FEP Medical Policy Manual

FEP 6.01.56 Myocardial Sympathetic Innervation Imaging in Patients With Heart Failure

Effective Policy Date: January 1, 2020

Original Policy Date: January 2020

Related Policies: None

Myocardial Sympathetic Innervation Imaging in Patients With Heart Failure

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. 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.

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.

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POLICY STATEMENT

Myocardial sympathetic innervation imaging with iodine 123 meta-iodobenzylguanidine is considered not medically necessary for patients 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 by the Food and Drug Administration new drug application process (22-290) for the detection of primary or metastatic pheochromocytoma or neuroblastoma as an adjunct to other diagnostic tests.4

The Food and Drug Administration (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 class II or class III heart failure and left ventricular ejection fraction less than 35%.5

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. 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 (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 the effects of the technology on health outcomes.

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SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute (2011) published a report on the translation of cardiovascular molecular imaging. In regard to heart imaging with meta-iodobenzylguanidine (MIBG), the report cited the AdreView Myocardial Imaging for Risk Evaluation in Heart Failure trial 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 College of Cardiology Foundation et al

The American College of Cardiology Foundation and the American Heart Association (2017) updated its 2013 joint guidelines on the management of heart failure with the Heart Failure Association of America. 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:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>December 2019</td>
<td>New policy</td>
<td>New policy with literature review through July 8, 2019. Policy statement: Myocardial sympathetic innervation imaging with iodine 123 meta-iodobenzylguanidine is considered <em>not medically necessary</em> for patients with heart failure.</td>
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