# Clinical Trials/Studies/Registry Claims

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## Scope and history

This guide applies to all providers, non-physician providers and subcontractors who submit surgical service claims. The purpose of this guide is to provide direction on CareOregon policy for all Clinical Trial/Studies/Registry claims submitted.

The Centers for Medicare & Medicaid Services (CMS) defines: Clinical Trial is a scientifically controlled study of the safety and effectiveness of a therapeutic agent (as a drug or vaccine) using consenting human subjects. Typically includes investigational medicinal products.

Clinical Trial Studies are similar to clinical trials except they do not involve investigational medicinal products.

Clinical Trial Registry is a long-term study of a device. To observe and record information in relation to the device, such as implantation, design flaw, if a patient develops allergies to the device, or the material of the device is made from, and/or failure/malfunction of the device.

## Cost sharing

**Medicare (Original):**

Medicare pays for the costs of routine services provided to a Medicare Advantage (MA) enrollee who joins a qualifying clinical trial, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participating in qualifying clinical trials. All other Medicare rules apply.

Section 2709 of the ACA set forth a national minimum coverage standard for approved clinical trials. “Medicare does not cover investigational items and services or services provided solely for the purpose of data collection and analysis. This includes provisions for coverage of any phase that are conducted in relation to any life-threatening disease.

The clinical trial must:

- have been approved by a federal organization
- be conducted under an investigational new drug application
- be reviewed by the US Food and Drug Administration, or be a drug trial that is exempt from the US Food and Drug Administration application review process

**Medicare Advantage Plans (MA):**

In 2011, CMS implemented a requirement on MA plans to pay the difference between original Medicare’s patient cost-share and the MA plan’s patient cost-share for the same items and services. This was passed to encourage participation and access to the clinical trial services for MA members.

**Medicaid:**

Mandatory benefit to cover routine patient costs for items and services furnished in connection with a qualifying clinical trial. OR State Plan Amendment (SPA) Transmittal Number OR-22-0006 4/5/2022.

## Policy/guidelines

CareOregon has moved into alignment with Medicare/Medicaid billing guidelines.

Effective 11/1/2024, CareOregon requires the following information on all claims submitted for clinical trials, clinical trial studies and clinical trial registries:

- diagnosis of Z00.6 in the primary or secondary position
- the 8-digit clinic trial/study/registry number
- modifiers Q0 or Q1
- appropriate value code D4 (used to enter the 8 digital clinical trial number) or FD (used when a credit is received by the manufacturer for a replace medical device)
- condition code 30 (clinical trial)
- when applicable: condition code 53 if it is related to the initial placement of a medical device

Clinical trial claims are always a covered Medicare benefit for members that are eligible for Medicare. Prior to submitting the claim to CareOregon Advantage (COA) plans, or CareOregon Medicaid, the claim must be submitted directly to Medicare. A Medicare Explanation of Payment or Explanation of Benefits will be required for all Medicare eligible members before the claim can be processed by CareOregon.

## References


Medicare Claims Processing Manual (cms.gov)
Extending Medicare Reimbursement in Clinical Trials - NLM
Who Pays for Clinical Trials? - National Cancer Institute
Responsibility for Costs Associated With Clinical Trials - NLM
A Hidden Opportunity — Medicaid's Role in Supporting Equitable Access to Clinical Trials - NLM
Oregon State Plan Amendment (SPA) Transmittal Number OR-22-0006
Registries for Medical Devices - Registries for Evaluating Patient Outcomes - NCBI Bookshelf (nih.gov)





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