

WellCare Health Plans, Inc.

The WellCare Group of Companies

Clinical Coverage Guideline

WellCare Prescription Insurance, Inc.

*'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.*

WellCare Health Insurance of Illinois, Inc.

WellCare Health Insurance of New York, Inc.

Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

WellCare of Texas, Inc.

WellCare Health Plans of New Jersey, Inc.

WellCare of Florida, Inc.

HealthEase of Florida, Inc.

WellCare of Louisiana, Inc.

WellCare of New York, Inc.

WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

Harmony Health Plan of Illinois, Inc.

WellCare of Ohio, Inc.



Clinical Trials, Coverage of Routine Patient Care Costs

Guideline Number: HS-090

Original Effective Date: 3/16/2009

Revision Date: n/a

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

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DISCLAIMER

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APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

CLINICAL COVERAGE GUIDELINE

Medically necessary routine patient care costs in clinical trials are covered according to the criteria below. All reimbursement policies for members in clinical trials are consistent with policies for members NOT in clinical trials.

Routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care)
- Items and 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
- Items and services needed for necessary treatment of conditions that result from unexpected complications of the trial

Routine costs of a clinical trial DO NOT INCLUDE:

- 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 member
- Items and services customarily provided by the research sponsors free of charge for the enrollee in the trial.

The following limitations apply to the coverage of routine costs in clinical trials:

- A. Members must meet all applicable plan requirements for pre-certification, registration, and referrals, **AND**,
- B. All applicable plan limitations for coverage of out-of-network care will apply to routine patient care costs in clinical trials; **AND**,
- C. All utilization management rules and coverage policies that apply to routine care for members **NOT** in clinical trials will

also apply to routine patient care for members in clinical trials.

Any clinical trial receiving coverage of routine costs MUST meet the following criteria:

- A clinical trial must have a written protocol that describes a scientifically sound study and have been approved by all relevant institutional review boards (IRBs) before participants are enrolled*; **AND**,
- The subject or purpose of the trial must be the evaluation of an item or service that falls within an existing benefit category (e.g., physician's service, durable medical equipment, diagnostic test) and is **NOT** statutorily excluded from coverage (e.g., cosmetic surgery, hearing aid); **AND**,
- The trial must have therapeutic intent, and must not be designed exclusively to test toxicity or disease pathophysiology; **AND**,
- 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); **AND**,
- The principal purpose of the trial is to test whether the intervention potentially improves the participant's health outcomes; **AND**,
- The trial is well-supported by available scientific and medical information of it is intended to clarify or establish the health outcomes of interventions already in common clinical use; **AND**,
- The trial does not unjustifiably duplicate existing studies; **AND**,
- The trial design is appropriate to answer the research question being asked in the trial; **AND**,
- The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully; **AND**,
- The trial is in compliance with Federal regulations relating to the protection of human subjects; **AND**,
- All aspects of the trial are conducted according to the appropriate standards of scientific integrity; **AND**,
- The facility and personnel are properly trained to provide treatment; **AND**,
- There is no alternative noninvestigational therapy that is clearly superior to the treatment being received in the trial

***NOTE:** Providers will not routinely be required to submit documentation about the trial to WellCare but WellCare can, at any time, request such documentation to confirm that the clinical trial meets current standards for scientific merit and has relevant IRB approval.

Clinical trials that are deemed to be automatically qualified for coverage of routine costs are:

- Trials funded by NIH, CDC, AHRQ, CMS, DOD and VA; **OR**,
- Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA; **OR**,
- Trials conducted under an investigational new drug application (IND) reviewed by the FDA.

BACKGROUND

Although there are many definitions of clinical trials, they are generally considered to be biomedical or health-related research studies in human beings that follow a pre-defined protocol. This includes both interventional and observational types of studies. Interventional studies are those in which the research subjects are assigned by the investigator to a

treatment or other intervention, and their outcomes are measured. Observational studies are those in which individuals are observed and their outcomes are measured by the investigators.

All clinical trials have guidelines about who can participate. Using inclusion/exclusion criteria is an important principle of medical research that helps to produce reliable results. The factors that allow someone to participate in a clinical trial are called "inclusion criteria" and those that disallow someone from participating are called "exclusion criteria". These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. Before joining a clinical trial, a participant must qualify for the study. Some research studies seek participants with illnesses or conditions to be studied in the clinical trial, while others need healthy participants. It is important to note that inclusion and exclusion criteria are not used to reject people personally. Instead, the criteria are used to identify appropriate participants and keep them safe. The criteria help ensure that researchers will be able to answer the questions they plan to study.

Informed Consent

Informed consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate. It is also a continuing process throughout the study to provide information for participants. To help someone decide whether or not to participate, the doctors and nurses involved in the trial explain the details of the study. If the participant's native language is not English, translation assistance can be provided. Then the research team provides an informed consent document that includes details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document. The participant then decides whether or not to sign the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time.

Study Protocols

A protocol is a study plan on which all clinical trials are based. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment.

Phases of Clinical Trials

Clinical trials are conducted in phases. The trials at each phase have a different purpose and help scientists answer different questions:

In Phase I trials, researchers test an experimental drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

In Phase II trials, the experimental study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.

In Phase III trials, the experimental study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.

In Phase IV trials, post marketing studies delineate additional information including the drug's risks, benefits, and optimal use.

CODING

CPT Codes

Medically necessary routine patient care procedures in clinical trials are covered according to the criteria above.

ICD-9-CM Procedure Codes

No applicable codes

HCPCS Codes

No applicable codes

Covered ICD-9-CM Diagnosis Codes

V70.7 Examination of participant in Clinical Trial

***Current Procedural Terminology (CPT®) ©2009 American Medical Association: Chicago, IL.**

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS), National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1). October 9, 2007.
2. Centers for Medicare and Medicaid Services Decision Memo for Clinical Trial Policy (CAG-00071R). July 9, 2007.
3. Centers for Medicare and Medicaid Services Decision Memo for Clinical Trial Policy (CAG-00071R2). October 17, 2007.
4. Understanding Clinical Trials. On clinicaltrials.gov. September 20, 2007.