



MEDICARE COVERAGE OF CLINICAL TRIALS

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CLINICAL TRIAL COVERAGE

- Medicare has **3** coverage policies for clinical trials/studies. (Note: CMS uses the word “trial” and “study” interchangeably. A registry may sometimes also be considered a study.)
 1. The Clinical Trial Policy (CTP)
 2. Coverage with Evidence Development (CED)
 3. The Investigational Device Exemption (IDE) rule

THE CLINICAL TRIAL POLICY (CTP)

Medicare may cover:

- 1. Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA;**
- 2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, and VA;**
- 3. Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and**
- 4. Drug trials that are exempt from having an IND...**

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THE CLINICAL TRIAL POLICY (CTP)

- Medicare covers the routine costs of qualifying clinical trials, and s reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials.
- Routine costs of a clinical trial include
 - Items or services that are typically provided absent a clinical trial (e.g., conventional care);
 - Items or services required solely for the provision of the investigational item or service, the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
 - Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications

THE CLINICAL TRIAL POLICY (CTP)

- **Routine costs of a clinical trial do not include:**
 - The investigational item or service, itself unless otherwise covered outside of the clinical trial;
 - Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; and
 - Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

COVERAGE WITH EVIDENCE DEVELOPMENT (CED)

- **CMS may cover an item or service only in a clinical trial, study, or registry**
- **The CED national coverage decision (NCD) comes after a review of the medical literature indicates that more evidence is needed.**
- **CMS issues coding instructions with each CED NCD**

THE INVESTIGATIONAL DEVICE EXEMPTION (IDE) RULE

- Medicare may cover items and services in FDA-approved IDE trials/studies
- **Category A IDE studies**
 - Device **not** covered
 - Routine services covered if study meets standards
- **Category B IDE studies**
 - Device and routine services covered if study meets standards

MANDATORY REPORTING OF THE 8-DIGIT CLINICAL TRIALS NUMBER (NCT)

- **The NCT identifier number is assigned by the National Library of Medicine (NLM) at <http://clinicaltrials.gov/> website when a new study appears in the NLM Clinical Trials data base.**
- **The NCT identifier number allows CMS to:**
 - **Track Medicare payments,**
 - **Ensure that the information gained from the research is used to inform coverage decisions, and,**
 - **Make certain that the research focuses on issues of importance to the Medicare population.**

CLINICAL TRIAL/STUDY/REGISTRY CODING

- ❖ **Claims for CMS approved or qualified trials/
studies/registries under CTP, CED, and IDE are
all coded the same way**

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CLINICAL TRIAL/STUDY/REGISTRY CODING

Billing for routine costs in qualified clinical trials or IDE studies (instructions are located in the Medicare Claims Processing Manual, Chapter 32, Section 69.2)

- HCPCS modifier 'Q1'
- ICD-9 diagnosis code V70.7
- Mandatory 8-digit clinical trial number
- IDE number for IDE studies

CLINICAL TRIAL/STUDY/REGISTRY CODING

Billing for the experimental item or service in CED studies (note: instructions are specific to each NCD)

- HCPCS modifier 'Q0'
- ICD-9 diagnosis code V70.7
- Mandatory 8-digit clinical trial number

CLINICAL TRIAL/STUDY/REGISTRY CODING

**Billing for a category B device in an IDE study/trial
(instructions are located in the Medicare Claims
Processing Manual, Chapter 32, Section 68.4)**

- HCPCS modifier 'Q1'
- ICD-9 diagnosis code V70.7
- Mandatory 8-digit clinical trial number
- IDE number

RESOURCES

- **MLN Matters:**
<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8401.pdf>
- **Claims Processing Manual:**
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c32.pdf>
- **ClinicalTrials.gov**
- **CMS Coverage with Evidence Development:**
<http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>