



*Easy Choice Health Plan*

*Harmony Health Plan of Illinois*

*Missouri Care*

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

*OneCare (Care1st Health Plan Arizona, Inc.)*

*Staywell of Florida*

*WellCare (Arizona, Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)*

*WellCare Prescription Insurance*

*WellCare Texan Plus (Medicare – Dallas & Houston markets)*

## Clinical Trials Coverage of Routine Patient Care Costs

Policy Number: HS-090

Original Effective Date: 3/16/2009

Revised Date(s): 3/31/2010; 3/31/2011;  
3/1/2012; 2/7/2013; 12/5/2013; 11/6/2014;  
12/6/2014; 10/1/2015; 10/6/2015; 7/6/2017;  
6/7/2018

### 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.

### DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). 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 CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on [www.wellcare.com](http://www.wellcare.com). Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

### 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** 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.

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.

#### *Coverage for Participants in Approved Clinical Trials (Patient Protection and Affordable Care Act of 2010 - PPACA)*

Section 10103(c) of PPACA added a new provision to the federal Public Health Service Act which imposes requirements on group health plans and health insurance issuers offering individual or group health insurance products to provide for coverage of routine patient costs associated with approved clinical trials. The provision, a new section 2709 of the Public Health Service Act, provides as follows:

**Prohibition on denials of coverage or on discrimination.** With respect to plan years beginning on or after January 1, 2014, if a group health plan or health insurance issuer offering group or individual coverage provides coverage to a qualified individual, then the plan or issuer is prohibited, under federal law, from:

1. Denying the individual participation in an approved clinical trial.
2. Denying or limiting, or imposing additional conditions on, the coverage of routine patient costs for items or services furnished in connection with participation in the approved clinical trial.
3. Discriminating against the individual on the basis of the individual's participation in an approved trial.

**Qualified individual.** A qualified individual is defined under the law as an individual who is enrolled or participating in a health plan or coverage and who is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or another life-threatening disease or condition. To be a qualified individual, there is an additional requirement that a determination be made that the individual's participation in the approved clinical trial is appropriate to treat the disease or condition. Determination can be made based on the referring provider's conclusion or based on the provision of medical and scientific information by the individual.

**Routine patient costs.** The term "routine patient costs" is also defined for purposes of these new federal requirements. With some important exceptions, routine patient costs generally include all items and services consistent with the coverage provided under the plan (or coverage) for a qualified individual (viz. for treatment of cancer or another life threatening disease or condition) who is not enrolled in a clinical trial. However, costs associated with the following are excluded from that definition, and the plan or issuer is not required under federal law to pay for the following:

1. The cost of the investigational item, device or service.
2. The cost of items and services provided solely to satisfy data collection and analysis needs and that are not used in direct clinical management.
3. The cost for a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

**Approved clinical trial.** The term "approved clinical trial" is defined in the statute as a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition and is one of the following:

1. A federally funded or approved trial.
2. A clinical trial conducted under an FDA investigational new drug application.
3. A drug trial that is exempt from the requirement of an FDA investigational new drug application.

**Network providers.** With respect to an individual's right to select providers, a plan or issuer may require the individual to participate in the approved clinical trial through a participating provider, if the provider will accept the individual as a participant in the trial. However, this authority granted to a plan or issuer does not preclude a qualified individual from participating in an approved clinical trial conducted outside the state where the individual resides. The provision includes a number of clarifications of the intent of Congress with respect to new federal requirements on plans and issuers. One clarification is that these new requirements are not intended to require a plan or issuer to provide benefits for routine patient services out of network unless out of network benefits are otherwise provided under the plan or coverage. Another is that the requirements imposed under this section are not intended to limit a plan's or issuer's coverage with respect to clinical trials—these are to be regarded as minimum requirements on plans and issuers.

**Effective date.** New federal requirements apply generally to group health plans and health insurance coverage offered for plan years beginning on or after January 1, 2014. Thus, the requirements will apply to plans and coverage sold after 2013 in the individual and small group markets, as well as to large group plans, including self-insured plans, and it will also apply to health plans offered under the Federal Employees Health Benefit Program (FEHBP).

**Limited application of requirements.** It is important to emphasize that these new federal requirements will not apply to grandfathered health plans. Under section 1251 of PPACA, a grandfathered health plan is a group health plan or health insurance coverage in which an individual was enrolled on the date of enactment (3/23/2010) and, unless otherwise specified, is exempt from the requirements of Title I of the Act. A grandfathered plan retains its status even though (1) family members are permitted to enroll after 3/23/2010; and (2) for group health plans, new

employees and their families are permitted to enroll in the plan after that date. Given that initially the vast majority of group health plans and health insurance coverage will be grandfathered, the impact of the application of these new federal requirements is far from sweeping.

**Interaction with state laws.** Section 2709 of the Public Health Service Act (the section imposing these new federal requirements for coverage of approved clinical trials) makes it very clear that it does not preempt any state laws that require a clinical trials policy for state regulated plans that is in addition to the policy required under this section. Thus the federal requirements are minimums; states may impose additional requirements.

**Implications for patients.** The answers to the specific questions that patients, practitioners, and group health plans and issuers will pose about the implications of this provision should first be addressed in the federal regulations that are promulgated to carry out the statutory intent of Congress. Regulations will afford the public notice and opportunity for comment. However, it is unclear whether a patient or provider will find the answers to all questions even with a careful regulatory process. Patients will have to consult with the plan or issuer for guidance on available coverage, and providers would be well-advised to follow federal and to the extent it is applicable state regulatory requirements on plans for required coverage of costs associated with treatment under an approved clinical trial.

## POSITION STATEMENT

### Applicable To:

- Medicaid
- Medicare

Medically necessary routine patient care costs in clinical trials **are covered** in Phase II and Phase III trials only, according to the criteria below. All Clinical Trial requests must be approved by a Medical Director. In addition, the criteria below must be met. 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:

- Members must meet all applicable plan requirements for pre-certification, registration, and referrals, **AND**,
- 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 **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 includes:
  - The therapeutic intent of the study; **AND**,

- A description that specifies it is a scientifically sound study that has received all necessary approvals by all relevant institutional review boards (IRBs) before participants are enrolled; **AND**,
- What is covered and provided by the trial and services requested for coverage by WellCare; **AND**,
- Documentation of informed consent for participation in the clinical trial in a manner consistent with current legal and ethical standards.

**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 non-investigational therapy that is clearly superior to the treatment being received in the trial.

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.

## CODING

### CPT © Codes

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

**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

Condition Code: 30 in addition to application of modifiers

**HCPCS Level II® Codes**

- S9992** Transportation costs to and from trial location and local transportation costs (e.g., fares for taxicab or bus) for clinical trial participant and one caregiver/companion
- S9994** Lodging costs (e.g., hotel charges) for clinical trial participant and one caregiver/companion
- S9996** Meals for clinical trial participant and one caregiver/companion
- 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
- G0293** Non-covered surgical procedure(s) using conscious sedation, regional, general or spinal anesthesia in a Medicare qualifying clinical trial, per day
- G0294** Non-covered surgical procedure(s) using either no anesthesia or local anesthesia only, in a Medicare qualifying clinical trial, per day

**Covered ICD-10-CM Diagnosis Codes**

- Z00.6** Encounter for examination for normal comparison and control in clinical research program

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

**REFERENCES**

1. Decision memo for clinical trial policy (CAG-00071R2). Centers for Medicare and Medicaid Services Web site. <http://www.cms.hhs.gov/mcd/search.asp>. Published October 17, 2007. Accessed June 1, 2018.
2. Centers for Medicare and Medicaid Services Web site. National coverage determination for routine costs in clinical trials (310.1). <http://www.cms.hhs.gov/mcd/search.asp>. Published October 9, 2007. Accessed June 1, 2018.
3. Decision memo for clinical trial policy (CAG-00071R). Centers for Medicare and Medicaid Services Web site. <http://www.cms.hhs.gov/mcd/search.asp>. Published July 9, 2007. Accessed June 1, 2018.
4. Understanding clinical trials. U.S. National Institutes of Health Web site. <http://clinicaltrials.gov>. Published September 20, 2007. Accessed June 1, 2018.

**MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS**

Date	Action
6/7/2018, 7/6/2017, 10/1/2015	<ul style="list-style-type: none"> <li>• Approved by MPC. No changes.</li> </ul>
12/4/2014	<ul style="list-style-type: none"> <li>• Approved by MPC. Included language re: Patient Protection and Affordable Care Act of 2010.</li> </ul>
11/6/2014	<ul style="list-style-type: none"> <li>• Approved by MPC. No changes.</li> </ul>
12/5/2013	<ul style="list-style-type: none"> <li>• Approved by MPC. Changes reflect required documentation for approval. Applies to Medicaid as well.</li> </ul>
2/7/2013, 3/1/2012	<ul style="list-style-type: none"> <li>• Approved by MPC. No changes.</li> </ul>
12/1/2011	<ul style="list-style-type: none"> <li>• New template design approved by MPC.</li> </ul>
3/31/2011	<ul style="list-style-type: none"> <li>• Approved by MPC.</li> </ul>