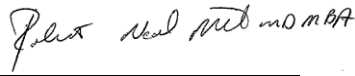


| | |
|--|-------------------------------|
| Origination Date: 1/09 | Revision Date(s): 2/11, 12/11 |
| Developed By: Medical Criteria Committee | |



Approved: Neal Mills MD, MBA **Date:** 3/15/2011

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:

Qualified clinical trials for Oregon members are limited to:

1. Funded, or supported by a center or cooperative group that is funded by the:
 - a. National Institutes of Health
 - b. Centers for Disease Control and Prevention
 - c. Agency for Healthcare Research and Quality
 - d. Centers for Medicare and Medicaid Services
 - e. United states Department of Defense

| | |
|--|-------------------------------|
| Origination Date: 1/09 | Revision Date(s): 2/11, 12/11 |
| Developed By: Medical Criteria Committee | |

- f. United States Department of Veterans Affairs
2. Conducted as an investigational new drug application, an investigational device exemption, or a biologics license application to the United States Food and Drug Administration; **or**
3. Exempt by federal law from the requirement to submit an investigational new drug application to the United States Food and Drug Administration.

Washington members should refer to their member handbook for benefit coverage.

Qualified clinical trials for Alaska members are limited to:

1. An approved clinical which means that it is:
 - a. A scientific study using human subjects designed to test and improve prevention, diagnosis, treatment, or palliative care of cancer, **or**
 - b. The safety and effectiveness of a drug, device, or procedure used in the prevention, diagnosis, treatment, or palliative care of a subject, **and**
2. The study must be approved by
 - a. An institutional review board that complies with 45 CFR Part 46 **and**
 - b. One or more of the following:
 - i. United States Department of Health and Human Services, National Institutes of Health, or its institutes or centers
 - ii. United States Department of Health and Human Services, United States Food and Drug Administration
 - iii. United States Department of Defense
 - iv. United States Department of Veterans Affairs. **or**
 - v. A nongovernmental research entity abiding by current national Institutes of Health guidelines.

Criteria for Coverage of Patient Care Costs in Clinical Trials:

Oregon Members:

ODS will cover routine costs in clinical trials for Oregon members:

1. Routine costs for the care of a member who is enrolled in or participating in a qualifying clinical trial are covered. Routine costs mean medically necessary conventional care, items or services covered by the health care insurance plan if typically provided absent a clinical trial.

ODS will cover the following costs of clinical trials.

Limitations:

1. Routine costs will be subject to the applicable deductible and standard copayment/coinsurance if provided in the absence of a clinical trial.
2. The health care insurance plan is not liable for any adverse effects of a clinical trial.

Not Covered:

The following services will not be covered by ODS:

1. The drug, device or service being tested in the clinical trial unless it would be covered by the ODS plan if provided outside of a clinical trial
2. Items or services required solely for the provision of the drug, device, or service being tested in the clinical trial

| | |
|--|-------------------------------|
| Origination Date: 1/09 | Revision Date(s): 2/11, 12/11 |
| Developed By: Medical Criteria Committee | |

3. Items or services required solely for the clinically appropriate monitoring of the drug, device, or service being tested in the clinical trial
4. Item or services required solely for the prevention, diagnosis, or treatment of complications arising from the provision of the drug, device, or service being tested in the clinical trial
5. Items or services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the member
6. Items or services customarily provided by a clinical trial sponsor free of charge to any person participating in the clinical trial; or
7. Items or services that are not covered by ODS if provided outside of the clinical trial.

Washington Members;

1. Refer to your member handbook for benefit coverage.

Alaska Members:

ODS will cover routine costs in cancer clinical trials for Alaska members:

1. Only if the member's treating physician determines that there is no clear superior noninvestigational treatment alternative **and**
2. Available clinical or preclinical data provide a reasonable expectation that the treatment provided in the clinical trial will be at least as efficacious as any noninvestigational alternative.

The following costs are covered:

1. Prevention, diagnosis, treatment, and palliative care of cancer
2. Medical care for an approved clinical trial related to cancer that would otherwise be covered under a health benefit plan if the medical care were not in connection with an approved clinical trial related to cancer.
3. Items or services necessary to provide an investigational item or service
4. The diagnosis or treatment of complications
5. A drug or device approved by the United States Food and Drug Administration without regard to whether the United States Food and Drug Administration approved the drug or device for use in treating a member's particular condition, but only to the extent that the drug or device is not paid for by the manufacturer, distributor, or provider of the drug or device
6. Services necessary to administer a drug or device under evaluation in the clinical trial
7. Transportation for the member that is primarily for and essential to the medical care

ODS does not cover:

1. A drug or device that is associated with the clinical trial that has not been approved by the United States Food and Drug Administration
2. Housing, companion expenses, or other nonclinical expenses associated with the clinical trial
3. An item or service provided solely to satisfy data collection and analysis and not used in the clinical management of the member
4. An item or service excluded from coverage
5. An item or service paid for or customarily paid for through grants or other funding

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

| | |
|--|-------------------------------|
| Origination Date: 1/09 | Revision Date(s): 2/11, 12/11 |
| Developed By: Medical Criteria Committee | |

References:

- Centers for Medicare & Medicaid Services. (2011). Medical clinical trials policies. Accessed on February 8, 2011 at <http://www.cms.hhs.gov>.
- Clinical Trials and Insurance Coverage. National Cancer Institute. Accessed on February 8, 2011 at: <http://www.cancer.gov/clinicaltrials/education/insurance-coverage/page2>
- National Cancer Institute. (2010). States that require health plans to cover patient core costs in clinical trials. Accessed on February 8, 2011 at <http://www.cancer.gov/clinicaltrials/developments/laws-about-clinical-trial-costs>
- State of Alaska Department of Commerce, Community, and Economic Development Division of Insurance, (2011). Coverage for clinical trials related to cancer. Sec. 21.42.415. Accessed February 8, 2011 at <http://www.legis.state.ak.us/basis/folioproxy.asp?url=http://www.jnu01.legis.state.ak.us/cgi-bin/folioisadll/stattx10/query=21!2E42!2E415/doc/%7B@1%7D?firsthit> .
- State of Oregon Chapter 743A—Health Insurance: Required Reimbursements 2009 Edition. 743A.192 Clinical trials. Accessed on February 8, 2011 at <http://www.leg.state.or.us/ors/743a.html>
- U.S. National Institutes of Health. (2008). Clinical trials. Accessed on February 7, 2011 at www.clinicaltrials.gov
- Physician Advisors