BlueCross BlueShield Federal Employee Program.

# FEP Medical Policy Manual

## FEP 6.01.56 Myocardial Sympathetic Innervation Imaging in Patients With Heart Failure

### Annual Effective Policy Date: January 1, 2024

### Original Policy Date: January 2020

### Related Policies:

None

# Myocardial Sympathetic Innervation Imaging in Patients With Heart Failure

## Description

## Description

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. Iodine 123 meta-iodobenzylguanidine 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.

## OBJECTIVE

The objective of this evidence review is to determine whether prognostic imaging with iodine 123 meta-iodobenzylguanidine improves the net health outcome in individuals with heart failure.

# POLICY STATEMENT

Myocardial sympathetic innervation imaging with iodine 123 meta-iodobenzylguanidine is considered **not medically necessary** for individuals with heart failure.

# POLICY GUIDELINES

None.

# BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

# FDA REGULATORY STATUS

In 2008, AdreView (Iobenguane I 123) Injection (GE Healthcare) was approved via the U.S. Food and Drug Administration (FDA) new drug application process (22-290) for the detection of primary or metastatic pheochromocytoma or neuroblastoma as an adjunct to other diagnostic tests.[5,]

The FDA (2013) approved a supplemental new drug application (22-290/S-001) for AdreView and expanded the labeled indication to include scintigraphic assessment of sympathetic innervation of the myocardium by measurement of the H/M ratio of radioactivity uptake in patients with New York Heart Association (NYHA) class II or class III heart failure and LVEF less than 35%.[6,]

# RATIONALE

## Summary of Evidence

For individuals with heart failure who receive imaging with iodine 123 meta-iodobenzylguanidine (MIBG) for prognosis, the evidence includes numerous studies that MIBG cardiac imaging findings predict outcomes in patients with heart failure. 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 (SHFM) 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 that the technology results in an improvement in the net health outcome.

# SUPPLEMENTAL INFORMATION

## Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute (2011) published a report on the translation of cardiovascular molecular imaging.[25,] In regard to heart imaging with meta-iodobenzylguanidine (MIBG), the report cited the ADMIRE-HF trial,[10,] and stated that additional clinical trials would be needed to determine the efficacy of heart failure management strategies using MIBG compared with usual care without MIBG imaging.

### American Heart Association et al

The American Heart Association, American College of Cardiology, and Heart Failure Society of America published joint guidelines on the management of heart failure in 2022.[26,]These guidelines did not address the use of MIBG imaging in heart failure management.

## U.S. Preventive Services Task Force Recommendations

Not applicable.

## Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

# REFERENCES


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## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

| Date | Action | Description |
|---|---|---|
| December 2019 | New policy | New policy with literature review through July 8, 2019. Policy statement: Myocardial sympathetic innervation imaging with iodine 123 meta-iodobenzylguanidine is considered not medically necessary for patients with heart failure. |
| December 2020 | Replace policy | Policy updated with literature review through July 8, 2020; no references added. Policy statement unchanged. |
| December 2021 | Replace policy | Policy updated with literature review through August 2, 2021; no references added. Policy statement unchanged. |
| December 2022 | Replace policy | Policy updated with literature review through July 14, 2022; references added. Minor refinement to policy statement, intent unchanged. |
| December 2023 | Replace policy | Policy updated with literature review through August 7, 2023; no references added. Policy statement unchanged. |