Clinical Policy: Clinical Trials

Reference Number: IN.CP.MP.94
Date of Last Revision: 07/26 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
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

I. It is the policy of health plans affiliated with Indiana Managed Health Services that 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.[1,2]

A. Routine costs in a clinical trial include all items and services generally considered medically necessary and a covered benefit to Plan members/enrollees that are provided in either the experimental or control arms and include:
   1. Items or services that are typically provided absent a clinical trial;
   2. 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;
   3. 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~~.~~;

B. Excluded costs/services:
   1. The investigational item or service itself;
   2. 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);
   3. Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial;

C. Administrative limitations:
   1. All applicable Plan limitations for coverage of out-of-network care applies to routine costs in a clinical trial;
   2. All existing utilization management guidelines apply to routine care for members/enrollees in clinical trials, including prior-authorization and notification requirements;

D. Qualifying clinical trials must meet the following:
   1. The clinical trial must have a written protocol that describes a scientifically sound study and be approved by all relevant institutional review boards (IRBs);

2. 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, etc.);
3. The trial must have therapeutic intent and not solely designed to test toxicity or disease pathophysiology;
4. Trials of therapeutic interventions must enroll members/enrollees with the diagnosed disease (trials of diagnostic interventions may enroll healthy patients in order to have a proper control group);
5. Trials must be federally-funded or approved by one of the following groups:
   a. Agency for Healthcare Research and Quality (AHRQ);
   b. Centers for Disease Control and Prevention (CDC);
   c. Centers for Medicare and Medicaid Services (CMS);
   d. National Institutes of Health (NIH), including institutes such as the National Institute of Mental Health (NIMH), National Institute on Drug Abuse (NIDA), National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute of Child Health and Human Development (NICHD), and National Institute on Aging (NIA);
   e. A cooperative group or center of any of the above listed entities or the Department of Defense (DoD) or Department of Veterans Affairs (VA);
   f. A qualified nongovernmental research entity identified in the guidelines issued by the NIH for center support grants;
   g. The Departments of VA, DoD, or Department of 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;
   h. The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration (FDA);
   i. The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

Background

This policy was adapted from Medicare Coverage ~ Clinical Trials, Final National Coverage Decision policy. Additionally, the criteria are supported by provisions of the Patient Protection and Affordable Care Act and incorporate recognition of federal agencies and institutes that fund behavioral health clinical trials.[2,5,6,7,8,9,10,11,12]

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Plan specific policy developed based on CP.MP.94.	07/26	

References

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical

policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Member/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.

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