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Medicare Advantage Policy Manual

Myocardial Strain Imaging

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCGTM criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

Myocardial strain refers to the deformation (shortening, lengthening, or thickening) of the myocardium through the cardiac cycle.

MEDICARE ADVANTAGE POLICY CRITERIA

Note: Only myocardial strain imaging is addressed by this Medicare Advantage medical policy. Echocardiograms (codes 93303-93304, 93306, 93307, 93308, 93350-93351 and 93356) reported with a myocardial strain imaging component are considered medically reasonable and necessary for Medicare Advantage, but the myocardial strain imaging component (add-on code 93356) is subject to the criteria noted below and denies as a non-reimbursable service (NRS) for Medicare Advantage.

CMS Coverage Manuals*	None

None
None
Medicare coverage guidance is not available for myocardial strain imaging. Therefore, the health plan's medical policy is applicable. Myocardial Strain Imaging, Medicine, Policy No. 168 (see

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an *objective, evidence-based process, based on authoritative evidence*. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REGULATORY STATUS

A number of image analysis systems have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Examples of these are shown in the table below.

Brand Name	Manufacturer	Clearance Date
Myostrain	Myocardial Solutions	02/14/2019
2D CARDIAC PERFORMANCE ANALYSIS	Tomtec	04/13/2012
Echolnsight	Epsilon Imaging	05/27/2011
Q-lab	Phillips	12/23/2002
Vivid	GE	10/25/2018
Aplio	Toshiba	01/11/2018

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety

and effectiveness, Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

<u>Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149</u>

REFERENCES

None

CODING		
Codes	Number	Description
CPT	93356	Myocardial strain imaging using speckle tracking-derived assessment of myocardial mechanics (List separately in addition to codes for echocardiography imaging)
HCPCS	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

*IMPORTANT NOTE: Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.