INTRODUCTION

Medtronic FocusOn℠ Monitoring Service (the service) is a virtual extension of your clinical team provided by Medtronic Monitoring Inc. (MMI), a wholly owned subsidiary of Medtronic. MMI is a Medicare-certified independent diagnostic testing facility (IDTF) that has met a set of performance standards in order to obtain and maintain Medicare billing privileges. Please reference 42 C.F.R. section 410.33(g) for details on these standards. The service helps you streamline patient management and cardiac data review for patients with a Reveal LINQ™ implantable loop recorder (ILR). Medtronic FocusOn℠ Monitoring Service is the program name for the work of performing remote monitoring technical services of the Reveal LINQ ILR.

DISCLAIMER

Medtronic provides this information for your convenience only. It does not constitute legal advice or a recommendation regarding clinical practice. Information provided is gathered from third-party sources and is subject to change without notice due to frequently changing laws, rules, and regulations. The provider has the responsibility to determine medical necessity and to submit appropriate codes and charges for care provided. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other payers as to the correct form of billing or the amount that will be paid to providers of service. Please contact your Medicare contractor, other payers, reimbursement specialists, and/or legal counsel for interpretation of coding, coverage, and payment policies. This document provides assistance for FDA-approved or cleared indications. Where reimbursement is sought for use of a product that may be inconsistent with, or not expressly specified in, the FDA-cleared or approved labeling (e.g., instructions for use, operator’s manual, or package insert), consult with your billing advisors or payers on handling such billing issues. Some payers may have policies that make it inappropriate to submit claims for such items or related service.

BILLING

1. How does Medtronic FocusOn℠ Monitoring Service work?

For patients with a Reveal LINQ ILR who are enrolled in the service, cardiac technicians perform the technical remote monitoring work. For Medicare patients, this work is described by CPT® G2066, which specifies “Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results.” This code was created by the Centers for Medicare and Medicaid Services (CMS) for Medicare services provided on or after January 1, 2020.

You will want to contact your private payers directly to confirm the CPT code that they require to report the technical portion of the remote monitoring work.

The service charges your clinic directly for the technical remote monitoring work for patients enrolled in the service. MMI is the legal entity that is the performing provider and that will send invoices for the service.

2. How will our clinic receive a bill from Medtronic FocusOn℠ Monitoring Service for patients enrolled in the service?

The service will create an invoice listing all of your patients who were monitored, and will provide the list to the clinic in the form of a monthly bill.

3. Can our clinic submit claims for performing the technical remote monitoring work for patients enrolled in Medtronic FocusOn℠ Monitoring Service?

For Medicare beneficiaries, Medicare allows technical and/or professional diagnostic services to be ordered by a physician and performed by a third party, subject to the anti-markup rule. Therefore, Medicare will accept claims from patients enrolled in the service. Report this service to Medicare using G2066.

Medicare Advantage plans follow their own claim processing instructions. We recommend contacting your Medicare Advantage plan directly to determine their individual policies and procedures. We also recommend confirming the appropriate CPT code with your Medicare Advantage plans to verify whether G2066 is the appropriate code for use in this situation.

For private payer beneficiaries, private payer claims submission requirements and billing policies vary by plan; we recommend contacting your private payers directly to determine their individual policies and procedures. We also recommend confirming the appropriate CPT code with your private payers to verify whether G2066 is the appropriate code for use in this situation.
4. What is the anti-markup rule?\(^3\,^4\)

The anti-markup rule limits the charge for diagnostic services (technical and/or professional) that are ordered by a physician and performed by a third party. Under the anti-markup rule, CMS is required to enforce payment restrictions on diagnostic tests where the provider performing or supervising the test does not share a practice with the billing provider. This prevents a practice from profiting from diagnostic tests when diagnostic services were not performed, supervised, or interpreted by the ordering physician. Medicare requires the billing provider to bill the lowest of the following amounts for diagnostic tests:

a. The performing provider’s net charge (minus the cost of equipment or leased space) to the billing physician or provider;

b. The billing provider or provider’s actual charge; or

c. The fee schedule amount of the diagnostic test that would be permitted if the performing provider billed Medicare directly. (The 2020 payment rate for CPT G2066 if MMI — located in Minnesota — billed Medicare directly is $125.00.)\(^2\,^5\)

5. How does the anti-markup rule affect my clinic when participating in Medtronic FocusOn\(^{SM}\) Monitoring Service?

For patients enrolled in the service, MMI is the performing provider for the technical service and your clinic is the billing provider of the work described by CPT G2066. Medtronic FocusOn\(^{SM}\) Monitoring Service is the program name. MMI is the entity that has obtained a national provider identification (NPI) number and received certification from CMS as an independent diagnostic testing facility (IDTF).

We suggest following the anti-markup rules listed above to stay compliant with CMS-enforced payment restrictions. We recommend speaking with your compliance department with questions or concerns regarding the anti-markup rule.

6. How do I submit claims for the patients enrolled in Medtronic FocusOn\(^{SM}\) Monitoring Service?

You will need to submit two separate claims — one to indicate that MMI performed the technical remote monitoring of work (CPT G2066), and another to indicate your clinic performed the professional remote monitoring work (CPT 93298).\(^3\)

7. How do I indicate that the work was performed by MMI?

You will list MMI as the provider that performed the technical remote monitoring work (CPT G2066) using MMI’s national provider identifier (NPI) and address on the CMS-1500 claim form.\(^6\) See the table at right for details.

<table>
<thead>
<tr>
<th>Claims identifying information to signify monitoring was performed by MMI and purchased by the billing provider</th>
<th>CMS 1500 Item (form locator)</th>
<th>Details to enter in the claim form</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPI</td>
<td>Item 32a</td>
<td>NPI: 1558845628</td>
</tr>
<tr>
<td>Performing Provider Address</td>
<td>Item 32</td>
<td>Medtronic Monitoring Inc. 800 53rd Avenue NE Columbia Heights, MN 55421-1241</td>
</tr>
<tr>
<td>Outside Lab?</td>
<td>Item 20</td>
<td>Select “Yes”</td>
</tr>
<tr>
<td>$ Charges</td>
<td>Item 20</td>
<td>Include the charge amount invoiced from MMI to the billing provider in this section</td>
</tr>
</tbody>
</table>

MMI is the legal entity name that will need to be listed on the billing providers’ CMS Form 1500 as the provider who provided the remote monitoring technical services. Medtronic FocusOn\(^{SM}\) Monitoring Service will not be known to CMS if Medtronic FocusOn\(^{SM}\) Monitoring Service is identified on the CMS form 1500.

The name, address, and nine-digit ZIP code should be reported in Item 32 of the CMS-1500 claim, or in the corresponding loop and segment of the electronic claim form. The NPI of the provider who performed the service should be reported in Item 32a of the CMS-1500 claim form or in the corresponding loop and segment of the electronic claim form.

In addition, Item 20 of the claim form should indicate that the service was performed by an outside lab. Select “yes” in Item 20 “Outside lab?” when submitting the claim, and include the invoiced amount from the invoice from MMI to the billing provider in Item 20 “$ Charges” area.

Contact your payer for any additional requirements that may be necessary.

8. What is the address and NPI for MMI?

NPI: 1558845628
Address: Medtronic Monitoring Inc.
800 53rd Avenue NE
Columbia Heights, MN 55421-1241
Medtronic FocusOn™ Monitoring Service is provided by Medtronic Monitoring Inc., a wholly owned subsidiary of Medtronic.

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.

**Brief Statement**

**Reveal LINQ™ Insertable Cardiac Monitor**

**Indications**

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

This device has not been specifically tested for pediatric use.

**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**

Patients with the Reveal LINQ insertable cardiac monitor should avoid sources of diarrhea, 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.

**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.

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 this device to sale by or on the order of a physician.

If you have questions regarding the invoice you received from MMI or regarding the service provided by MMI, please contact MMI at 877-247-7449, 8 a.m.–5 p.m. CT.

If you have additional questions, please visit our website at www.medtronic.com/CRHFreimbursement or contact the Medtronic Cardiac Rhythm and Monitoring Reimbursement Support Team by phone at 866-877-4102 Monday–Friday, 8 a.m.–5 p.m. CT., or by email at rs.healthcareeconomics@medtronic.com.