



Frequently Asked Questions Regarding Medtronic CRDM Investigational Device Exemption (IDE) Trials

Medtronic is providing this information to assist you in properly coding claims in IDE clinical trials. Nevertheless, these coding suggestions 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.

SEEKING COVERAGE FOR A CATEGORY B CLINICAL TRIAL: MEDICARE

Does a Category B designation assure coverage and payment by Medicare?

No. While the Category B designation makes the trial eligible for Medicare coverage, it does not require Medicare Contractors to cover and pay for the trial. The decision to cover and pay for those services is at their discretion and will be based on the consideration of "Reasonable and Necessary."

Is an IDE number on the claim of a Category B device sufficient to ensure coverage?

No. While the IDE number is an important component of claims submission, it is not sufficient to ensure coverage. A coverage decision should be sought from your local Medicare Contractor.

Is a coverage decision needed by my local Medicare contractor(s)?

Yes. To ensure compliance, a coverage decision should be pursued and received by your local Medicare Contractor(s). For those who still have a Part A and Part B Medical Director, it is possible for Medicare Part A and Part B to disagree regarding coverage (split decision). If this occurs, in some cases, Medtronic may work with a site to appeal a denial of coverage.

Does each Medicare subject need a separate coverage decision?

No. If the request is approved, Medicare typically provides an approval for the site to enroll participants under the IDE (umbrella approval).

How long will it take to receive a coverage decision from Medicare?

There is no established norm for Medicare response time. Response time for a Medicare decision may depend on a number of factors, such as the number of other clinical trials currently under review and the completeness of the information provided to the Medicare reviewer.

Who would submit the request to Medicare?

The institution would submit the request to Medicare. Medtronic may provide reimbursement materials relating to your clinical trial to the research coordinator and the hospital compliance officer or other designated hospital contacts to support the request.

If my local Medicare Contractor(s) agrees to cover a Category B trial, does that mean that follow-up services will be covered?

Not necessarily. Services considered standard follow-up (e.g., echocardiogram once a year) should be eligible for coverage. However, any service that is being performed to solely meet the clinical trial's protocol requirements and/or data collection would not be eligible for coverage and should not be billed to Medicare. Compensation for these services is addressed in the clinical trial agreement.

SEEKING COVERAGE FOR A CATEGORY B CLINICAL TRIAL: NON-MEDICARE PAYERS

Why would I submit to non-Medicare payers (commercial payers or Medicaid)? Won't they deny coverage?

The clinical trial agreement between your institution and Medtronic requires you to seek a coverage decision/prior authorization from non-Medicare payers. Some non-Medicare payers will provide coverage; others will deny coverage.

If a non-Medicare payer approves a patient's participation in a clinical trial, does that mean that the payer will cover all follow-up services?

Not necessarily. Services considered standard follow-up (e.g., echocardiogram once a year) should be eligible for coverage. However, any service that is being performed solely to meet the clinical trial's protocol requirements and/or data collection would not be eligible for coverage and should not be billed to non-Medicare payers. Compensation for these services is addressed in the clinical trial agreement.

DENIAL OF COVERAGE

What if Medicare or a patient's non-Medicare payer denies coverage?

Please contact the CRDM Clinical Reimbursement Compliance Group at 1 (800) 328-2518, extension 62940 or 62942 to discuss "next steps." Medtronic may help with an appeal letter if it is determined that an appeal is required.

SPECIFIC BILLING REQUIREMENTS FOR MEDICARE*

Are there billing requirements to identify a clinical trial claims submission?

Yes. All claims related to a clinical trial (both hospital claims and physician claims) should include the unique IDE number in order to identify the specific clinical trial. In addition, depending on the type of claim submitted, and the payer, there should also be a Hospital Claim Identifier or Physician Claim Modifier, as noted below.

Hospital Claim Identifier

When medical devices are implanted and associated procedures are performed under an FDA Investigational Device Exemption (IDE) Trial, Revenue Code 624 should be added to the hospital claim for the medical device. This will identify the medical device is part of a clinical trial.

Physician Claim Modifier

Physician claims (submitted on the CMS-1500 form) should append the 'Q0' modifier to the specific CPT code(s) used for investigational clinical trial procedures. In addition, claims should append the 'Q1' modifier to specific CPT code(s) to identify those items and services that are covered for Medicare beneficiaries outside of the clinical research study, e.g., routine device interrogations.

**These requirements may or may not be applicable to non-Medicare payers. Please check billing requirements with the payer.*

May I also bill payers for services that have been compensated by Medtronic under the Clinical Trial Agreement (CTA)?

No. Through its clinical trial agreement, Medtronic pays for services that are required by the protocol and that are not standard care. It is not permissible to bill for these services again through claims to payers.

OTHER COVERAGE AND PAYMENT CONSIDERATIONS

Why doesn't Medtronic pay for the co-payments for trial participants?

Routine waiver of Medicare co-payments and deductibles is subject to law enforcement scrutiny to sponsors and providers.

Who is responsible for covering costs associated with a complication?

Medicare

According to the Federal Register Vol. 60, No. 181, September 19, 1995, Section 48420, "Services furnished to address complications arising from the use of the device (and that are not incident to normal recovery) may be covered."

Non-Medicare payer

Contact the non-Medicare payer.

May I enroll uninsured patients?

Please discuss this with your Medtronic clinical trial manager.

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