MEDICAL POLICY

POLICY TITLE	CLINICAL TRIALS
POLICY NUMBER	MP 2.010

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**RETIRED 2/1/2026**

I. POLICY

Interventions within Clinical Trials
Coverage for an intervention within a clinical trial will be reviewed on an individual basis and must meet **all** of the following criteria:

1) The study or investigation is approved, funded (which may include funding through in-kind contributions), and/or conducted by one or more of the following:
   a) U.S. government, including, but not limited to:
      i) The National Institutes of Health.
      ii) The Centers for Disease Control and Prevention.
      iii) The Agency for Health Care Research and Quality.
      iv) The Centers for Medicare & Medicaid Services.
      v) Department of Defense.
      vi) Department of Veterans Affairs.
   b) A qualified non-governmental research entity that meets criteria issued by the National Institutes of Health for center support grants, including but not limited to additional sites conducting research with such an entity, including approval and oversight by an Institutional Review Board. (IRB)
2) The study is not otherwise funded by a pharmaceutical, medical device, or other commercial entity.

Routine Patient Costs associated with Clinical Trials

Patient Protection and Affordable Care Act of 2010 (PPACA) does not require group health plans or health insurance issuers to cover the costs of the approved clinical trial itself, but rather just the routine patient costs (e.g., laboratory services) associated with the clinical trial.

Coverage of routine patient costs associated with any clinical trial do not include the following:

1. The investigational drug, biological product, device, medical treatment or procedure itself;
2. Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient;
3. Any service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis;
4. Services and supplies customarily provided by the research sponsors free of charge for any enrollee in the approved clinical trial;
5. Member travel expenses.

II. PRODUCT VARIATIONS TOP

This policy is applicable to all programs and products administered by Capital Blue Cross unless otherwise indicated below.

FEP PPO:

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies .

III. DESCRIPTION/BACKGROUND TOP

Clinical Trials
A clinical trial is a strictly regulated scientific study of a new therapy or device for the treatment, palliation, or prevention of disease in human beings. The purpose of clinical trials is to help investigators discover new ways to treat illness and improve healthcare.

IV. RATIONALE TOP

N/A

V. DEFINITIONS TOP

N/A

VI. BENEFIT VARIATIONS TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and

providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

TOP

Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Services not covered:

Procedure Codes							
S9992	S9994	S9996					

Covered when medically necessary:

Procedure Codes							
S9988	S9990	S9991					

ICD-10-CM Diagnosis Code	Description
Z00.6	Encounter for examination for normal comparison and control in clinical research program

IX. REFERENCES

TOP

Clinical Trials

1. *ClinicalTrials.gov. U.S. National Institutes of Health*

2. *Center for Medicare and Medicaid Services National Coverage Determination 310.1, NCD for Routine Costs in Clinical Trials. CMS.*
3. *Food and Drug Administration (FDA) Access to Investigational Drugs Outside of a Clinical Trial (Expanded Access)*
4. *Guidance for Industry Expanded Access to Investigational Drugs for Treatment Use — Qs & As*
5. *National Cancer Institute: Cancer Facts. Clinical Trials: Questions and Answers. Last*
6. *PPACA and HCERA Provisions Amending Public Health Service Act SEC. 2709. Coverage for Individuals Participating in Approved Clinical Trials.*
7. *Centers for Medicare and Medicaid Services (CMS) Medicare Benefit Policy Manual. Publication 100-02. Chapter 14 Section 20. Medical Devices. Effective 11/6/14.*

X. POLICY HISTORY

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MP 2.010	**03/20/2020 Consensus Review**. Policy Statements unchanged. References updated. Coding reviewed. Product variations updated.
	02/11/2021 Consensus Review. Policy statement unchanged. References and coding reviewed.
	07/01/2021 Administrative Review. New code 0646T added to the policy as investigational.
	09/30/2022 Major Review. Transferred Expanded Access to new policy. Updated the criteria for clinical trials. Updated criteria. Removed code 0646T.
	01/13/2023 Minor Review. Transferred additional expanded access to new policy, MP 2.386. Updates to criteria.
	04/19/2024 Consensus Review. No change to policy statement
	08/04/2025 Consensus review. No change to policy statement.

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