

02.02.20 Intracardiac Ischemia Monitoring

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This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

Related Policies

None

Summary

Description

Intracardiac ischemia monitoring utilizes an implantable electrogram device that records cardiac data and detects ischemic events using a standard pacemaker intracardiac lead positioned in the right ventricular apex. This implantable warning system emits a vibrational alarm when impending acute ischemic events are detected prior to symptom onset. The device is currently intended only for use in individuals considered high risk for ischemic cardiac events, such as those with previous acute coronary events, diabetes, or renal insufficiency. The device is proposed to reduce the time from ischemic event onset to presentation in an emergency room with clinical benefits related to faster emergent care.

Summary of Evidence

For individuals considered high risk for ischemic cardiac events who receive intracardiac ischemia monitoring, the evidence includes one randomized controlled trial (ALERTS) evaluating the AngelMed Guardian System. Relevant outcomes include disease-specific survival, morbid events, functional outcomes, and quality of life. The ALERTS trial failed to meet the primary composite endpoint of cardiac or unexplained death, new Q-wave MI, or detection-to-presentation time >2 h for a documented coronary occlusion event. As a result, uncertainty remains regarding the effect of intracardiac ischemia monitoring on clinically meaningful health outcomes. Additional studies are needed to establish whether use of this technology results in improvements in patient-centered outcomes, including mortality, myocardial infarction, heart failure, functional status, and quality of life. The evidence is insufficient to determine that the technology results in an improvement in net health outcomes.

Additional Information

None

OBJECTIVE

The objective of this evidence review is to determine whether the use of intracardiac ischemia monitoring improves the net health outcome in individuals considered high risk for ischemic cardiac events.

PRIOR APPROVAL

Not applicable.

POLICY

Intracardiac ischemia monitoring (i.e., AngelMed® Guardian System) is considered **investigational** for all indications including but not limited to the detection of acute myocardial ischemic events because the evidence is insufficient to determine the technology results in an improvement in net health outcomes.

POLICY GUIDELINES

Definitions

Ischemia: A decrease in the blood supply to a bodily organ, tissue, or part caused by constriction or obstruction of the blood vessels.

ST Elevation MI (STEMI): Refers to the characteristic changes read on an EKG where a segment of the EKG tracing is elevated (ST segment) which corresponds with ventricular systolic depolarization. A STEMI indicates the location of damage to the myocardium which, in the case of myocardial infarction (MI), indicates that an evolving MI is either occurring or has already occurred.

Coding

See the [Codes table](#) for details.

BACKGROUND

In 2025, the American Heart Association (AHA) published their "[At-a-Glance](#)" fact sheet compiled annually by the AHA, the National Institutes of Health, and other collaborators. The fact sheet reported, "according to data from 2005 to 2014, the estimated annual incidence of heart attack in the United States was 605,000 new attacks and 200,000 recurrent attacks. Average age at the first heart attack was 65.6 years

for XY individuals and 72.0 years for XX individuals.” “In 2022, stroke accounted for approximately 1 of every 20 deaths in the United States.”

Early identification of acute myocardial infarction (AMI) and prompt treatment has been shown to significantly improve clinical outcomes. Clinical studies have shown that most of the irreversible damage to the myocardium occurs during the first 2 hours after coronary occlusion.

The mean time from AMI symptom onset to arrival at a hospital for treatment has been estimated to be 2.5-3.0 hours. Restoration of coronary blood flow, regardless of the method used, can abort infarction within the first 30 minutes after coronary occlusion. Investigators have noted the benefit of fibrinolytic therapy, compared with placebo, as considerably higher in individuals treated within 2 hours after symptom onset compared to those treated later. Evidence exists that expeditious restoration of blood flow in the obstructed artery after the onset of symptoms in individuals with the most severe type of AMI, the ST elevation MI (STEMI), is a key determinant of short- and long-term outcomes.

AngelMed® Guardian System

The AngelMed® Guardian System (Avertix, Inc., Eatontown, NJ) is proposed to reduce the time from ischemic event onset to presentation in an emergency room with proposed potential clinical benefits related to faster emergent care.

The AngelMed® Guardian System is an intracardiac ST-segment electrogram device currently being manufactured as an implantable ischemia monitor. The Guardian detects acute ischemic events by analyzing ST-segment shifts which are typically identified by electrocardiography (ECG) in the emergency room setting after the onset of symptoms, such as chest pain, shortness of breath, nausea, diaphoresis (sweating), etc. A Guardian System alert is a more accurate predictor of ACS events when compared to patient recognized symptoms alone and demonstrates a reduced rate over time of patient presentations without ACS events (false positives) when compared to patient recognized symptoms alone.

The ST-segment shifts are calculated by the device as the difference between the ST deviation of a current 10-second electrogram window and a baseline ST deviation value. If the ST-segment shift is greater than a heart rate-dependent programmable threshold, then the device generates an emergency alert signal. Device components include a programmable implantable monitoring device (IMD), right ventricle lead, lead adapter, external alarm device (EXD) and a programmer.

In the absence of symptoms, the Guardian System may identify asymptomatic ACS events and prompt the individual to seek medical attention.

Regulatory Status

In 2018, the United States FDA approved the AngelMed Guardian System. The AngelMed Guardian System is an implantable cardiac monitor with patient alerting capability and an additional external alarm device. The Guardian System is indicated for use in individuals who have had prior acute coronary syndrome (ACS) events and who remain at high risk for recurrent ACS events.

On March 16, 2016, the FDA Circulatory System Devices Panel issued a Premarket Approval (PMA) final report with 6-month results of the ALERTS trial, at the end of the randomized period of the study, there were 52 confirmed occlusive events (34 events in 27 subjects in the treatment group, and 18 events in 17 subjects in the control group) that had positive tests by cardiac enzymes, ECG, angiography, stress test, or multiple tests. The PMA report concluded that the results of the ALERTS study demonstrated the Guardian's ability to reduce the time from onset of a coronary occlusion to presentation at a medical facility for treatment. According to the FDA, the PMA final report the request for FDA clearance was

rejected, based on multiple study limitations that were identified, including the quality of the ECG data and the inconsistency of the Q-wave results which caused the sponsor to terminate the study earlier than the protocol required (FDA, 2016; Rogers, 2016). However, an amended protocol of trial data analysis from the ALERTS trial was resubmitted to the FDA and was the basis for FDA approval of the AngelMed Guardian System on April 9, 2018. According to the FDA, this approval was based, in part, on this additional retrospective post-hoc analysis. In 2019 final results of the ALERTS trial were published which noted the implantable cardiac system detects early ST-segment deviation and alerts patients of a potential occlusive event. Although the trial did not meet its pre-specified primary efficacy endpoint, results suggest that the device may be beneficial among high-risk subjects in potentially identifying asymptomatic events (Gibson, 2019; Holmes, 2019).

Product code: QBI

RATIONALE

This evidence review was created in January 2016 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through July 2026.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Intracardiac Ischemia Monitoring AngelMed Guardian System

Clinical Context and Therapy Purpose

The purpose of intracardiac ischemia monitoring in individuals considered high risk for ischemic cardiac events is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals considered high risk for ischemic cardiac events.

Interventions

The therapy being considered is intracardiac ischemia monitoring (AngelMed® Guardian System).

The Guardian detects acute ischemic events by analyzing ST-segment shifts which are typically identified by electrocardiography (ECG) in the emergency room setting after the onset of symptoms, such as chest pain, shortness of breath, nausea, diaphoresis (sweating), etc. The ST-segment shifts are calculated by the device as the difference between the ST deviation of a current 10-second electrogram window and a baseline ST deviation value. If the ST-segment shift is greater than a heart rate-dependent programmable threshold, then the device generates an emergency alert signal. Device components include a programmable implantable monitoring device (IMD), right ventricle lead, lead adapter, external alarm device (EXD) and a programmer. The proposed purpose of the device is to reduce the time from ischemic event onset to presentation in an emergency room with proposed potential clinical benefits related to faster emergent care.

Comparators

Comparators of interest are standard of care measures. Management of patients at risk for ACS relies primarily on the individual's ability to recognize symptoms predictive of an ACS event and promptly seek medical attention.

Practice recommendations suggest that, in individuals presenting with chest pain, assessments should include a 12-lead electrocardiography within 10 minutes of presentation, medical history, physical examination, and cardiac troponin assessment at presentation and then 3 to 6 hours after the onset of symptoms.

Outcomes

Irreversible ischemic damage to heart muscle occurs primarily within the first 2 hours of coronary artery blockage; prompt restoration of blood flow decreases risks for morbidity and mortality.

The general outcomes of interest are disease-specific survival, morbid events, functional outcomes, and quality of life.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Randomized Controlled Trials

Evidence for intracardiac ischemia monitoring consists primarily of the ALERTS trial, a multicenter randomized controlled trial published by Gibson et al. (2019). The study enrolled 907 high-risk ACS patients who were randomized to an activated-alert group or a control group with alarms disabled for 6 months. The primary safety endpoint was met, with 96.7% freedom from system-related complications. However, the trial failed to meet its prespecified primary efficacy endpoint, a composite of cardiac or unexplained death, new Q-wave myocardial infarction, or delayed presentation (>2 hours) following a confirmed occlusive event. The incidence of the primary endpoint was numerically lower in the treatment group but did not differ significantly from the control group.

The study demonstrated a significant reduction in time from ischemic event detection to presentation at a medical facility among patients with activated alarms. Exploratory and expanded analyses also reported improvements in positive predictive value, reductions in false-positive rates, detection of asymptomatic ischemic events, and preservation of left ventricular function following occlusive events. However, these analyses were secondary, exploratory, or post hoc and should be interpreted with caution. The trial was further limited by lower-than-expected event rates and did not demonstrate statistically significant improvements in major clinical outcomes such as mortality or myocardial infarction.

No additional randomized controlled trials evaluating the intracardiac ischemia monitoring were identified. Therefore, although available evidence suggests the device may facilitate earlier recognition of ischemic events, evidence demonstrating improvement in clinically meaningful health outcomes remains insufficient. Additional studies are needed to establish whether reductions in time to presentation translate into improvements in morbidity, mortality, or other patient-centered outcomes.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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.

There are currently no practice guidelines or position statements identified that address the use of intracardiac ischemia monitoring (AngelMed® Guardian System) for individuals considered at high risk for ischemic cardiac events.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis 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	Insertion or replacement of intracardiac ischemia monitoring system including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; electrode only
	0527T	Insertion or replacement of intracardiac ischemia monitoring system including testing of the lead and monitor, initial system programming and imaging supervision and interpretation; 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	Removal of intracardiac ischemia monitoring system including all imaging supervision and interpretation; electrode only
	0532T	Removal of intracardiac ischemia monitoring system including all imaging supervision and interpretation; implantable monitor only
HCPCS		
	C1833	Monitor, cardiac, including intracardiac lead and all system components (implantable)
Type of Service	Medicine	
Place of Service	Inpatient/Outpatient	

POLICY HISTORY

Date	Reason	Action
July 2026	Annual Review	Policy Renewed
July 2025	Annual Review	Policy Renewed
July 2024	Annual Review	Policy Renewal
July 2023	Annual Review	Policy Renewed
January 2023	Annual Review	Policy Revised
January 2022	Annual Review	Policy Revised, Content Moved and New Medical Policy Created

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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