

Reimbursement overview

CareLink Express™ Mobile

Overview

CareLink Express™ Mobile (CLEM) enables easy retrieval of Medtronic cardiac implantable electronic device (CIED) data to be reviewed remotely on the CareLink Express or CareLink™ websites.

This document outlines reimbursement considerations for CareLink Express Mobile.

Coding

CareLink Express Mobile CIED device interrogations are described by in person CIED interrogation CPT® codes. These codes vary by device type (see table at right).

In person interrogation codes are appropriate when the patient receives the service while at a healthcare facility (as opposed to remote interrogation codes which are appropriate when the patient is at home).

Interrogation codes consist of two different components:

- Technical Component: report using modifier -TC. The technical component of the in person monitoring may be performed by the device clinic staff and includes all non-physician work.
- Professional Component: report using modifier -26. The professional component of the in person monitoring includes analysis, review and report by a physician or other qualified health care professional.

For Global service (inclusive of both technical and professional components): report without the use of modifiers.

The provider must verify all CPT® code requirements and components are met prior to reporting a CPT® code. Do not bill for the service unless all requirements have been met.

In person interrogation CPT® codes by device type ^{1,2}	
Pacemaker (including CRT-P)	CPT 93288
Implantable Defibrillator (including CRT-D)	CPT 93289
Implantable Cardiovascular Physiologic Monitor	CPT 93290
Subcutaneous Cardiac Rhythm Monitor (e.g., Reveal™ LINQ)	CPT 93291

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 Considerations

Consider the following for CareLink Express Mobile services billing:

Potential scenarios for CLEM billing	CLEM Technical Component	CLEM Professional Component
The patient's device is remotely monitored by their device clinic* ²	Not billable	Not billable
The patient received device programming service during the same visit as the CLEM interrogation ²	Not billable	Not billable
An industry representative participated in the CLEM ³	Not billable	Billable if code requirements met
Direct supervision requirements are met during CLEM interrogation ⁴⁻⁷	Billable if code requirements met	Billable if code requirements met

*In person interrogation services and remote monitoring services cannot be billed concurrently

Frequently Asked Questions

- Q: Is a CLEM interrogation reported with remote or in person interrogation codes?**

A: A CareLink Express™ interrogation is considered an in person interrogation because the patient is in person at the healthcare facility.
- Q: Is the technical component billable when a Medtronic personnel participates in the CLEM interrogation?**

A. If an industry representative participates in the technical component of an in person CIED management service, the practice can only bill the professional component using modifier -26 on the professional claim form.
- Q: Is the CLEM interrogation billable if the patient is remotely monitored?**

A: No. All interrogations (remote and in person) are included in the remote monitoring period and not separately billable.²
- Q: When CLEM interrogation is performed in the office, can the office bill for both the technical component and the professional component?**

A: It depends. If your clinic staff and provider performed both the professional and technical elements of this service and all code requirements are met ([see Billing Considerations above](#)), then both can be billed. If an industry representative participates in the technical portion of the service, only the professional portion can be billed.
- Q: How does a physician bill for CareLink Express Mobile when performed in the hospital?**

A: The physician will bill for the professional interpretation of the service with a -26 modifier.

Contact us

For more details on in person device interrogation reimbursement, please see the Medtronic CIED Management Services Reimbursement Guide located [here](#), call us at 866-877- 4102 (Monday-Friday from 8 a.m. to 5 p.m. CST), email us at rs.healthcareconomics@medtronic.com or contact your local Medtronic Regional Economic Manager (REM).

References

¹ CPT copyright 2022 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS restrictions apply to government use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for the data contained or not contained herein.

² American Medical Association, 2022 CPT Professional Edition. Details may be found in the Cardiovascular monitoring section.

³ HRS Coding Guide for Heart Rhythm SocietySM Coding Guide, 2016.

⁴ Direct supervision definition may be found in the Code of Federal Regulations 42 CFR 410.32(b)(3)(ii), Chapter 42: Public Health, Part 410: SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS, Section 32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions. Accessed via <https://www.govinfo.gov/app/details/CFR-2011-title42-vol2/CFR-2011-title42-vol2-sec410-32> on February 10, 2023.

⁵ Supervision Requirements: Cardiac device monitoring services are defined by Medicare as diagnostic services. As such, Medicare regulations require specific supervision for diagnostic tests. These are applicable to the technical component of the electronic analysis of implanted cardiac devices. These supervision requirements are in addition to any other Medicare coverage requirements.

Medicare requires direct supervision of the technical component for all in person cardiac device evaluations. Direct supervision in a hospital (facility) setting means that the supervising clinician must be immediately available to furnish assistance and direction throughout the performance of the procedure. The supervising clinician is not required to be present in the room where the procedure is being performed in this hospital (facility) setting or within any other physical boundary as long as he or she is immediately available.

⁶ The Medicare supervision requirements for individual CPT codes are available by accessing the "PFS Relative Value Files" or "Medicare Physician Schedule Look- Up" located at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html>. Accessed February 10, 2023.

⁷ Medicare diagnostic testing rules state that the supervisor must be a Physician. A Non-Physician Practitioner (NPP) such as a nurse practitioner or a physician assistant cannot supervise staff. As of January 1, 2021, Medicare allows certain NPPs to supervise diagnostic tests ONLY in states where state law and scope of practice allows it. CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies. Display Copy: <https://public-inspection.federalregister.gov/2020-26815.pdf>. Accessed February 10, 2023

Brief Statement

CareLink Express™ Mobile System, including the CareLink Express Apps (Model 31301 and 31302) and Patient Connector

Indications (or intended use): The CareLink Express app is intended for interrogating Medtronic cardiac devices and uploading the data to the CareLink™ network. The CareLink Express app is installed on a compatible mobile device with internet access. The CareLink Express app communicates with the Medtronic Patient Connector and sends implanted cardiac device data to the Medtronic propriety CareLink network for clinical review. The CareLink Express app should be used by healthcare personnel only in a clinical or hospital environment.

Contraindications: There are no known contraindications for the CareLink Express app or the Patient Connector.

Warnings and precautions: Only use the Patient Connector to communicate with the intended implanted device.

Use of wireless devices: The Patient Connector incorporates radiofrequency (RF) communications components which may affect other devices and equipment in the medical environment. The use of wireless devices in the medical environment must be evaluated and authorized by the responsible organization. RF interference may affect device performance. Electromagnetic Compliance (EMC) testing shows that the Patient Connector provides reasonable protection against harmful interference and provides EMC immunity in a typical medical installation. The use of wireless devices in the medical environment must be evaluated and authorized by the responsible organization. However, there is no guarantee that interference will not occur in a particular installation. If the Patient Connector does cause harmful interference to other devices or is negatively impacted by other devices, correct the interference by one or more of the following measures: reorient or relocate the Patient Connector and other devices; increase the separation between the Patient Connector and other devices by at least 2 meters (approximately 6 feet); and/or turn off any interfering equipment. **Radiofrequency (RF) interference:** Portable and mobile RF communications equipment can interfere with the operation of the Patient Connector. There is no guarantee that it will not receive interference or

that any particular transmission from this system will be free from interference. To avoid interference, do not use the Patient Connector and mobile device within 2 m (6 feet) of other wireless communications equipment. **Security:** Maintain adequate physical security of the Patient Connector to prevent unauthorized use that could lead to harm to patients. Bluetooth® communication in the Patient Connector is encrypted for security. Medtronic inductive telemetry uses short-range communication to protect patient information. If the Patient Connector should fail, there is no risk of patient harm. **Environmental precautions:** To ensure safe and effective operation, use the device with care to avoid damage to the Patient Connector from environmental factors that may impair its function. Care is exercised in design and manufacturing to minimize damage to devices under normal use. However, electronic devices are susceptible to many environmental stresses. Specifically, the Patient Connector may be affected by electrostatic discharge (ESD). In an environment likely to cause ESD, such as a carpeted floor, discharge any charge collected on your body before touching the device.

Potential complications: See the device manuals for detailed information regarding the instructions for use, intended use, 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 system to sale by or on the order of a physician.

Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432-5604 USA

Toll-free in USA: 800.633.8766
Worldwide: +1.763.514.4000

medtronic.com

UC20201371d EN ©2023
Medtronic. Minneapolis, MN.
All Rights Reserved. Printed in the USA. 03/2023

Medtronic and the Medtronic logo are trademarks of Medtronic.™
Third party brands are trademarks of their respective owners.
All other brands are trademarks of a Medtronic company.

Medtronic