MASSACHUSETTS

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Medical Policy

Myocardial Sympathetic Innervation Imaging in Patients with Heart Failure

Table of Contents

Policy Number: 576

BCBSA Reference Number: 6.01.56
NCD/LCD: NA

Related Policies

- Homocysteine Testing in the Screening, Diagnosis, and Management of Cardiovascular Disease and Venous Thromboembolic Disease, #016
- Measurement of Lipoprotein-Associated Phospholipase A2 - Lp-PLA2 - in the Assessment of Cardiovascular Risk, #558

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Myocardial sympathetic innervation imaging with ^{123}Iodine meta-iodobenzylguanidine (MIBG) is **INVESTIGATIONAL** for patients with heart failure.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is **not** a covered service.
Commercial PPO and Indemnity	This is **not** a covered service.
Medicare HMO Blue℠	This is **not** a covered service.
Medicare PPO Blue℠	This is **not** a covered service.

CPT Codes / HCPCS Codes / ICD-9 Codes

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

CPT codes:	Code Description
0331T	Myocardial sympathetic innervations imaging, planar qualitative and quantitative assessment;
0332T	Myocardial sympathetic innervations imaging, planar qualitative and quantitative assessment; with tomographic SPECT

HCPCS Codes

HCPCS codes:	Code Description
A9582	Iodine I-123 iobenguane, diagnostic, per study dose, up to 15 millicuries

Diagnosis Codes

Investigational for all diagnoses.

DESCRIPTION

Heart Failure

An estimated 5.7 million adults in the U. S. have heart failure, which is the main cause of death for approximately 58300 Americans each year.[1,] Underlying causes of heart failure include coronary artery disease, hypertension, valvular disorders, and primary cardiomyopathies. These conditions reduce myocardial pump function and decrease left ventricular ejection fraction. An early mechanism to compensate for this decreased myocardial function is activation of the sympathetic nervous system. The increased sympathetic activity initially helps compensate for heart failure by increasing heart rate and myocardial contractility to maintain blood pressure and organ perfusion. However, over time, this places additional strain on the myocardium, increasing coronary perfusion requirements, which can lead to worsening of ischemic heart disease and or myocardial damage. As the ability of the heart to compensate for reduced myocardial function diminishes, clinical symptoms of heart failure develop. Another detrimental effect of heightened sympathetic activity is an increased susceptibility to potentially fatal ventricular arrhythmias.

Overactive sympathetic innervation associated with heart failure involves increased neuronal release of norepinephrine (NE), the main neurotransmitter of the cardiac sympathetic nervous system. In response to sympathetic stimulation, vesicles containing NE are released into the neuronal synaptic cleft. The released NE binds to postsynaptic β_1, β_2, and αreceptors enhance adenyl cyclase activity and bring about the desired cardiac stimulatory effects. NE is then taken back into the presynaptic space for storage or catabolic disposal that terminates the synaptic response by the uptake-1 pathway. The increased release of NE is usually accompanied by decreased NE reuptake, thereby further increasing circulating NE levels.
Diagnostic Imaging

Guanethidine is a false neurotransmitter that is an analogue of NE; it is also taken up by the uptake-1 pathway. Iodine 123 meta-iodobenzylguanidine (^{123}I-MIBG or MIBG) is chemically modified guanethidine labeled with radioactive iodine. MIBG moves into the synaptic cleft and then is taken up and stored in the presynaptic nerve space in a manner similar to NE. However, unlike NE, MIBG is not catabolized and thus concentrates in myocardial sympathetic nerve endings. This concentrated MIBG can be imaged with

a conventional gamma camera.[2,] The concentration of MIBG over several hours after injection is thus a reflection of sympathetic neuronal activity, which in turn may correlate with the severity of heart failure. MIBG myocardial imaging has been in use in Europe and Japan, and standardized procedures for imaging have been proposed by European organizations.[3,] Administration of MIBG is recommended by slow (1-2 minutes) injection. Planar images of the thorax are acquired 15 minutes (early image) and 4 hours (late image) after injection. In addition, optional single-photon emission computed tomography can be performed following the early and late planar images. MIBG uptake is semiquantified by determining the average count per pixel in regions of interest drawn over the heart and the upper mediastinum in the planar anterior view. There is no single universally used myocardial MIBG index. The most commonly used myocardial MIBG indices are the early heart to mediastinum (H/M) ratio, late H/M ratio, and the myocardial MIBG washout rate. The H/M ratio is calculated by taking the average count per pixel in the myocardium divided by the average count per pixel in the mediastinum. The myocardial washout rate is expressed as the rate of decrease in myocardial counts over time between early and late imaging (normalized to mediastinal activity).

MIBG activity is proposed as a prognostic marker in patients with heart failure, to be used in conjunction with established markers or prognostic models to identify heart failure patients at increased risk of short-term mortality. MIBG activity could also be used to guide treatment decisions or to monitor the effectiveness of heart failure treatments.

Summary

In patients with heart failure, activation of the sympathetic nervous system is an early response to compensate for decreased myocardial function. The concentration of iodine 123 meta-iodobenzylguanidine (MIBG) over several hours after the injection of the agent is a potential marker of sympathetic neuronal activity. MIBG activity is proposed as a prognostic marker in patients with heart failure to aid in the identification of patients at risk of 1- and 2-year mortality. The marker could also be used to guide treatment decisions or to monitor the effectiveness of heart failure treatments.

For individuals with heart failure who receive imaging with MIBG for prognosis, the evidence includes numerous studies that MIBG cardiac imaging findings predict outcomes in patients with heart failure. The relevant outcomes are overall survival, disease-specific survival, functional outcomes, health status measures, quality of life, hospitalizations, and medication use. While the available studies vary in their patient inclusion criteria and methods for analyzing MIBG parameters, the highest quality studies have demonstrated a significant association between MIBG imaging results and adverse cardiac events, including cardiac death. Moreover, MIBG findings have been shown to improve the ability of the Seattle Heart Failure Model and other risk models to predict mortality. However, there is no direct published evidence on the clinical utility of MIBG (ie, whether findings of the test would lead to patient management changes that improve health outcomes) and no chain of evidence can be constructed to support clinical utility. Management changes made as a result of MIBG imaging are uncertain, and it is not possible to determine whether management changes based on MIBG results lead to improved health outcomes compared with management without MIBG imaging. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
10/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
10/2018	BCBSA National medical policy review. Description, summary and references updated. Policy statement unchanged.
10/2017	New references added from BCBSA National medical policy.
10/2016	New references added from BCBSA National medical policy.
8/2015	New references added from BCBSA National medical policy.
9/2014	New references added from BCBSA National medical policy.
12/2013	New medical policy describing investigational indications. Effective 12/1/2013.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

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