



March 15, 2011

Robert Muscalus, DO  
Contractor Medical Director  
Highmark Medicare Services  
1800 Center Street, 1AL3  
Camp Hill, PA 17089

Dear Dr. Muscalus:

We the undersigned are providing comment to the LCD DL27520, Real-Time, Outpatient Cardiac Monitoring, to be implemented later this month. We strongly believe in the value of this powerful technology in the diagnosis and management of patients with known or suspected arrhythmias. Our concern is and has been about offering the right test to the right patient at the right time. We believe in avoiding unnecessary and duplicative testing in the management of our patients and believe we should be appropriate stewards of medical resources. We therefore believe that decisions regarding this testing modality afford us the opportunity to define appropriate ordering, functional elements and clinical scenarios in which the benefits of this testing can be maximized.

In general terms the technology is most useful in the patient with known or suspected arrhythmias in whom symptoms are intermittent. Patients so monitored run the spectrum from those with significant structural heart disease and those with no structural heart disease. The decision after such a monitoring period may be to treat or not to treat. The findings may require prompt intervention or may not. The indications are not the same as a Holter monitor. The yield of a Holter in these patients is low and may be redundant and an unneeded expense. The following are suggestions that would make the LCD stronger and more clinically relevant.

Concerns regarding LCD DL27520, Real Time Outpatient Cardiac Telemetry:

**Covered Indications**

At this time, Medicare coverage for this service is limited to a very select patient population who have demonstrated a need for cardiac monitoring, and for whom all the following pertain:

Other testing and/or monitoring has been unrevealing. The referring physician must document the prior testing performed and results. This information must be maintained in the patient's medical record and be available upon request.

Other monitoring is deemed inappropriate. The frequency of the events is highly suggestive of an intermittent arrhythmia that is unlikely to be captured by other types of monitoring and is not infrequent enough to warrant an implantable loop recorder. Daily events or events several times a week monitored by this technology will be considered reasonable **and necessary only after prior monitoring has been found to be unrevealing.**

**These statements are conflicting. The first requires preliminary tests that are unrevealing and the second recognizes that these tests may be deemed inappropriate. We recommend that the first paragraph above be deleted.**

It is anticipated that the results of this service would provide diagnostic and treatment information. The provider requesting this service must act upon the results in real time and use this testing to make a treatment decision. This technology is not to be used for screening purposes.

**The above paragraph implies that treatment is anticipated. The rationale for a test may be solely diagnostic and some finding will not require treatment. The second sentence is actually Medicare practicing medicine, directing a physician to act upon the results. In addition it mandates that this be done real time. Most findings of MCOT do NOT require real time management of a patient. There are specific notification criteria determined by the prescribing physician to the monitoring entity (or if it is a non-IDTF entity,-see under NON-IDTF entities, notification criteria will be delineated in writing. The test may be done without making a treatment decision, because other testing, for example an electrophysiology study, may then be indicated. We recommend that this paragraph (with exception of the last sentence) be deleted.**

**The arrhythmia** must be occurring infrequently enough to not be captured by other monitoring devices and not infrequently enough to be more appropriately monitored with an implantable loop recorder.

**Outpatient telemetry is also useful and utilized for symptoms, in the absence of documented arrhythmias in order to make a diagnosis. Symptoms may include palpitations (which may correspond to PACs, PVCs, nonsustained atrial or ventricular tachyarrhythmias, or no arrhythmias), presyncope, and syncope. One may not know if there is an arrhythmia before telemetry monitoring is initiated. We propose that the term "arrhythmia or symptoms" be substituted for the word "arrhythmia."**

Patients with symptomatic underlying structural disease and intermittent symptoms, as defined above.

Patients with no structural heart disease but who have intermittent, recurrent, severe symptoms (i.e., recurrent true syncope), of a frequency unlikely to be captured by other devices, in whom all testing is negative and in whom an implantable event recorder is contemplated as the next step if the real-time monitoring is negative.

Patients with uncontrolled atrial fibrillation post-pneumonectomy.

**What is described above this sentence are specific diagnoses not symptoms. This document must distinguish between symptoms and specific diagnoses for the purpose of appropriate ICD codes for indications. We propose the inclusion of both specific diagnoses *and* symptoms (see paragraph regarding recommended ICD codes for indication) for indications. We would propose eliminating the distinction between structural heart disease and absence of structural heart disease with regards to indications. They are shared between the two, and do not differ. Would change this to read: Patients with and without structural heart disease who have symptoms of syncope, palpitations accompanied by other symptoms (dyspnea, chest pain, dizziness, syncope) or for patients who require monitoring for known, non life-threatening arrhythmias, such as paroxysmal atrial fibrillation, other paroxysmal supra-ventricular arrhythmias, evaluation of various bradyarrhythmias and intermittent bundle branch block or AV block.**

The arrhythmia must be occurring infrequently enough to not be captured by other monitoring devices and not infrequently enough to be more appropriately monitored with an implantable loop recorder.

**This needs to be deleted because a cardiac event recorder is indicated for the same time period as outpatient telemetry but has a different indication.**

Performance of this service is currently restricted to providers registered as an Independent Diagnostic Testing Facility (IDTF). All entities providing the technical portion of this service (procedure code 93229) must be registered as an IDTF with Medicare Provider Enrollment.

**We propose that this procedure should be approved for any entity that provides the same quality standards regarding supervision and qualifications of staff and technical performance and specifications even if it is not an IDTF.**

Use of cardiac surveillance and Holter or event monitoring for the same patient on the same day is NOT medically necessary. Routine use of several types of monitoring in the same patient for the same disease episode is considered not reasonable and necessary.

**What is the definition of disease episode? Arrhythmias or symptoms may be paroxysmal or persistent for extended but limited amounts of time. The first sentence is reasonable. In addition, a patient with an implanted pacemaker or defibrillator has a type of monitor in it but may not be adequate enough to diagnose an arrhythmia and outpatient telemetry is indicated. We propose that the second sentence in this paragraph be deleted.**

ICD 9 Codes supporting medical necessity:

We propose the addition of:

- 785.1 palpitations
- 427.89 ventricular premature beats
- 427.1 paroxysmal ventricular tachycardia
- 427.89 supraventricular premature beats
- 785.0 unspecified tachycardia.

1. The following documentation supports the technical component of the service and must be maintained by the monitoring entity and be available to the contractor upon request:

- The order for the service
- Appropriate patient selection criteria as outlined in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy
- Copies of transmitted ECG and response by the monitoring entity
- Daily reports to the referring physician
- Physician contacts and responses
- Summary report at the end of the monitoring episode

**We object to the bullet point regarding physician contacts and responses as there may not be any physician contacts/responses until the end of the monitoring period. We propose: physician daily and summary interpretation be substituted for contacts and responses.**

In summary, real-time telemetry monitoring is a powerful tool in the diagnosis and management of patients with known or suspected cardiac arrhythmias. We believe incorporating the above suggestions would make the LCD a stronger document. We also believe that if physician practices and hospitals are able to meet the quality standards set forth in the LCD they should be allowed to do so. We look forward to your comments and the opportunity to help further strengthen the document.

Sincerely,



Ralph G. Brindis, MD, MPH, FACC  
President, American College of Cardiology



Samuel D. Goldberg, MD, FACC  
President, Maryland Chapter  
American College of Cardiology

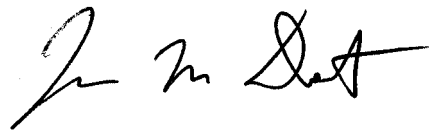


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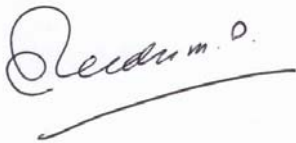
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A handwritten signature in black ink, appearing to read "Gaetano N. Pastore". The signature is fluid and cursive, with a large initial "G" and "P".

Gaetano N. Pastore, MD, FACC  
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A handwritten signature in black ink, appearing to read "Stuart Floyd Seides". The signature is cursive and includes the initials "M.D." at the end.

Stuart Floyd Seides, MD, FACC  
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