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| Department of Origin: Integrated Healthcare Services | Effective Date: 03/06/24 |
| Approved by: Chief Medical Officer | Date Approved: 02/29/24 |
| Clinical Policy Document: Investigative Services | Replaces Effective Clinical Policy Dated: 09/12/23 |
| Reference #: MP/I001 | Page: 1 of 2 |

PURPOSE:

The intent of this clinical policy is to provide coverage guidelines for investigative health care services.

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:

Health care services that are considered investigative are not eligible for coverage when current *reliable evidence* does not permit conclusions concerning its safety, effectiveness, or effect on health outcomes.

The Plan maintains a list of services considered to be *investigative*. This list is not all-inclusive. Additions and deletions to the list will be made as new issues arise or the *investigative* status of a service changes. The list can be found on the Plan's website.

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. All *health care services* listed on the *Investigative* List are excluded from coverage.
- II. New FDA-approved drugs and clinical indications for provider-administered medications, newly released CPT and HCPCS codes for emerging technology, services, and procedures, such as but not limited to Category III and other temporary codes may be designated as excluded, until the Plan has determined if *reliable evidence* permits conclusions concerning its safety, effectiveness, or effect on health outcomes.
- III. An *investigative* determination will be made for all *health care services* that lack *reliable evidence* (see MP/L004 Levels of Evidence and the Evaluation of Health Care Services)
 - Includes, but not limited to, *health care services* designated by the CMS Medicare program as Coverage with Evidence Development (CED)
- IV. Methods of distribution of *Investigative* List to members and providers
 - A. Available on the internet on the Plan's web site
 - B. Revisions are published in provider newsletters
 - C. The List is available on request

DEFINITIONS:**Health Care Service:**

Medical or behavioral services including pharmaceuticals, devices, technologies, tests, treatments, therapies, supplies, procedures, hospitalizations, or *provider* visits.

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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.

Reliable evidence:

The Plan considers 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.

REFERENCES:

1. Integrated Healthcare Services Utilization Process Manual: UR009 Referral to Medical Policy
2. Integrated Healthcare Services Utilization Process Manual: UR015 Use of Medical Policy and Criteria
3. Integrated Healthcare Services Medical Policy Process Manual: MP001 Medical Policy Process for Research Related to Potentially Investigative Healthcare Services
4. Integrated Healthcare Services Medical Policy Process Manual: MP002 Investigative List Oversight
5. Clinical Policy: Clinical Trials (MP/C008)
6. Clinical Policy: Clinical Policy Application, Development, Oversight, and Distribution (MP/C014)
7. Clinical Policy: Levels of Evidence and the Evaluation of Health Care Services (MP/L004)
8. Clinical Policy: New/ Emerging Technology/ Health Care Services, Omnibus Code List (MP/N003)
9. Pharmacy Policy: Off-Label Drug Use (PP/O001)
10. Pharmacy Policy: Off-Label Drug Use (PP/O002)
11. Pharmacy Policy: Review of New FDA-Approved Drugs and Clinical Indications (PP/R001)
12. 2023 NCQA Standards and Guidelines for the Accreditation of Health Plans
- UM10 Evaluation of New Technology

DOCUMENT HISTORY:

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PreferredOne Community Health Plan Nondiscrimination Notice

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).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

ໂບດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອຕໍ່ພາສາ, ໂດຍບໍ່ເສຍຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ
1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው፡ 763.847.4013) .

ဟ်သ့ဟ်သး- နမံကတိ၊ ကညိ ကျိာ်အယံ၊ နမံကျိာ်အတိမၤစၢလၢ တလၢာ်ဘျဉ်လၢာ်စၢ နီတမံဘျဉ်သန့လီၤ. ကိ: 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតល្បួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013)។

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

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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PreferredOne Insurance Company
PO Box 59212
Minneapolis, MN 55459-0212
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customerservice@preferredone.com

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
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ဟံသာဝတီ: နမူနာတို့ ကညီ ကျိအသိ, နမူနာ ကျိအတိအကျတို့ တလက်ကွက်လက်စွာ နှိတ်ခံဘက်သို့လွှဲလိ။ ကိ: 1.800.940.5049 (TTY: 763.847.4013).

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