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Description:

Clinical trials are research studies designed to evaluate the safety and effectiveness of new medical treatments, drugs, diagnostic tests, and screenings. They are scientific investigations that compare new, untested, or non-standard treatment to standard treatments that are currently accepted and utilized in the medical community. All clinical trials are based on a set of rules called a protocol. The protocol describes all study details including characteristics of people who may or may not participate, the length of the study, schedule of tests, procedures, medications, etc. Clinical trials generally consist of the following four phases:

Phase I: Researchers test a new drug or treatment in a small group of people for the first time to evaluate safety, determine a safe dosage range, and identify side effects.

Phase II: The drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.

Phase III: The drug of treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

Phase IV: Studies are performed after the drug or treatment has been marketed to gather information about its effect in various populations and any side effects associated with long term use.

There are two types of costs associated with a clinical trial: patient care costs and research costs.

Patient care costs fall into two categories:

Usual care costs, such as doctor visits, hospital stays, clinical laboratory tests, x-rays, etc. which occur whether the patient is participating in a trial or receiving standard treatment. These costs are usually covered by a third-party health plan

Extra care costs associated with clinical trial participation, such as the additional tests that may or may not be fully covered by the clinical trial sponsor and/or research institution.

Research costs are those associated with conducting the clinical trial, such as data collection and management, research physician and nurse time, analysis of results and tests purely performed for research purposes. Such costs are usually covered by the organization sponsoring the clinical trial. Costs for the drugs or devices being studied may also be covered by the organization sponsoring the clinical trial.

Qualifying Clinical Trials:

Any clinical trial receiving ODS coverage of usual care costs must meet ALL of the following requirements:

1. The purpose of the trial must be the evaluation of an item or service that is not specifically excluded by the member's plan (e.g. a clinical trial evaluating cosmetic surgery would not be covered); and

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2. The trial must have a therapeutic intent and be designed exclusively to test toxicity or disease pathophysiology; and
3. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy patients in order to have a proper control group; and
4. The trial must be approved and monitored by an Institutional Review Board (IRB); and
5. The trial must be conducted in the United States; and
6. The technology or medication must be a treatment for a condition that is life-threatening and that has a poor prognosis with the most effective available treatment; and
7. The technology or medication must be therapeutic, used to directly improve health outcomes and not for diagnosis, supportive care, disease prevention or screening; and
8. The technology must have approval from the appropriate government regulatory bodies, if applicable:
 - a. *Devices* must be FDA-approved via one of the following processes:
 - i. PMA (Premarket Approval)
 - ii. 510(k)
 - iii. HDE (Humanitarian Device Exemption)
 - iv. IDE (Investigational Device Exemption)

Note: The cost of investigational devices with an IDE are assumed by the manufacturer, as are costs of lab, imaging or other procedures required by the FDA for monitoring the device's effect.
 - b. *Drugs* must have one of the following:
 - i. Final FDA approval for marketing for at least one indication via the NDA (New Drug Application) process
 - ii. IND (Investigational New Drug) approval

Note: The cost of investigational drugs that are not yet FDA approved for any indication are assumed by the pharmaceutical company, as are costs of lab or x-ray procedures required by the FDA for monitoring the drug's effect.
9. The trial does not unjustifiably duplicate existing studies; and
10. The trial is sponsored by a credible organization or individual capable of executing the purpose of the trial successfully; and
11. The trial is in compliance with Federal regulations relating to the protection of human subjects

Criteria for Coverage of Patient Care Costs in Clinical Trials:

ODS will review requests for coverage of clinical trials on a case-by-case basis. If approved, the following care may be covered in relation to the clinical trial:

1. The costs for items and services that ODS would pay for if the member was not in a clinical trial. (i.e. hospital room and board, physician office visits, routine labs and diagnostic tests, etc).
2. The cost for items and services that are needed to treat side effects and complications during the course of the clinical trial.

Limitations:

1. Plan limitations for coverage out-of-network will apply to routine patient care costs incurred during the clinical trial.

Not Covered:

The following services will not be covered by ODS:

1. The investigational item or service itself
2. Exclusions or other limitations of the health plan contract
3. Items and services provided solely to satisfy data collection needs
4. Items and services provided by the trial sponsor without charge

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5. Costs for services identified as member responsibility

Information to be Submitted with Pre-Authorization Request:

1. History and physical
2. Treatment history for the condition for which a clinical trial is being requested
3. A detailed clinical trial protocol
4. A copy of the informed-consent document signed by the patient
5. A copy of the Institutional Review Board (IRB) approval

References:

- www.clinicaltrials.gov
- Clinical Trials and Insurance Coverage. National Cancer Institute. Available at URL address: www.nci.nih.gov/clinicaltrials/learning/insurance-coverage/ accessed on January 15, 2009.
- <http://www.cms.hhs.gov>
- <http://www.cancer.gov/clinicaltrials/developments/laws-about-clinical-trial-costs>
- Physician Advisors