Qualifying Clinical Trials

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The National Coverage Decision (NCD) offers specific guidance concerning Clinical Trials Billing.

Under the National Coverage Decision (NCD), Medicare will cover those routine costs of qualifying clinical trials and the costs of items and services that are reasonable and necessary* to diagnose and treat complications arising from participation in all clinical trials (Centers for Medicare and Medicaid Publication 100-3, Ch 1, Part 4, Section 310.1).

What is a Qualifying Clinical Trial?

Deemed Automatically Qualifying Trial (Any one criterion must be "Yes"):

- Is funded/supported by NIH, CDC, AHRQ, CMS, DOD or VA
- Is supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA
- Has an IND number: Trial conducted under an investigational new drug application (IND) reviewed by the FDA
- Trial is exempt from having an IND

Qualifying Criteria (All three criteria must be "Yes"):

- Evaluates a Medicare benefit
- Has therapeutic intent
- Enrolls diagnosed beneficiaries

*Some commonly ordered tests may not be considered “reasonable and necessary” under the NCD, or may be reasonable and necessary at some frequency less than that required by the sponsor in a protocol. See the NCD Alphabetical Index for CMS’ indications and limitations for common procedures.

Routine Costs Provided to Qualifying Clinical Trials

- Items or services required solely for the provision of the investigational item or service (e.g., infusion)
- Items or services typically provided absent a clinical trial
- Clinically appropriate monitoring of the effects of the item or service (e.g., monitoring side effects or complications)
- Prevention of complications
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service (e.g., hydration fluids as part of chemotherapy treatment)

Items Excluded from Routine Costs Provided to Qualifying Clinical Trials

- Items or services provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient or not used to monitor the effects of the item or service (e.g., plasma biomarkers)
- An investigational item or service itself if used in a non-FDA approved way
- Items or services customarily provided by the sponsors free of charge
- Items or services provided solely to determine trial eligibility
- Treatment of healthy volunteers unless used as controls
- Cosmetic surgery, some prosthetics, herbal remedies, relaxation therapies, etc.

Learn more about Qualifying Clinical Trials for Devices.

If you have questions or need assistance, please contact the CTSI for non-cancer studies and JCCC for cancer studies.

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