PreferredOne®

Department of Origin: Integrated Healthcare Services	**Effective Date:** 09/12/23
Approved by: Chief Medical Officer	**Date Approved:** 09/01/23
Clinical Policy Document: Clinical Policy Application, Development, Oversight and Distribution	**Replaces Effective Clinical Policy Dated:** 09/27/22
Reference #: MP/C014	**Page:** 1 of 5

PURPOSE:
The intent of this policy is to outline the processes for clinical policy application, development, oversight and distribution.

POLICY:
Clinical policies do not constitute or substitute for medical treatment or advice, nor do they constitute or substitute for the exercise of independent medical judgment in member-specific matters. They are intended to promote objectivity and consistency in the health care medical necessity determination process and are necessarily general in their approach; therefore, medical discretion must be exercised in their application. All practitioners will have ready access to peer reviewers and criteria to discuss specific member circumstances that do not fall within the stated criteria.

Clinical policies meet the requirements of regulating and accrediting bodies. State and federal mandates are addressed when appropriate.

I. Application

A. Clinical policy documents are used by Integrated Healthcare Services (including Pharmacy) staff to promote objectivity and consistency in determining the medical appropriateness of health care services.

B. When information obtained does not meet medical necessity requirements, cases are referred to peer review for consideration of special circumstances, on a case-by-case basis, before a determination is rendered. Appropriate characteristics that will be considered when applicable, include but are not limited to the following:
   1. Age
   2. Comorbidities
   3. Complications
   4. Progress of treatment
   5. Psychosocial situation
   6. Home environment
   7. Geographic location/local delivery system when it impacts available services required by the member, such as, but not limited to, the following:
      a. Availability of mental health, substance use and medical-surgical inpatient, outpatient, residential and transitional facilities.
      b. Availability of outpatient services in lieu of inpatient services such as -
         1) Infusion centers or home infusion versus inpatient hospital; or
         2) Intensive outpatient mental health or substance use treatment versus inpatient; or
         3) Surgicenters versus inpatient hospital.
      c. Availability of highly specialized services, such as transplant facilities or cancer centers.
      d. Availability of skilled nursing facilities, subacute care facilities, or home care in the organization's service area to support the patient after hospital discharge.

e. Local hospitals' ability to provide all recommended services within the estimated length of stay.

II. Development

A. Need for clinical policy is identified based on the following:
1. Variation in practice: There is variation in medical practice and/or complex clinical decision making is required for determining treatment options.

2. Evidence: Clinical evidence exists that defines appropriate member selection or exclusion criteria.

3. Utilization patterns: Clinical diagnosis or treatment occurs frequently in medical practice, involves a large population, and/or is associated with high costs.

4. External organizations' policies: Concerns for quality or coverage result in criteria or guideline development by governmental agencies (such as, but not limited to, Advisory Committee on Immunization Practices [ACIP] Agency for Healthcare Research and Quality [AHRQ], United States Preventive Services Task Force [USPSTF], regulatory bodies, and/or professional societies.

5. Unclear benefit language where further direction is required

6. State or federal mandates need clarification or direction

7. Requests by the Quality Management Committee, a quality management subcommittee, or the Board of Directors

B. Drafting, sources, annual review, revision and adoption
1. Health plan staff (such as, but not limited to, Medical Policy, Integrated Healthcare Services, Pharmacy, Chief Medical Officer, Medical Directors and other appropriate physicians) may draft new clinical policy documents.
   - Health plan staff from other departments (such as, but not limited to, Claims, Coding, Compliance, Legal, Network Management, Sales, etc.) are consulted as needs are identified.

2. Sources for content include, but are not limited to, the following:
   a. Medical/surgical (including behavioral health [mental health/substance related disorders]) clinical policies are based on available scientific literature, including but not limited to, government agencies, expert professional practice guidelines, specialty/ professional society guidelines, technology assessment bodies, point of care synthesized resources, peer-reviewed journal articles, and/or expert consensus opinion.
   b. Pharmacy clinical policies (including step therapy protocols) are based on U.S. Food and Drug Administration (FDA) approved labeling, contracted pharmacy benefit manager's (PBM) drug class reviews, government agencies, medical associations, national commissions, peer-reviewed journals, authoritative compendia, scientific literature, expert professional practice guidelines, specialty/professional society guidelines, technology assessment bodies, point of care synthesized resources, and/or expert consensus opinion.

3. Annual review and/or revision
   a. Clinical policies are reviewed annually, or more frequently when a need is identified, for continued usefulness and appropriateness.
   b. Revisions are based on any of the following:
      1) An abbreviated search of scientific literature, expert professional practice guidelines, and specialty/professional society organizations; to assess for changes to previous positions.
      2) A change in status of medications, such as, but not limited to, FDA approvals, FDA withdrawals, FDA warnings or instructions.
      3) A PBM drug class review.
      4) A change in expert consensus opinion.
      5) Health plan medical/surgical (including behavioral health [mental health/substance related disorders]) and pharmacy impact and utilization data may also be incorporated.
      6) Benefit language and state and federal mandates are assessed to determine if any changes to clinical policies are required.

4. Adoption of external criteria or guidelines based on sound medical evidence and reviewed and approved by the appropriate physician or provider specialty may be adopted for health plan medical necessity decision making. This includes, but is not limited to, the following:
   a. Centers for Medicare and Medicaid Services (CMS) or National Committee for Quality Assurance (NCQA) accredited health plans' criteria or guidelines.
   b. Delegated entities' criteria or guidelines.
   c. Expert professional practice guidelines or specialty/professional society guidelines. This includes, but is not limited to, local and national physician associations, National Comprehensive Cancer Network (NCCN), or American College of Radiology (ACR).
   d. NCQA or Utilization Review Accreditation Commission (URAC) accredited or contracted PBM criteria or guidelines.

III. Oversight by expert review and approval

A. Health plan internally developed clinical policies
   1. All action (newly developed, annual review, and revision) on health plan internally developed clinical policies require approval from the Chief Medical Officer or appropriate physician. Clinical Policy documents that have been approved by the Chief Medical Officer or appropriate physician may be used as a reference for medical necessity determinations until the policy is approved by the applicable quality management subcommittee. This includes mid-cycle revision of a pharmacy clinical policy due to a change in status or availability of medications.

   2. Medical necessity determination elements within the policy documents (newly developed, annual review and clinical revision) are brought to the applicable quality management subcommittee meeting for expert review and approval.
      a. A quorum of 50% must be present and greater than 50% of "Yes" votes are required for approval.
      b. As an alternative to a formal subcommittee presentation, a ballot process may be utilized for approval of newly developed or revised clinical policies.
         1) Ballot process is being used in place of a formal subcommittee meeting

a) A quorum of 50% of ballots must be received and unanimous "Yes" votes are required for approval
b) If less than a quorum response, or any "No" votes are received, the policy is not accepted via ballot and is brought to the next formal subcommittee meeting for discussion and action
c) Minutes reflecting the ballot process are generated and submitted to the subcommittee for review and action.

2) Ballot process is being used as an adjunct to a formal subcommittee meeting
a) A quorum of 50% of ballots must be received and unanimous "Yes" votes are required for approval
b) If less than a quorum response, or any "No" votes are received, the policy is not accepted via ballot. The policy is discussed at the subcommittee meeting for discussion and action
c) The ballot process is reflected in the subcommittee meeting minutes

3. Benefit coverage determination elements within the policy documents are brought to the applicable quality management subcommittee for informational purposes.

4. Retirement of clinical policies are brought to the applicable quality management subcommittee for informational purposes and are based on any of the following:
a. Benefit language changes
b. Change in a law or mandate
c. Utilization pattern changes, such as but not limited to:
1) Minimal requests for the health care service over the past year.
2) Utilization of health care service has become community standard, there is no longer a variation in practice and members are being selected appropriately as evidenced by the absence of any denials over the past year.

[Note: Retired clinical policies may be re-adopted following the applicable processes outlined above.]

B. Adopted external criteria or guidelines for medical necessity determination
1. If the health plan adopts external criteria or guidelines that are based on sound medical evidence and reviewed and approved by the expert specialty service practitioners, health plan quality management subcommittee voting action is not required.

2. Notice of adoption of external criteria or guideline is bought to the applicable quality management subcommittee for informational purposes.

IV. Methods of distribution to members and providers

A. Available on internet on health plan web site

B. Notice of newly approved clinical policies and revisions are published in the provider newsletter

C. Clinical policies are available upon request

PreferredOne®

Department of Origin: Integrated Healthcare Services	**Effective Date:** 09/12/23
Approved by: Chief Medical Officer	**Date Approved:** 09/01/23
Clinical Policy Document: Clinical Policy Application, Development, Oversight and Distribution	**Replaces Effective Clinical Policy Dated:** 09/27/22
Reference #: MP/C014	**Page:** 5 of 5

REFERENCES:

2023 NCQA Standards and Guidelines for the Accreditation of Health Plans
-UM 2: Clinical Criteria for UM Decisions
-UM 11: Procedures for Pharmaceutical Management

DOCUMENT HISTORY:

Created Date: 11/24/20 (previously included in MP/C003 and MP/P008)
Reviewed Date: 07/28/21, 07/26/22, 07/26/23
Revised Date: 07/28/21

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).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.800.940.5049 (TTY: 763.847.4013).

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

ဟသျှဉ်ဟသး– နမ့်ကတိ၊ ကညီ ကျိာ်အယိ, နမၤန့် ကျိာ်အတ်မၤစၢၤလ၊ တလၫ်ဘူဉ်လၫ်စ့၊ နီတမံၤဘဉ်သ့နှဉ်လီၤ. ကိး 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 ដោយមិនគិតឈ្នួល 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).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

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).

PreferredOne Insurance Company Nondiscrimination Notice

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

PIC:
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 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

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).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.800.940.5049 (TTY: 763.847.4013).

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

ဟသူဉ်ဟ်သး– နမ့ါကတိၤ ကညီ ကျိာ်အယိ, နမၤန့ါ ကျိာ်အတ၊်မၤစၢၤလၢ တလၢာ်ဘူဉ်လၢာ်စ့ၤ နီတမံၤဘဉ်သ့နှဉ်လီၤ. ကိး 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 ដោយមិនគិតឈ្នួល 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).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

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).