Contraindications

There are no contraindications for the CareLink Monitor.

Warnings and Precautions

The CareLink Monitor is intended only for use within the prescribing country.

See the device manual 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 Medtronic’s website at www.medtronic.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Medtronic CareLink® Monitor/CareLink® Network

Intended Use

The CareLink Monitor and the 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. 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.

Contraindications

There are no contraindications for the CareLink Monitor.

Warnings and Precautions

The CareLink Monitor is intended for use within the prescribing country.

See the device manual 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 Medtronic’s website at www.medtronic.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
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For questions or for more information, please contact Medtronic at 1 (866) 877-4102, select option 1, or visit our website at www.Medtronic.com/CRDMreimbursement.

Coding suggestions and coverage guidelines in this guide do not replace seeking coding advice from the payer and/or your own coding staff. The ultimate responsibility for correct coding lies with the provider of services. Please contact your local payer for interpretation of the appropriate codes to use for specific procedures. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other third-party payers as to the correct form of billing or the amount that will be paid to providers of service.
Reveal Insertable Cardiac Monitors (ICMs) Procedure Coding

Physician and Outpatient Hospital Procedures

For coding assistance or questions regarding reimbursement for Reveal ICMs, please call our Coding Hotline at 1 (866) 877-4102, option 1.

Please note that the CPT® codes for monitoring cardiac devices classify the Reveal ICMs to be implantable loop recorders (ILRs), rather than implantable cardiac monitors (ICMs).

The following codes may be helpful in billing for Reveal ICM procedures.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>CPT/HCPSC® Code</th>
<th>CPT Code Description</th>
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</thead>
<tbody>
<tr>
<td>Insertion</td>
<td>33282</td>
<td>Implantation of patient-activated cardiac event recorder</td>
</tr>
<tr>
<td>Removal</td>
<td>33284</td>
<td>Removal of an implantable, patient-activated cardiac event recorder</td>
</tr>
</tbody>
</table>

In Person Programming

- 93285  Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with physician analysis, review and report; implantable loop recorder system

In Person Interrogation

- 93291  Interrogation device evaluation (in person) with physician analysis, review and report; includes connection, recording and disconnection per patient encounter; implantable loop recorder system, including heart rhythm-derived data-derived analysis

Remote Interrogation

- Physician Analysis
  - 93299  Interrogation device evaluation(s), (remote) up to 30 days; implantable loop recorder system, including analysis of recorded heart rhythm-derived data analysis, physician analysis, review(s) and report(s)

- Technical Service
  - 93299  Interrogation device evaluation(s), (remote) up to 30 days; implantable loop recorder system, including analysis of recorded heart rhythm-derived data analysis, physician analysis, review(s) and report(s)

Device C-code

- C1764*  Hospital Only
  - Event recorder, cardiac (implantable) required when billing Medicare for an Outpatient implant

* Healthcare Common Procedure Coding System (HCPCS)

Inpatient Hospital Procedures

<table>
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<tr>
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<tbody>
<tr>
<td>Insertion</td>
<td>37.79</td>
<td>Revision or relocation of cardiac device pocket (includes implantation of ILR)</td>
</tr>
<tr>
<td>Removal</td>
<td>86.05</td>
<td>Incision with removal of foreign body or device from skin and subcutaneous tissue</td>
</tr>
</tbody>
</table>

These coding suggestions and coverage guidelines do not replace seeking coding advice from the payer and/or your own coding staff. The ultimate responsibility for correct coding lies with the provider of services. Please contact your local payer for interpretation of the appropriate codes to use for specific procedures. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other third-party payers as to the correct form of billing or the amount that will be paid to providers of service.

Coverage Status – Reveal Insertable Cardiac Monitors for Unexplained Syncope

Reveal ICM is indicated for patients with clinical syndromes or situations at increased risk of cardiac arrhythmias or patients who experience transient symptoms such as dizziness, palpitation, syncope and chest pain, that may suggest an arrhythmia.

Coverage Status – Medicare

All local coverage determination (LCD) policies that were issued for the insertable loop recorder (Reveal Plus) have been retired, as of May 1, 2009. Whether or not a written local (LCD) or national (NCD) coverage decision exists, all services provided to Medicare beneficiaries must be “reasonable and necessary” as well as consistent with FDA labeling. Physicians are encouraged to contact their Contractor Medical Director (CMD) directly with any coverage- or billing-related questions.

Coverage Status – Non-Medicare

Non-Medicare payer coverage is based on an individual’s health plan certificate of benefits. Payer policies differ depending on the type of contract, and a number of other factors. As such, many non-Medicare payers have a prior authorization process through which a provider or beneficiary can determine whether an item or service is covered.

Prior authorization requests may be obtained for physician services and for hospital services, depending on the payer policy. Contact your local payers for further instructions. Ask whether the process includes authorization for physician and hospital services. If separate authorizations are needed, find out what information is required to complete the requests. You may want to involve the hospital pre-admission staff to assist in submitting a prior authorization for the hospital services.

Payers may utilize “coverage policies” to identify the specific clinical situations in which the use of a device will be considered to be a covered service, such as which diagnosis codes are appropriate, whether any diagnostic procedures are required prior to the implant of an ILR device, etc. Most payers make their medical coverage policies publicly available through their website or available to their network providers through a secure provider website. Contact your payers to determine whether a coverage policy exists for the use of Reveal ICM or other ILR device.
Coverage Status –
Reveal Insertable Cardiac Monitor
for Arrhythmia Monitoring

Coverage Status – Medicare
In the absence of a specific local coverage determination (LCD) or national coverage determination (NCD),
Medicare coverage is governed by Section 1862 [42 U.S.C. 1395y] of the Social Security Act, which states,
“(a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any
expenses incurred for items or services –

(1)(A) which, ... are not reasonable and necessary for the diagnosis or treatment of illness or injury or to
improve the functioning of a malformed body member”

We encourage providers to contact their Contractor Medical Director to seek coverage clarification for the use
of Reveal ICM for monitoring arrhythmias.

Coverage Status – Non-Medicare
Coverage for implanting a Reveal ICM device to monitor patients with diagnoses other than that of unexplained
syncope has generally not been addressed by third-party payers. Providers should contact their payer directly to
determine coverage. Prior authorization may be required.

Prior Authorization Resource
A sample letter template for Prior Authorization is available through the Medtronic Coding Hotline at
1 (866) 877-4102, option 1 or by contacting your Medtronic representative. You can reach your representative by
calling 1 (800) 633-8766.

Procedure Site of Service

Hospital
CPT 33282 is payable in the inpatient and outpatient settings of a hospital facility (Place of Service codes 21 and
22). The hospital bills for the costs associated with the device and implant procedure, and the physician bills for
the professional services associated with the implant procedure and its 90-day global period.

Ambulatory Surgery Center
CPT 33282 is payable in the Ambulatory Surgery Center (Place of Service code 24). The ASC facility bills for the
costs associated with the device and implant procedure, and the physician bills for the professional services
associated with the implant procedure and its 90-day global period.

Physician Office
If a physician determines it is clinically appropriate to implant a Reveal ICM in his or her office (Place of Service
code 11), they should be aware that the current US reimbursement system does not provide for payment of the
Practice Expense RVUs associated with the implant procedure in this setting. Therefore, a physician will receive
payment only for his or her professional services when implanting a Reveal device in the office setting.