**Policy:** Meridian Health Plan (MHP) considers the use of implantable loop recorder cardiac event monitors (i.e., FDA approved Reveal Insertable Loop Recorders, including Reveal XT, DX and LINQ) medically necessary only in a limited role, in a very small subset of patients, who experience at least two episodes of recurrent, infrequent*, unexplained symptoms of pre-syncope, syncope, or tachycardia with severe symptoms of hemodynamic instability, when both of the following criteria are met:

1. A cardiac arrhythmia is suspected as the cause of the symptoms; and
2. A prior trial of Holter Monitor and other external ambulatory event monitors have been unsuccessful in determining a definitive diagnosis, or a diagnostic ECG.

*An infrequent but recurrent symptom of pre-syncope, syncope, or tachycardia with severe symptoms of hemodynamic instability would be indicative of frequency of at least two episodes within six months.

MHP considers the use of implantable loop recorder cardiac event monitors (i.e., FDA approved Reveal Insertable Loop Recorders, including Reveal XT, DX and LINQ) for detection of atrial fibrillation following cryptogenic stroke **investigational.** Peer review literature is limited and although the prevention of recurrent strokes in patients with cryptogenic stroke is feasible through enhanced detection provided by ICM, additional randomized trials are needed to assess whether the information yielded by ILR monitoring improves clinical management and influences the rate of secondary stroke and overall morbidity and mortality in patients who have experienced a cryptogenic stroke. In addition, the patient population most likely to benefit from monitoring needs to be better defined.
**Procedure:** Per the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: Executive Summary, “Atrial fibrillation (AF) may be described by the duration of the episode. Implant loop recorders, pacemakers, and defibrillators offer the possibility of reporting frequency, rate, and duration of abnormal atrial rhythms, including atrial fibrillation (AF). Episodes often increase in frequency and duration over time.

Per the FDA: The Reveal LINQ Insertable Cardiac Monitor is an implantable patient-activated and automatically-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias;
- Patients who experience transient symptoms such as dizziness, palpitation, syncope and chest pain that may suggest a cardiac arrhythmia;
- The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates the data management features in the Reveal LINQ ICM to initiate recording of cardiac event data in the implanted device memory.

The Centers for Medicare & Medicaid Services (CMS) has a national coverage determination for electrocardiographic (EKG) services (20.15), publication number 100-3, which states that an implantable or insertable loop recorder (ILR) is another type of pre-symptom memory loop recorder (MLR), that is implanted subcutaneously in a patient’s upper left chest and may remain implanted for many months. An ILR is used when syncope is thought to be cardiac-related, but is too infrequent to be detected by either a Holter Monitor or a traditional pre-symptom MLR.

1. Certain cardiac event monitors capture electrical activity with a single electrode attached to the skin. Other devices may employ multiple electrodes in order to record more complex EKG tracings. Additionally, devices may be individually programmed to detect patient-specific factors, electrode malfunction, or other factors. Cardiac event monitors can be further categorized as either “pre-event” or “post-event” recorders, based on their memory capabilities:
   a. Pre-symptom Memory Loop Recorder (MLR): Upon detecting symptoms, the wearer presses a button, which activates the Recorder to save (i.e., memorize) an interval of pre-symptom EKG data along with data during and subsequent to the symptomatic event. Self-sensing Recorders (also known as event-activated or automatic trigger) do not require patient input to capture these data. Single or multiple events may be recorded. The device is worn at all times, usually for up to 30 days.
   b. Implantable (or Insertable Loop) Recorder (ILR): Another type of pre-symptom MLR, it is implanted subcutaneously in a patient’s upper left chest and may remain implanted for many months. An ILR is used when syncope is thought to be cardiac-related, but is too infrequent to be detected by either a Holter™ monitor or a traditional pre-symptom MLR.
   c. Post-symptom Recorder: The patient temporarily places this device against the chest when symptoms occur and activates it by pressing a button. These Recorders represent old technology, as they do not include a memory Loop. The device transmits EKG data telephonically in real-time and is usually used for up to 30 days.

**Special Instructions:** N/A

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5. Cardiac arrhythmias. Washington (DC): American College of Cardiology (ACC); 2007

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