PreferredOne®

Department of Origin: Integrated Healthcare Services	**Effective Date:** 05/09/24
Approved by: Chief Medical Officer	**Date Approved:** 05/09/24
Clinical Policy Document: Clinical Trials	**Replaces Effective Clinical Policy Dated:** 06/12/23
Reference #: MP/C008	**Page:** 1 of 5

PURPOSE:
The intent of this clinical policy is to provide coverage guidelines for health care services rendered in the scope of a *clinical trial*.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:
The Plan covers *routine patient costs* associated with an eligible clinical trial; and

- does not deny participation in a clinical trial;
- deny (or limit or impose additional conditions on) the coverage of *routine patient costs* for items and services furnished in connection with participation in the clinical trial; or
- discriminate against a member on the basis of their participation in the clinical trial

Services may be subject to a post-service review, on a case-by-case basis, to determine the *routine patient costs* versus *protocol induced costs*.

All costs associated with the clinical trial protocol are not eligible for coverage.

Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

COVERAGE:

I. The member is qualified to participate in an approved clinical trial according to trial protocol

II. Providers of clinical trials

   A. Coverage applies for in-network providers and for out of network providers that are located in a state other than the member's residence.

   B. Out of network providers will be approved for provision of *routine patient costs* in an eligible clinical trial when all of the following are met
      1. When benefits are available for non-participating providers; and

      2. When an in-network provider is not participating in the clinical trial; and

      3. When the Plan provides benefits for referrals or standing referrals; and

      4. With prior authorization approval of the referral or standing referral.

III. The study is 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 and other conditions, as reflected in the applicable plan language

IV. The clinical trial is described by one of the three categories below

A. The clinical trial is federally approved or funded (which may include funding through in-kind contributions) by one or more of the following entities
   1. The National Institutes of Health (NIH), which includes the National Cancer Institute (NCI); or
   2. The Center for Disease Control and Prevention (CDC); or
   3. The Agency for Health Care Research and Quality (AHRQ); or
   4. The Centers for Medicare & Medicaid Services (CMS); or
   5. Cooperative group or center of any of the entities 1 - 4 above, or the Department of Defense (DOD), or the Veterans Administration (VA); or
   6. A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health (NIH) for center support grants; or
   7. The Department of Veterans Affairs, the Department of Defense or the Department of Energy as long as the study or investigation has been reviewed and approved through a system of peer review that is determined by the Secretary of Health and Human Services to meet both of the following
      a. Comparable to the system of peer review of studies and investigations used by the National Institutes of Health.
      b. Ensures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

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.

EXCLUSIONS (not limited to):
Refer to member's Certificate of Coverage or Summary Plan Description

DEFINITIONS:
Covered Services:
Services or supplies that are provided by a licensed provider or clinic and covered by the Plan, subject to all of the terms, conditions, limitations and exclusions of the contract.

Investigative:

As determined by the Plan, a drug, device or medical treatment or procedure is investigative if reliable evidence does not permit conclusions concerning its safety, effectiveness, or effect on health outcomes. The Plan will consider the following categories of reliable evidence, none of which shall be determinative by itself:

1. Whether there is a final approval from the appropriate government regulatory agency, if required. This includes whether a drug or device can be lawfully marketed for its proposed use by the FDA; or if the drug, device or medical treatment or procedure is under study or if further studies are needed to determine its maximum tolerated dose, toxicity, safety or efficacy as compared to standard means of treatment or diagnosis; and
2. Whether there are consensus opinions or recommendations in relevant scientific and medical literature, peer-reviewed journals, or reports of clinical trial committees and other technology assessment bodies. This includes consideration of whether an oncology treatment is included in the applicable National Comprehensive Cancer Network (NCCN) guideline, as appropriate for its proposed use, or whether a drug is included in any authoritative compendia as identified by the Medicare program such as, the National Comprehensive Cancer Network Drugs and Biologics Compendium, as appropriate for its proposed use; and
3. Whether there are consensus opinions of national and local health care providers in the applicable specialty as determined by a sampling of providers, including whether there are protocols used by the treating facility or another facility, studying the same drug, device, medical treatment or procedure.

Institutional Review Board:

A duly constituted board, committee or other group formally designated by an institution to review, to approve the initiation of, or to conduct periodic review of, biomedical research involving human subjects to ensure the protection of the safety, welfare and rights of those subjects and which meets or exceeds the requirements of Title 21, Parts of 50 and 56, and Title 45, Part 46 of the US Code of Federal Regulations (CFR), and is registered with the Office of Human Research Protection (OHRP) of the US Department of Health and Humans Services.

Program Participants:

Those individuals who been diagnosed with a disease or are a risk of developing a disease based on the presence of biological or disease factors shown to be associated with that disease and who:

- are members of the plan
- have signed an informed consent to participate in a clinical trial
- have signed the necessary authorization or other appropriate privacy consent to allow for release of information to allow communication among the parties for payment, statistical analysis, and administrative issues related to the clinical trial program
- are receiving the Protocol Treatment

Protocol-Induced Costs:

Those costs incurred in the administration of any item or service that are:

- required for the completion of the *protocol treatment* but are not usual, customary, and appropriate for the patient's condition and would not typically be provided to that patient when cared for outside of a clinical trial
- would be incurred by performance of tasks directly related to data collection, reporting or analysis for purposes of the clinical trial
- that would be provided by the trial administrator or performance site for purposes of the clinical trial
- that would be provided by the trial administrator or performance site and not otherwise charged to the health plan

Protocol Treatment:
Those items, drugs, procedure, services and schedule for administration described in the *IRB* approved protocol document. In the case of comparative studies, *protocol treatment* refers to all arms in the protocol document (eg, the “standard” arm and the “experimental” arm).

Routine Patient Costs**:**
The cost of any *covered services* that would typically be covered if *you* were not enrolled in an approved *clinical trial. Routine patient costs* do not include:
1. the cost of the investigative item, device, or service that is the subject of the approved *clinical trial*.
2. items and services that are provided solely to satisfy data collection and analysis needs and that are not used in direct clinical management.
3. a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

CMS - Clinical Trials
In general, the routine costs of a *clinical trial* include those costs that a member would be eligible for if there were no clinical trial. This principle tries to ensure that members are not penalized nor have items or services taken away from them if they participate in a qualifying clinical trial. These routine costs include:
* Items or services typically provided absent a *clinical trial* (e.g., conventional care);
* Items or services required solely for the provision of the investigational item or service;
* Clinically appropriate monitoring of the effects of the investigational item or service;
* Prevention of complications; and
* Items or services for reasonable and necessary care arising from the provision of an investigational item or service, especially for the diagnosis and treatment of complications.
Limitations:
Items and services not covered as "routine services" in a *clinical trial* include:
* The investigational item or service itself, unless otherwise covered outside the clinical trial;
* Items and services for the purpose of determining eligibility for the study not related to medically necessary clinical care;
* Items and services provided solely to satisfy data collection and not necessary for clinical management; and
* Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

Prior Authorization: Yes, per network provider agreement

REFERENCES:

1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy: Coverage Determination Guidelines (MP/C009)
3. Clinical Policy: Investigative Services (MP/I001)
4. Affordable Care Act of 2010. Section 2709. Retrieved from https://www.hhs.gov/sites/default/files/ppacacon.pdf. Accessed 05-07-24.
5. National Institutes of Health (NIH). NIH Clinical Research Trials and You. The Basics. Last Reviewed: October 3, 2022. Retrieved from https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics. Last Accessed 05-07-24.
6. Centers for Medical & Medicaid Services (CMS). National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1). Effective 7/9/2007. Retrieved from https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Minnesota&KeyWord=clinical+trials&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAA&. Accessed 05-07-24.
7. Centers for Medical & Medicaid Services (CMS). Local Coverage Article: Clinical Trials – Medical Policy Article (A52840) Effective 10/01/2015. Retrieved from: https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52840&ContrId=273 Accessed 05-07-24.

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PreferredOne Community Health Plan ("PCHP") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PCHP does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PCHP:
Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

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ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

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PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).

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PIC:
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If you believe that PIC has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Insurance Company
PO Box 59212
Minneapolis, MN 55459-0212
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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