs, MD (Primary Care Physician) **Peer reviewed by:** Carter Newton, MD FACC (Cardiologist), Russell Rotondo, MD FACC (Cardiologist) **Approving Physician:** Russell Rotondo, MD FACC (Cardiologist)
October 25, 2022 (V.2)	**Peer reviewed by:** Ania Garlitski, MD (Cardiologist) **Approving Physician:** Russell Rotondo, MD FACC (Cardiologist)