Missouri Care

WellCare (Nebraska)

Clinical Trials:
Policy Number: CP.MP.94

Last Review Date: 06/20

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. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

This policy was adapted from Medicare Coverage ~ Clinical Trials, Final National Coverage Decision policy.

POSITION STATEMENT

Medical necessity guidelines for routine costs of clinical trials in accordance with Centers for Medicare & Medicaid (CMS) and the Patient Protection and Affordable Care Act (PPACA) requirements.

Note: For experimental technologies, refer to *CP.MP.36 Experimental Technologies*

Policy/Criteria

Routine costs of a qualifying clinical trial and services used to diagnose and treat complications arising from participating in a qualifying clinical trial are **medically necessary** based upon the following guidelines and limitations:

I. *Routine costs in a clinical trial include all items and services generally considered medically necessary and a covered benefit to Plan members that are provided in either the experimental or control arms and include:*
- A. Items or services that are typically provided absent a clinical trial, and
- B. Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapy agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- C. 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.

II. *Excluded costs/services*
- A. The investigational item or service itself, and

B. 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
C. Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

III. *Administrative limitations*
A. All applicable Plan limitations for coverage of out-of-network care applies to routine costs in a clinical trial; and
B. All existing utilization management guidelines apply to routine care for members in clinical trials, including prior-authorization and notification requirements; and

IV. *Qualifying clinical trials must meet the following:*
A. The clinical trial must have a written protocol that describes a scientifically sound study and be approved by all relevant institutional review boards (IRBs); and
B. The subject or purpose of the trial must be the evaluation of an item or service that falls within a covered benefit category (i.e. physician's service, durable medical equipment, diagnostic test, et al); and
C. The trial must have therapeutic intent and not solely designed to test toxicity or disease pathophysiology; and
D. Trials of therapeutic interventions must enroll patients with the diagnosed disease; trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.
E. Trials must be federally-funded or approved by one of the following groups:
   1. Agency for Healthcare Research and Quality (AHRQ); or
   2. Centers for Disease Control and Prevention (CDC); or
   3. Centers for Medicare and Medicaid Services (CMS); or
   4. National Institutes of Health (NIH); or
   5. A cooperative group or center of any of the above listed entities or the Department of Defense (DoD) or Department of Veterans Affairs (VA); or
   6. A qualified nongovernmental research entity identified in the guidelines issued by the NIH for center support grants; or
   7. The Departments of VA, DoD, or Energy (DoE) if the trial has been reviewed and approved through a system of peer review comparable to the system used by the NIH and that ensures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review; or
   8. The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration (FDA); or
   9. The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

REFERENCES

1. Centers for Medicare and Medicaid. National Coverage Determination for routine costs in clinical trials (301.1). 2007 Oct 9. http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&bc=BAABAAAAAAAA& Accessed 5/21/20
2. Patient Protection and Affordable Care Act and Health-Related Portions of the Health Care and Education Reconciliation Act Of 2010. 42 U.S.C. § 18001 et seq. (2010). https://www.hhs.gov/sites/default/files/ppacacon.pdf?language=es Accessed 5/21/20
3. US National Institutes of Health. ClinicalTrials.gov. http://clinicaltrials.gov/ct2/home Accessed 5/21/20

REVIEWS, REVISIONS, AND APPROVALS

	Date	Approval Date
Policy developed	12/13	01/14
References reviewed	01/15	01/15
Converted into new template Added parameters for what qualifies as a "qualified clinical trial" in IV.E	01/16	01/16
References reviewed	12/16	12/16
References reviewed	11/17	12/17
References reviewed.	09/18	10/18
References reviewed and updated.	10/19	10/19
Added reference to CP.MP.36 Experimental Technologies. References reviewed and updated.	06/20	06/20