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Medicare Advantage Policy Manual **Policy ID:** M-SUR208

Intracardiac Ischemia Monitoring

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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 MCG™ 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

Intracardiac ischemia monitoring acts as a warning system, using electrogram devices to record cardiac data and detect ischemic events in patients who have had prior acute coronary syndrome (ACS) events and who remain at high risk for recurrent ACS events. It emits a vibrational alarm when impending acute ischemic events are detected prior to symptom onset and is intended to provide an early warning of ischemic events and to minimize the time between ischemic event onset and medical care.

MEDICARE ADVANTAGE POLICY CRITERIA

Note: This policy does not address the use of implantable cardioverter defibrillators (ICDs) with an ST-segment monitoring feature, also called ICD-based ischemia monitors (see Cross References section).

CMS Coverage Manuals*	None

National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	None
Medical Policy Manual	*Medicare coverage guidance is not available for intracardiac ischemia monitoring. Therefore, the health plan's medical policy is applicable.* Intracardiac Ischemia Monitoring, Surgery, Policy No. 208 *(see "NOTE" below)*

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

The AngelMed Guardian® System (Angel Medical Systems, Inc.) received premarket approval (PMA) from the U.S. Food and Drug Administration (FDA) in April 2018, for use in patients who have had prior acute coronary syndrome (ACS) events and who remain at high risk for recurrent ACS events.[1] According to the FDA website, "Product requiring PMAs are Class III devices are high risk devices that pose a significant risk of illness or injury, or devices found not substantially equivalent to Class I and II predicate through the 510(k) process. The PMA process is more involved and includes the submission of clinical data to support claims made for the device."[2] *PMA: P150009*

The only FDA approved implantable intracardiac ischemia monitor is the AngelMed Guardian System.

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, CMS 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

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

Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting, Medicine, Policy No. M-33

Leadless Pacemakers, Surgery, Policy No. M-217

REFERENCES

1. U.S. Food and Drug Administration (FDA). AngelMed Guardian® System Approval Letter. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150009A.pdf
2. U.S. FDA. Overview of Device Regulation. Available at: https://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/default.htm
3. U.S. FDA. Circulatory System Devices Panel. AngelMed Guardian® System for the Alerting of Patients to ST Segment Changes Indicative of Coronary Artery Occlusion. PMA P150009S. March 16, 2016. Available at: http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/medicaldevices/medicaldevicesadvisorycommittee/circulatorysystemdevicespanel/ucm490461.pdf.

CODING

Codes	Number	Description
CPT	0525T	Insertion or replacement of intra-cardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; complete system (electrode and implantable monitor)
	0526T	; electrode only
	0527T	; implantable monitor only
	0528T	Programming device evaluation (in person) of intra-cardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report
	0529T	Interrogation device evaluation (in person) of intra-cardiac ischemia monitoring system with analysis, review, and report
	0530T	Removal of intra-cardiac ischemia monitoring system, including all imaging supervision and interpretation; complete system (electrode and implantable monitor)
	0531T	; electrode only
	0532T	; implantable monitor only
HCPCS	C1833	Monitor, cardiac, including intracardiac lead and all system components (implantable)

***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.*