Intracardiac Ischemia Monitoring

Effective: November 1, 2024

Next Review: September 2025
Last Review: September 2024

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IMPORTANT REMINDER

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Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Implantable cardiac monitors utilize 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. The devices are intended to provide an early warning of ischemic events and to minimize the time between ischemic event onset and medical care.

MEDICAL POLICY CRITERIA

Notes: 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).

Intracardiac ischemia monitoring with an implantable device, including but not limited to the AngelMed Guardian System®, is considered **investigational** for any indication, including but not limited to detection of acute myocardial ischemic events.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. <u>Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting</u>, Medicine, Policy No 33

BACKGROUND

Acute coronary syndrome (ACS) is a broad term for conditions where blood flow to the heart is compromised, a condition also known as myocardial or cardiac ischemia. Common examples include heart attack and unstable angina (sudden chest pain typically occurring at rest). Patients generally present to the emergency department following symptoms such as ischemic pain, shortness of breath, nausea, and dizziness. The timing of treatment initiation is critical, as research has shown improved myocardial salvage is associated with treatments that restore blood flow (reperfusion) before the two-hour post-event time point. Additionally, time to reperfusion is an independent predictor of early death from ST-elevation myocardial infarction.[1, 2]

The use of implantable cardiac monitors has been proposed to reduce the time between ischemic incident onset and medical care in individuals with a history of ACS who remain at high risk for recurrent ACS events. Implantable cardiac monitors use implantable electrogram devices to record cardiac data and detect ischemic events. They are intended to provide an early warning of ischemic events, which are otherwise detected by patient symptoms, and to reduce the time between the ischemic event onset and medical care.

The only FDA approved implantable intracardiac ischemia monitor is the AngelMed Guardian System®. This system consists of three main components. An implantable medical device (IMD) is implanted in the left pectoral subcutaneous pocket similar to a permanent pacemaker and connects to a lead placed in the right ventricular apex. The IMD communicates via wireless telemetry with an external device, which provides additional alerts when an event is detected, and a portable computer, which is used to configure the IMD and retrieve and store data collected by the IMD. The device monitors the ST-segment of the intracardiac electrogram signal and computes the ST-segment shift of each beat by comparing with the average baseline ST-segment levels measured over the prior 24 hours.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) has approved the AngelMed Guardian System® (Angel Medical Systems, Inc.) under the Premarket Approval Application (PMA) process (#P150009) for use in patients who have had prior acute coronary syndrome (ACS) events and who remain at high risk for recurrent ACS events. The AngelMed Guardian System® consists of the following components:

1. Implantable Medical Device (IMD)
2. External Device (EXD)
3. A Programmer

EVIDENCE SUMMARY

The primary beneficial outcomes of interest are increased emergency department (ED) visits following ACS events, reduced visits based on false alarms, and reduced death from cardiac events. Evaluating the safety and effectiveness of implantable cardiac monitors requires

randomized comparisons with standard care. These comparisons are necessary to determine whether the benefits of implantable cardiac monitors outweigh any risks and whether they offer advantages over conventional methods with respect to increasing quality of life and decreasing long-term morbidity and mortality.

Randomized Controlled Trials

A randomized controlled trial (RCT) of the AngelMed Guardian System®, the ALERTS Clinical Study, was used to support FDA approval of the AngelMed Guardian System®.[3] The results of this study are described in Gibson (2019).[4] In this trial, 907 high-risk ACS patients were randomized to the control arm, with alarms deactivated, or the active alarm group. After six months, alarms were activated in all subjects. The mean duration of follow-up was 3.05 years. The primary safety endpoint, greater than 90% absence of system-related complications, was met (96.7%). The primary efficacy endpoint was a composite endpoint consisting of cardiac or unexplained death, new Q-wave myocardial infarction (MI), or detection-to-presentation time of greater than two hours for a documented coronary occlusion event. There was no difference in the primary efficacy endpoint between groups using the pre-specified seven-day look-back period. Increasing the look-back window to 90 days resulted in a difference in detection-to-presentation time between groups (51 min for the treatment group vs. 30.6 days for the control group). Differences between the groups for new Q-wave MI were not statistically significant using any of the pre-specified look-back windows. Overall, including data from the subjects in the control arm who had alarms activated after six months, the false positive rate for all emergency visits during the alarms on period was 0.499 per patient year, which is a 26% reduction compared to alarms off.

Nonrandomized Studies

In 2010, Fischell published a small study of intracardiac ST-segment monitoring in patients at risk for acute coronary syndromes.[5] Data were collected from two phase 1 clinical studies, with 20 and 17 patients per study. Each patient was implanted with the AngelMed Guardian® implantable ischemia detection system. The devices were programmed for an ischemia detection threshold using a data from initial period of up to two weeks. Patients were trained to distinguish between the "Emergency" and "See Doctor" alarms. Follow-up occurred at one, three, and six months, with subsequent follow-up visits at six-month intervals. Three types of alarm triggers were reported: alarms triggered by persistent excessive ST-shift% detected during or after an elevated heart-rate (type 1 events), false-positive alarms for which no verifiable ischemic condition was identified (type 2 events), and alarms triggered by excessive ST-shifts detected at normal heart rates with no associated elevated heart rate consistent with coronary thrombosis (type 3 events). Median follow-up was 1.53 years (range 126 – 974 years). One device replacement occurred due to a failure of the vibration alarm motor. Four patients experienced type 1 events, three experienced type 2 events, and four experienced type 3 events. The four patients in this final group experienced a total of seven type 3, true positive Emergency alarm events. Median alarm-to-door time for type 3 events was 19.5 minutes. Authors concluded that this study demonstrates the safety and feasibility of intracardiac ST-segment monitoring.

PRACTICE GUIDELINE SUMMARY

There are no evidence-based clinical practice guidelines that recommend the use of intracardiac ischemia monitoring.

SUMMARY

There is not enough research to show that intracardiac ischemia monitoring improves health outcomes for people with prior acute coronary syndrome (ACS) events or any other condition. No clinical practice guidelines based on research recommend intracardiac ischemia monitoring. Therefore, intracardiac ischemia monitoring is considered investigational for all indications, including but not limited to use in patients with a history of ACS events.

REFERENCES

1. Milavetz JJ, Giebel DW, Christian TF, et al. Time to therapy and salvage in myocardial infarction. *Journal of the American College of Cardiology.* 1998;31(6):1246-51. PMID: 9581715
2. O'Gara PT, Kushner FG, Ascheim DD, et al. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation.* 2013;127(4):e362-425. PMID: 23247304
3. Food and Drug Administration, Premarket Approval Letter for the AngelMed Guardian System. [cited 9/19/2024]. 'Available from:' https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150009B.pdf.
4. Gibson CM, Holmes D, Mikdadi G, et al. Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. *Journal of the American College of Cardiology.* 2019;73(15):1919-27. PMID: 30842028
5. Fischell TA, Fischell DR, Avezum A, et al. Initial clinical results using intracardiac electrogram monitoring to detect and alert patients during coronary plaque rupture and ischemia. *Journal of the American College of Cardiology.* 2010;56(14):1089-98. PMID: 20863952

CODES

Codes	Number	Description
CPT	0525T	Insertion or replacement of intracardiac 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 intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report
	0529T	Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report
	0530T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; complete system (electrode and implantable monitor)
	0531T	;electrode only
	0532T	;implantable monitor only
	33999	Unlisted procedure, cardiac surgery

Codes	Number	Description
	93799	Unlisted cardiovascular service or procedure
HCPCS	C1833	Monitor, cardiac, including intracardiac lead and all system components (implantable)

Date of Origin: September 2018