FREQUENTLY ASKED QUESTIONS
Medtronic FocusOn℠

Economics, Reimbursement, and Evidence

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)[1] for details on these standards. The Service helps you streamline patient management and cardiac data review for patients with a LINQ Family of ICMs (Insertable Cardiac Monitors) device. Medtronic FocusOn℠ Monitoring Service is the program name for the work of performing remote monitoring technical services of the LINQ devices.

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 Family of ICM device who are enrolled in the Service, cardiac technicians perform the technical remote monitoring work. This work is described by HCPCS 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."[2] This code was created by the Centers for Medicare and Medicaid Services (CMS) for Medicare services provided on or after January 1, 2020.

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

The Service charges your clinic directly for the technical remote monitoring work for patients enrolled in the Service. Medtronic Monitoring Inc (MMI) is the performing provider, Invoices will come from MMI on a monthly basis.

3. Can clinics still bill for the **professional** remote monitoring work for patients enrolled in Medtronic FocusOn℠ Monitoring Service?

Yes, when clinics perform the professional remote monitoring work (CPT®[3] 93298) for patients enrolled in the Service. This is not subject to the anti-markup rule.

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

For Medicare beneficiaries, Medicare will accept claims for patients enrolled in the Service, Medicare allows technical and/or professional diagnostic services (including device monitoring procedures) to be ordered by a physician and performed by a third party, subject to the anti-markup rule. Report this service to Medicare using G2066.[4]

For Medicare Advantage beneficiaries, plans follow their own claim processing instructions. For private payer beneficiaries, some payers may not accept claims for services performed by a third party.

We recommend contacting Medicare Advantage and private payers directly to determine their individual policies, procedures and limitations. We also recommend confirming the appropriate code with payers to verify whether G2066 is the appropriate code for use in this situation.

5. What does the anti-markup rule mean?[5,6]

The Medicare anti-markup rule allows providers to be reimbursed at their cost 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 enforces 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.

6. How does the anti-markup rule apply to Medtronic FocusOn℠ Monitoring Service?

Since the Service is a diagnostic service performed by a third party (MMI), Medicare's anti-markup rules must be followed as listed below. CMS has issued specific rules on claims submissions for billing anti-mark up services. We recommend speaking with your compliance department with questions or concerns regarding the anti-markup rule.

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 2021 payment rate for HCPCS G2066 if MMI, located in Minnesota, billed Medicare directly is $183.54.)[2,7]

7. How do I submit claims for the patients enrolled in Medtronic FocusOn℠ Monitoring Service?

You will need to submit two separate claims — one to indicate that MMI performed the technical remote monitoring of work (HCPCS G2066), and another to indicate your clinic performed the professional remote monitoring work (CPT 93298).[5]

You will list MMI as the provider that performed the technical remote monitoring work (HCPCS G2066) using MMI's national provider identifier (NPI) and address on the CMS-1500 claim form.[8] Note: billing on the CMS-1500 claim form is required for all providers, regardless of clinic type (provider-based or independent clinic). See the table at right for details.

Claims identifying information to signify monitoring was performed by MMI and purchased by the billing provider	CMS 1500 Item (form locator)	Electronic claim 837P format field	Details to enter in the claim form
NPI	Item 32a	Loop 2310C	NPI: 1558845628
Performing Provider Address	Item 32	Loop 2310C	Medtronic Monitoring Inc. 800 53rd Avenue NE Columbia Heights, MN 55421-1241
Outside Lab?	Item 20	Loop 2400	Select "Yes"
$ Charges	Item 20	Loop 2400	Include the charge amount per the anti-markup rule. See question 6 for details.

MMI is the 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℠ Monitoring Service will not be known to CMS if Medtronic FocusOn℠ 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.

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

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.

References

[1] United States Code of Federal Regulations. 42 CFR § 410.33 Independent diagnostic testing facility. Available at: https://www.govinfo.gov/app/details/CFR-2011- title42-vol2/CFR-2011-title42-vol2-sec410-33. Accessed on December 11, 2020.

[2] *HCPCS 2021 Level II Professional Edition.* American Medical Association; 2020.

[3] CPT codes and descriptions only are copyright ©2020 American Medical Association. All rights reserved. No fee schedules are included in CPT. The American Medical Association assumes no liability for data contained or not contained herein.

[4] Publication #100-04 Medicare Claims Processing Manual Chapter 1 is located at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf. Accessed January 29, 2021.

[5] CMS MLN Matters MM8806. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8806.pdf. Accessed January 29, 2021.

[6] CMS MLN Matters MM6371. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6371.pdf. Accessed January 29, 2021.

[7] Medicare local 2021 Minnesota contractor-priced payment rates. National Government Services. Available at: https://www.ngsmedicare.com/ngs/PA_CodeSearchTool/download/Minnesota/06202/00/01-19-2021/Medicare_Physician_Fee_Schedule_Pricing.xlsx.

[8] CMS Professional Paper Claim Form (CMS-1500). Available at: https://www.cms.gov/Medicare/Billing/ElectronicBillingEDITrans/16_1500. Accessed January 19, 2021.

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 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.

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.

Medtronic FocusOn℠ Monitoring Service is provided by Medtronic Monitoring Inc., a wholly owned subsidiary of Medtronic.

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