Guardian System, Implantable Cardiac Monitoring Device

April, 2024

Device

The American Heart Association and the American College of Cardiology have published (and updated) guidelines that have been implemented nationally improving hospital door to intervention times in myocardial infarction (MI) which are associated with improved clinical outcomes.[1,2] Strategies for the reduction of time from onset of symptoms to hospital arrival remain challenging. Symptoms vary and may be misconstrued by patients, may be late onset, or could potentially be asymptomatic.[2] According to the manufacturer, the Guardian System "can detect a heart attack even if a person has no symptoms or atypical symptoms."[3] It is an implantable device for continuous cardiac monitoring that detects resting heart rate electrical changes which can indicate cardiac ischemia. When an event is detected the device vibrates inside the chest as well as signaling audible and visual alerts to an accessory handheld device. The system will instruct a patient to call 9-11 for urgent events or to see a doctor for non-urgent events (non-acute arrythmias).[3]

Actions for Consideration

Partner: Identify cardiologists, interventional cardiologists, cardiac surgeons, nurses, quality personnel, and additional applicable value analysis team members (both clinical and non-clinical). Reimbursement specialists may be particularly helpful within this category (Centers for Medicare and Medicaid Services pass through codes available found here).

Connect: Collecting and reviewing physician interest (and/or prior experience with device) including populations served, cost/reimbursement, and potential impact on patient outcomes will help inform decision making. Identify any available evidence.

Communicate: Share and discuss product indication with team, gauge interest, and develop a common goal. Discuss pricing, reimbursement, available evidence, and potential outcomes impact. Robust data sharing will not only enhance discussions, but may lead to actionable conversations between peers.

HealthTrust Resources: Access the Clinical Knowledge Insights Library to find other relevant documents and toolkits with actionable information. Examples for this product include resources on introduction of new products, value analysis, and clinical trials.[4] Network on HealthTrust Huddle, our member community that shares ideas and seeks guidance from colleagues.[5]

FDA Approval

The Guardian system has FDA Pre-Market Approval (# P150009) as indicated for use "in patients who have had prior acute coronary syndrome (ACS) events and who remain at high risk for recurrent ACS events." Found here.[6]

Clinical Evidence

There are limited studies on the use of the Guardian system, with studies being industry sponsored. A sample is included below:

- A 2019 multicenter, randomized trial by Gibson et. al. (Angelmed Early Recognition and Treatment of STEMI "ALERTS" study) included 907 high risk ACS subjects divided into a control (no alarm activated) or treatment group (alarms activated) for 6 months. They evaluated endpoints including system-related complications, instances of cardiac/unexplained death, new Q-wave MI, or greater than 2-hour

detection to presentation time. They concluded that the system did not result in subjects ignoring symptoms, did not cause "excess utilization of resources", and had a low rate of complications. An expanded analysis was conducted as the endpoints in the initial trial period were numerically, but not statistically, reduced in the treatment group. In the expanded analysis the positive predictive value was higher and false positive rate was lower for the treatment group which they concluded suggests the system may be beneficial to identify both symptomatic and asymptomatic occlusive events in high risk ASC patients. Limitations included low event rates, no difference in "hard" clinical outcomes. Expanded analysis was necessary after early termination of the study due to discrepancies in electrocardiogram tracings.[7]

- Gibson et. al. further evaluated the expanded analysis of the ALERTS study in an additional 2019 study to include the endpoints of symptom to door, and alarm to doors times. All emergency department (ED) visits for ACS events within 2 hours increased from 10% in the control group (alarms off) to 55% in the treatment group (alarms on). In the alarms on group 77% of arrivals were less than 2 hours from alarm time for silent MI. For the alarms off group, the median symptom to door time was 8 hours, while the median time for the treatment group ranged between 1.4 (only alarm) and 1.0 (alarm with symptoms). They concluded that the system resulted in a statistically significant decrease in median pre-hospital delay compared to current standards (symptoms only) which could potentially improve outcomes. Limitations included a need for better understanding of the sources of false positives and negatives, as well as a need for further assessment on potential benefit to clinical outcomes in future studies.[8]

Physician Advisor Insight

A panel of cardiologists, interventional cardiologists, and cardiac surgeons within our HealthTrust Physician Advisor Network offered the following insight with regard to the Guardian System[9]:

- Would potentially use for high risk patients whose initial myocardial infarction (MI) had atypical or no symptoms or those with diffuse coronary artery disease (CAD).
- Potential benefits include the ability to tailor therapy to frequency of device detected silent events, may differentiate ischemic versus non-ischemic chest pain episodes, and may assist those with cardiac signal disorders.
- Potential risks include intracardiac lead placement, potential to delay emergency response if device does not detect/alarm, infection, possible false positive alarms, and could be cost prohibitive.

Healthtrust Huddle Insight

Members within our HealthTrust Member Network offered the following insight (via survey within Healthtrust Huddle) with regard to the Guardian System[10]:

- Reimbursement considerations are important for this product.
- Benefits may include potential for earlier detection, pre-symptom early warning, customizable to patient, and potential to detect asymptomatic ACS.
- Risks may include discomfort, battery failure, potential to ignore symptoms if device does not alarm, and lack of evidence in long term outcomes.
- Would incorporate into the care of patients who qualify with high risk of ACS event.

Summary

Careful review and understanding of interest, specific population needs, cost (including reimbursement), and potential for impact on patient outcomes will help determine direction and opportunity. Due to limited evidence with direct utilization of a product, a trial of the product(s) is a potential consideration. Share data to engage clinicians. When considering a change of product ensure physicians are included in the discussion, that evidence and pricing are shared, and appropriate support is provided from the supplier.

References

1. Lawton JS, Tamis-Holland JE, Bangalore S, et al. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: a Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2022;145(3). doi:https://doi.org/10.1161/cir.0000000000001038
2. Kazmi SHA, Datta S, Chi G, et al. The AngelMed Guardian® System in the Detection of Coronary Artery Occlusion: Current Perspectives. Med Devices (Auckl). 2020;13:1-12. Published 2020 Jan 7. doi:10.2147/MDER.S219865
3. Guardian: Providing Peace of Mind. avertix.com. https://avertix.com/guardian-system
4. Healthtrust Purchasing Group. Clinical Knowledge Insights. Updated 2024. Accessed February 9, 2024. http://www.hpginsights.com/
5. HealthTrust Purchasing Group. HealthTrust Huddle. Updated 2024. Accessed February 9, 2024. https://huddle.healthtrustpg.com/forum/
6. Premarket Approval (PMA). www.accessdata.fda.gov. Accessed March 27, 2024. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P150009
7. Gibson CM, Holmes D, Mikdadi G, et al. Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. J Am Coll Cardiol. 2019;73(15):1919-1927. doi:10.1016/j.jacc.2019.01.014
8. Holmes DR Jr, Krucoff MW, Mullin C, et al. Implanted Monitor Alerting to Reduce Treatment Delay in Patients With Acute Coronary Syndrome Events. J Am Coll Cardiol. 2019;74(16):2047-2055. doi:10.1016/j.jacc.2019.07.084
9. 2024 Physician Advisor Network: Cardiologist Survey. Collected February 16th through March 8th, 2024.
10. 2024 Healthtrust Huddle Member Network Survey. Collected February 13th through March 5th, 2024.