EmblemHealth

Clinical Trials — Medicare

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Background

The Centers for Medicare & Medicaid Services (CMS) Medicare National Coverage Determination (NCD) for Routine Costs in Clinical Trials is intended to encourage the greater use of clinical trials by Medicare beneficiaries. Medical researchers believe that increased participation in clinical trials could lead to faster development of new treatment options. Assuring Medicare beneficiaries that their routine medical costs will be covered by the plan is expected to increase their participation in clinical trials.

Coverage Statements

1. EmblemHealth does not cover the cost of clinical trials (i.e., the investigational item or service itself, unless otherwise covered outside of the trial, see Limitations/Exclusions).
2. EmblemHealth does cover the routine costs of a qualified clinical trial, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in a qualifying trial.

*Prior approval is **not** required for a Medicare member to enroll in a Medicare-qualified clinical trial. The prior approval is created to allow payment of routine medical costs that would be covered if the member was not in a clinical trial.*

The following routine costs are covered:

1. Items or services that are typically provided absent a clinical trial (e.g., medically necessary conventional care).
2. Items and services required for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent).
3. Items and services required for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications).
4. Items and services regarded as medically necessary for the diagnosis or treatment of complications arising from the provision of an investigational item or service.

Qualified Clinical Trials

The Medicare NCD for Routine Costs in Clinical Trials identifies categories of trials covered by Medicare. In order for a particular trial to be eligible for coverage, it must fall within one of the following categories of clinical trials defined within the Medicare NCD; such as:

1. Trials funded by any of the following sources are automatically qualified:
    a. National Institutes of Health (NIH).
    b. Centers for Disease Control and Prevention (CDC).
    c. Agency for Healthcare Research and Quality (AHRQ).
    d. Centers for Medicare and Medicaid Services (CMS).
    e. Department of Defense (DOD).
    f. Department of Veterans' Affairs (VA).
2. Trials supported by centers or cooperative groups which are funded by the one of the above.
3. Trials of drugs or biologics conducted under an investigational new drug application (IND) reviewed by the Food and Drug Administration (FDA).
4. Drug trials exempt from having an IND applications number.

    These will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that time the principal investigators of these trials must certify that the trial meets the qualifying criteria in order to maintain Medicare coverage of routine costs. This certification process will only affect the future status of the trial and will not be used to retroactively change the earlier deemed status.
5. Coverage with Evidence Development (CED) — refers to items and services in clinical research trials for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a "reasonable and necessary" determination.

In addition, the deemed trial must also meet all four of these basic requirements:

1. The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physician's service, durable medical equipment, diagnostic test) that is not statutorily excluded from coverage [e.g., cosmetic surgery]).
2. The trial must have therapeutic intent and not be designed to exclusively test toxicity or disease pathophysiology.
3. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers (trials of diagnostic interventions may, however, enroll healthy patients in order to have a proper control group).
4. Has desirable characteristics; such as:
    a. The purpose tests interventions to potentially improve health outcomes.
    b. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
    c. The trial does not unjustifiably duplicate existing studies.
    d. The trial design is appropriate to answer the research question being asked in the trial.
    e. The trial is sponsored by a credible organization or individual capable of exacting the proposed trial successfully.
    f. The trial is in compliance with Federal regulations relating to the protection of human subjects.

   g. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

5. If a particular trial falls into a deemed category and meets all of the requirements, it is considered covered. If it does not, it will not be covered by fee-for-service Medicare until qualifying criteria have been developed and the self-certification process and clinical trials registry has been implemented.

Limitations/Exclusions

Medicare, and therefore EmblemHealth, does not approve coverage on a trial–by–trial basis for Medicare members. (Currently, in order for a particular trial to be eligible for Medicare coverage, it must fall within one of the deemed categories of clinical trials as described in the Qualified Trials Section above)

Routine costs do not include any of the following:

1. Experimental or investigational medical and surgical procedures, equipment and medications that are otherwise not covered by Fee-for-Service Medicare or covered under clinical trials.
2. The investigational item or service, itself unless otherwise covered outside of the clinical trial.
3. Items and services for which there is no Medicare benefit category.
4. Items and services which are statutorily excluded.
5. Items and services that fall under a national non-coverage policy.
6. 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 (e.g., monthly CT scans for a condition usually requiring only a single scan).
7. Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

References

Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Routine Costs in Clinical Trials. October 2007. https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&fromdb=true. Accessed September 17, 2019.