BENEFIT COVERAGE POLICY

Title: BCP-83 Clinical Trials

Effective Date: 04/01/2024

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following coverage policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Coverage determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

Health Plan covers medically necessary routine patient care costs and services related to an approved clinical trial for a qualified individual consistent with the Affordable Care Act (ACA) according to the indications and limitations outlined below.

For all non-network covered services to be paid at the network benefit level except for emergency/urgent services, prior approval is required.

Refer to the member's benefit coverage document for specific benefit descriptions, guidelines, coverage, and exclusions.

Health Plan covers routine patient care costs associated with an approved clinical trial and will include coverage of routine costs in clinical trials including services that are typically covered for a member who is not enrolled in a clinical trial.

All prior approval requirements and coverage policies that apply to routine care for members, not in clinical trials also apply to routine patient care for members in clinical trials.

All applicable plan limitations for out-of-network care will apply to routine patient care costs in the clinical trials when performed by an out-of-network provider.

The purpose of the trial must be a service that is consistent with the coverage provided in the benefit plan for the qualifying member and is not a specific exclusion.

2.0 Background:

Clinical Trials are a type of research that studies new tests and treatments and evaluates their effects on human health outcomes. People volunteer to take part in clinical trials to test medical interventions including drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioral treatments, and preventive care (WHO, 2023).

Clinical trials are carefully designed, reviewed, and completed, and need to be approved before they can start. People of all ages can take part in clinical trials, including children.

The Food and Drug Administration tests medicine and medical devices to ensure safety and effectiveness before they're released to the public. Clinical trials are based on a set of rules called

protocols that describe eligibility, test schedules, procedures, medications, and study length. The research staff regularly monitors participants' health and determines the safety and effectiveness of the treatment. Participants may decline to be a part of the trial or withdraw from it at any time. (AHA, 2023)

Biomedical clinical trials of an experimental treatment, device, or behavioral intervention may proceed through four phases:

- **Phase I –** Test a new biomedical intervention in a small group of people (e.g. 20-80) for the first time to evaluate safety (e.g., determine a safe dosage range and identify side effects).
- **Phase II –** Study the biomedical or behavioral intervention in a larger group of people (100-300) to further evaluate safety.
- **Phase III –** Study to determine the efficacy of the biomedical or behavioral intervention in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and collect information that will allow the interventions to be used safely.
- **Phase IV –** trial takes place after the FDA approves the device. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

There are strict guidelines and safeguards to protect those who choose to participate in clinical trials. Every clinical trial in the US must be approved and monitored by an Institutional Review Board (IRB) to make sure the risks are as low as possible and are worth any potential benefits. The IRB, which consists of medical specialists, statisticians, nurses, social workers, and medical ethicists, is the advocate of the volunteer subject that ensures a clinical trial is ethical and the rights of study participants are protected. (NIH, 2022)

Trials can take place in a variety of locations, including hospitals, university medical research centers, physician offices, or community clinics.

3.0 Clinical Determination Guidelines:

A. Covered Services:

Coverage for routine patient care costs in a clinical trial may be a covered benefit as defined in the Patient Protection and Affordable Care Act (PPACA) when all of the following are met:

1. Member is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of:
    a. Cancer, or
    b. Other life-threatening diseases or conditions are defined as a terminal illness or a chronic, life-threatening, severely disabling disease that is causing serious clinical deterioration.
2. The referring health care professional is a participating health care provider who concludes that the individual's participation in such trial would be appropriate for the eligible disease or condition **or** the member or the referring health care provider provides medical and scientific information establishing that participation in such a trial would be appropriate.
3. The clinical trial is an approved trial. An approved clinical trial is defined 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 meets any of the following:

    a. Federally funded trials, the study or investigation is approved or funded (which may include funding through in-kind contributions) by a nationally recognized sponsor as listed below:

i. The National Institutes of Health (NIH) – which includes the National Cancer Institute (NCI)
ii. The Centers for Disease Control and Prevention (CDC)
iii. The Agency for Health Care Research and Quality (AHRQ)
iv. The Centers for Medicare & Medicaid Services (CMS)
v. Department of Defense (DOD)
vi. Department of Veterans Affairs (VA)
vii. Department of Energy (DOE)
viii. Cooperative group or center of any of the entities described above.
ix. A qualified non-governmental research entity identified in the guidelines issued by NIH for center support grants.

b. The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration (FDA)

c. The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

B. The plan does not cover:

1. Items and services that are not routine costs:

a. Experimental or Investigational item, drug, device, or service itself

b. The item and/or service is solely for data collection and analysis purposes and not for direct clinical management of the patient.

For a service inconsistent with the established standards of care for the patient's diagnosis.

2. Expenses for travel (personal vehicle, rental vehicle, taxi, medical van, ambulance, commercial airline, train, or mileage reimbursement), lodging, and meals associated with participating in a clinical trial.

3. Care outside of the United States.

4.0 Coding:

Modifiers:

Report the appropriate modifier for services reported as part of a clinical trial and include the 8-digit national clinical trial number (NCT). Do not append modifiers to service lines that are unrelated to the clinical trial protocol.

Modifier	Description
Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study
Q1	Routine clinical service provided in a clinical research study that is in an approved clinical research study

Revenue Codes:

Report the appropriate revenue code for services reported as part of a clinical trial and include the 8-digit national clinical trial number (NCT) for inpatient services.

CPT/HCPCS Revenue Codes	Description *Reportable, no charge, no payment*
0256	Experimental drugs
0624	FDA investigational devices

National Clinical Trial Number (NCT):

Facility Claims

The 8-digit numeric clinical trial number must be placed in the value amount of value code D4 on the UB

Professional Claims

The 8-digit numeric clinical trial must be placed in Field 19 of the CMS-1500

Unlisted Codes:

Explanatory notes must accompany claims billed with unlisted codes. Please refer to PRP-03 Unlisted CPT-HCPCS codes.

Prior Approval Legend: Y = All lines of business; N = None required; 1 = HMO/POS; 2 = EPO/PPO; 3 = ASO group L0000264; 4 = ASO group L0001269 Non-Union & Union; 5 = ASO group L0001631; 6 = ASO group L0002011; 7 = ASO group L0001269 Union Only; 8 = ASO group L0002184; 9 = ASO group L0002237, 10 = ASO group L0002193.

NON-COVERED CODES:		
Code	**Description**	**Benefit Plan Reference/ Reason**
S9988	Services provided as a part of a Phase I clinical trial	Clinical Trials
S9990	Services provided as a part of a Phase II clinical trial	Clinical Trials
S9991	Services provided as a part of a Phase III clinical trial	Clinical Trials
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	What's Not Covered; Travel
S9994	Lodging costs (e.g., hotel charges) for clinical trial participant and one caregiver/companion	What's Not Covered; Travel

NON-COVERED CODES:		
Code	**Description**	**Benefit Plan Reference/ Reason**
S9996	Meals for clinical trial participant and one caregiver/companion	What's Not Covered; Travel

ICD-10 DIAGNOSIS CODES (not all-inclusive)	
Code	**Description**
Z00.6	Encounter for examination for normal comparison and control in a clinical research program

5.0 Unique Configuration/Prior Approval/Coverage Details:

None.

6.0 Terms & Definitions:

Clinical Trials: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Institutional Review Board (IRB): An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the organization with which it is affiliated. The Institutional Review Board has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction.

National Clinical Trial Number: The number used to identify all items and line-item services provided to a beneficiary during their participation in a clinical trial. The NCT identifier number is assigned by the National Library of Medicine (NLM) at http://clinicaltrials.gov/ website when a new study appears in the NLM Clinical Trials database.

Terminal illness: An irreversible or incurable disease condition from which death is expected in the foreseeable future.

Life-Threatening Condition – any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

7.0 References, Citations & Resources:

American Heart Association (AHA). Finding Clinical Trials (2023). Accessed November 29, 2023. https://www.stroke.org/en/about-stroke/types-of-stroke/finding-clinical-trials

American Society of Clinical Oncology (ASCO). Affordable Care Act Provision Requiring Insurance Coverage of Clinical Trials (2014). Accessed November 29, 2023. https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/research-and-progress/documents/affordable-care-act-clinical-trials-coverage-provision.pdf

National Institutes of Health (NIH). NIH's Definition of a Clinical Trial (2017). Accessed November 29. 2023. https://grants.nih.gov/policy/clinical-trials/definition.htm

National Institutes of Health (NIH) Clinical Center. FAQs About Clinical Studies (2022). Accessed November 29, 2023. https://clinicalcenter.nih.gov/participate/faqaboutcs.html#clinicalstudies

U.S. National Institute of Health, ClinicalTrials.gov available at: https://clinicaltrials.gov/.

World Health Organization, Clinical Trials (2023). Accessed November 29, 2023. https://www.who.int/health-topics/clinical-trials#tab=tab_1

8.0 Associated Documents [For internal use only]:

Policy and Procedure (P&P) - MMP-09 Benefit Determinations , MMP-02 Transition and Continuity of Care , PRP-03 Unlisted CPT-HCPCS Codes

Standard Operating Procedure (SOP) – MMS-03 Algorithm for Use of Criteria for Benefit Determinations ; MMS-45 UM Nurse Review , MMS-52 Inpatient Case Process in CCA ; MMS-53 Outpatient Case Process in CCA

Sample Letter – TCS Approval Letter; Clinically Reviewed Exclusion Letter; Specific Exclusion Letter; Lack of Information Letter

Form – Request Form: Out of Network/ Prior Authorization

9.0 Revision History

Original Effective Date: 4/1/2024

Next Review Date: 04/02/2025

Revision Date	Reason for Revision