The Reveal LINQ™ Monitoring Service is provided by Medtronic Monitoring, Inc. (MMI), for patients who have received a Reveal LINQ™ insertable cardiac monitor (ICM) and who have a Medtronic MyCareLink™ patient monitor.

The Medtronic Monitoring Center is a CMS Certified Independent Diagnostic Testing Facility supervised by a Cardiac Electrophysiologist with a staff of Certified Technicians.

**SERVICE OBJECTIVES**
- Follow-up with the patient if no device transmission has occurred for 5 days.
- Event Report delivery within 12 hours of receipt of ECG when a patient-activated event or rhythm that meets notification criteria is identified.
- Summary Report delivery within 5 days of the end of the 30 day monitoring cycle.
- Process requests to exit a patient within 48 hours of receipt of written request.
- Bill sent to patient for any applicable balance within 30 days of final insurance payment(s).
- Provide responses to all customer calls and inquiries within 4 hours.

**PATIENT DATA**
The Monitoring Center does not identify or respond to emergencies. Rather, the center periodically provides reports about the monitoring data to the patient’s physician so the physician can evaluate the information and take any action needed. Neither MMI nor its staff has a physician/patient (or other healthcare provider/patient) relationship with the patients who are monitored by MMI. The patient should continue to rely on the patient’s physician for all medical treatment. All communication and data transmissions are subject to local telephone/cellular coverage and adherence to instructions for use.

**CUSTOMER SUPPORT**
**CONTACT**
Telephone: 1-877-247-7449
Email: USLINQMonitoring@medtronic.com

**HOURS OF OPERATION**
M-F: 8 a.m.-10 p.m. Eastern time
Sat/Sun: 8 a.m.-6 p.m. Eastern time

**CERTIFIED TECHNICIANS**
**HOURS OF OPERATION**
24 hours a day, 7 days a week

**SERVICE OVERVIEW**
Upon receipt of a prescription, Customer Support will proactively contact the patient to introduce the service, confirm insurance information, and acquire patient authorization for Medtronic Monitoring to perform and bill for the service.* They will also facilitate a prior-authorization process, if required by the insurance carrier.† Following insurance verification and patient authorization, Customer Support will email “Confirmation of Prescription” to the prescribing clinic and initiate a request in the CareLink network to transfer the patient to the MMI CareLink clinic. Clinic acceptance of this transfer in the CareLink network marks official enrollment into the Reveal LINQ Monitoring Service.

Customer support will contact the patient to provide education regarding the home monitor and assure initiation of a manual transmission. Receipt of that manual transmission will initiate the patient’s 30-day monitoring period. During the prescription period, MMI will monitor Reveal LINQ ICM transmissions and call the patient in an attempt to resolve any unexpected device connectivity issue that reaches or exceeds 5 days. Summary Reports and Event Reports will be distributed in accordance with the stated service objectives and physician-specified event notification criteria.

**PATIENT DATA**
The Monitoring Center does not identify or respond to emergencies. Rather, the center periodically provides reports about the monitoring data to the patient’s physician so the physician can evaluate the information and take any action needed. Neither MMI nor its staff has a physician/patient (or other healthcare provider/patient) relationship with the patients who are monitored by MMI. The patient should continue to rely on the patient’s physician for all medical treatment. All communication and data transmissions are subject to local telephone/cellular coverage and adherence to instructions for use.

**References**
* Authorization must be verbally obtained from the patient.
† If prior authorization or additional eligibility and benefit check is required.
‡ Receipt refers to the time the event or request was received by MMI.
†† During Customer Support Hours of Operation as specified above.
The Medtronic MyCareLink™ Patient Monitor and the Medtronic CareLink™ Network are indicated for use in the transfer of patient data from Medtronic implantable cardiac devices. These products are not a substitute for appropriate medical attention in the event of an emergency. Data availability and alert notifications are subject to Internet connectivity and access, and service availability. The MyCareLink Patient Monitor must be on and in range of the device. Alert notifications are not intended to be used as the sole basis for making decisions about patient medical care.

**Potential Complications**
Potential complications include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.

**Intended Use**
The Medtronic MyCareLink Patient Monitor and CareLink Network are indicated for use in the transfer of patient data from some Medtronic implantable cardiac devices based on physician instructions and as described in the product manual. The CareLink Mobile Application is intended to provide current CareLink Network customers access to CareLink Network data via a mobile device for their convenience. The CareLink Mobile Application is not replacing the full workstation. These products are not a substitute for appropriate medical attention in the event of an emergency and should only be used as directed by a physician. CareLink Network availability and mobile device accessibility may be unavailable at times due to maintenance or updates, or due to coverage being unavailable in your area. Mobile device access to the Internet is required and subject to coverage availability. Standard text message rates apply.

**Contraindications**
There are no known contraindications.

**Warnings and Precautions**
The MyCareLink Patient Monitor must only be used for interrogating compatible Medtronic implantable devices. See the device manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com.

**Caution:** Federal law (USA) restricts these devices to sale by or on the order of a physician.

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**Brief Statement**
**Reveal LINQ™ LNQ11 Insertable Cardiac Monitor and Patient Assistant**

**Indications**
Reveal LINQ LNQ11 Insertable Cardiac Monitor:
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, syncpe, and chest pain, that may suggest a cardiac arrhythmia

This device has not been specifically tested for pediatric use.

**Patient Assistant**
The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates the data management feature in the Reveal™ Insertable Cardiac Monitor to initiate recording of cardiac event data in the implanted device memory.

**Contraindications**
There are no known contraindications for the implant of the Reveal LINQ Insertable Cardiac Monitor. However, the patient’s particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

**Warnings/Precautions**
Reveal LINQ LNQ11 Insertable Cardiac Monitor: Patients with the Reveal LINQ Insertable Cardiac Monitor should avoid sources of diathermy, high sources of radiation, electrosurgical cautery, external defibrillation, lithotripsy, therapeutic ultrasound, and radiofrequency ablation to avoid electrical reset of the device, and/or inappropriate sensing as described in the Medical procedure and EMI precautions manual. MRI scans should be performed only in a specified MR environment under specified conditions as described in the Reveal LINQ MRI Technical Manual.

**Patient Assistant**
Operation of the Patient Assistant near sources of electromagnetic interference, such as cellular phones, computer monitors, etc., may adversely affect the performance of this device.

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The Reveal LINQ™ Monitoring Service and the Medtronic Monitoring Center are provided by Medtronic Monitoring Inc., a wholly owned subsidiary of Medtronic.