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Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

Clinical Trials Policy

Indication/Usage:

The Patient Protection and Affordable Care Act (PPACA) requires non-grandfathered health plans to cover routine patient costs incurred by covered individuals participating in Approved Clinical Trials. Benefits include the reasonable and necessary items and services used to prevent, diagnose, and treat complications arising from participation in a qualifying clinical trial. The covered individual must meet the researcher's clinical criteria for participation in an approved clinical trial.

Medical Indications for Authorization Commercial Members

SummaCare covers medically necessary routine patient care costs in clinical trials (the benefits that would normally cover absent the trial) AND all medically necessary complications when ALL the following criteria has been met.

- All applicable plan limitations for coverage of out-of-network care will apply to routine patient care costs in clinical trials; *and*
- All utilization management rules and coverage policies that apply to routine care for members in clinical trials *and*
- Members must meet all applicable plan requirements for precertification and referrals; *and*
- Documentation of the member's appropriateness for the clinical trial and willingness to participate along with meeting the criteria for approved clinical trials.
- To qualify, a clinical trial must have a written protocol that describes a scientifically sound study and have been approved by all relevant institutional review boards before participants are enrolled.
- The study in which the individual requests participation is a Phase I, - Phase IV clinical trial that is conducted in relation to the prevention, detection or treatment of cancer or other life- threatening disease or condition.
- The trial must funded or approved by ONE of the following:
    1. National Institutes of Health (NIH)
    2. National Cancer Institute (NCI)
    3. Centers for Disease Control and Prevention (CDC)
    4. Agency for Healthcare Research and Quality (AHRQ)
    5. Centers for Medicare and Medicaid Services (CMS)
    6. A cooperative group or center of any of the entities noted above
    7. Department of Defense (DOD)
    8. Department of Veterans Affairs
    9. A qualified non-governmental research

Medicare Members

CMS

NCD ID 310.1 Routine Costs in Clinical Trials

Indications and Limitations of Coverage

Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a

national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

- 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 (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

ROUTINE COSTS IN CLINICAL TRIALS 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 (e.g., administration of a non-covered chemotherapeutic agent), 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.

This policy does not withdraw Medicare coverage for items and services that may be covered according to local coverage determination (LCDs) or the regulations on category B investigational device exemptions found in 42 CFR 405.201-405.215, 411.15, and 411.406. For information about *LCDs,* refer to *https://www.cms.gov/medicare-coverage-database/search.aspx* a searchable database of *Medicare Administrative Contractor* local policies.

For non-covered items and services, including items and services for which Medicare payment is statutorily prohibited, Medicare only covers the treatment of complications arising from the delivery of the noncovered item or service and unrelated reasonable and necessary care. However, if the item or service is not covered by virtue of a national non-coverage policy in Pub. 100-03, National Coverage Determination (NCD) Manual, and is the focus of a qualifying clinical trial, the routine costs of the clinical trial (as defined above) will be covered by Medicare but the non-covered item or service, itself, will not.

A. Requirements for Medicare Coverage of Routine Costs

Any clinical trial receiving Medicare coverage of routine costs must meet the following three requirements:

- 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., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
- The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.

- Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

The three requirements above are insufficient by themselves to qualify a clinical trial for Medicare coverage of routine costs. Clinical trials also should have the following desirable characteristics; however, some trials, as described below, are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
2. 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;
3. The trial does not unjustifiably duplicate existing studies;
4. The trial design is appropriate to answer the research question being asked in the trial;
5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

CPT Codes

- **S9988:** Services provided as a part of a phase I clinical trial
- **S9990:** Services provided as a part of a phase II clinical trial
- **S9991:** Services provided as a part of a phase III clinical trial
- **Modifier Q0:** Investigational clinical service provided in a clinical research study that is in an approved clinical research study
- **Modifier Q1:** Routine clinical service provided in a clinical research study that is in an approved clinical research study

Limitations

SummaCare does not cover the following clinical trial costs

Coverage of routine patient costs incurred by members participating in clinical trials being conducted in relation to the detection of non-life threatening cardiovascular disease, surgical musculoskeletal disorders of the spine, hip and knees and/or other clinical trials related to diseases or conditions that are not life threatening are not currently mandated by PPACA and are left to the determination of the local insurance provider.

- The item or service being evaluated by the trial must meet the definition of covered services or items that are not excluded under the policy.

- Laboratory tests and imaging done at a frequency not consistent with signs and symptoms and standards of care for that disease or condition.

- All travel and transportation expenses, rentals, mileage, meals, lodging.
- Routine patient care expenses incurred out of network where the plan has no out of network benefit.
- The health plan may stipulate the member participate in an in-network provider if the clinical trial is available through an in-network provider.
- The health plan may not deny participation solely because there is no participating in-network provider.

Coverage Decisions

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

Plans Covered By This Policy

Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

Sources Reviewed

CMS

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