

Department of Origin: Pharmacy	Date approved: 1/19/2023
Approved by: Chief Medical Officer	Effective Date: 1/23/2023
Pharmacy Clinical Policy Document: Off-label Drug Use	Replaces Effective Policy Dated: 2/4/2022
Reference #: PP/O001	Page: 1 of 4

PURPOSE:

The intent of this policy is to ensure coverage of off-label cancer drug use and provide coverage guidelines for non-cancer off-label drug use.

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:

PreferredOne covers off-label drugs when their use is proven effective by *reliable evidence* and/or *medical literature*.

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. Cancer *off-label drug use* – all of the following: A - C

A. Product Application – 1 or 2

1. PAS ERISA - such drug is recognized for cancer treatment in the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium; or
2. PIC and PAS Non-ERISA (political sub-divisions) such drug is recognized as appropriate for cancer treatment in a *standard reference compendia* such as the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium or one article in the *medical literature*.

B. If, due to the rarity of the cancer, the cancer condition is not addressed in the NCCN Drugs and Biologics Compendium, the safety and effectiveness of use for this indication has been adequately demonstrated in the *medical literature*.

C. The drug is not being provided as part of a clinical trial (see MP/C008 Clinical Trials)

II. Non-cancer *off-label drug use* – all of the following: A - C

A. The drug is deemed appropriate for its use by any authoritative compendia identified by the Medicare program; and/or

B. Is supported by an article in *medical literature* from a major peer reviewed medical journal, provided that such article uses generally acceptable scientific standards other than case-reports.

C. The drug is not being provided as part of a clinical trial (see MP/C008 Clinical Trials)

Department of Origin: Pharmacy	Date approved: 1/19/2023
Approved by: Chief Medical Officer	Effective Date: 1/23/2023
Pharmacy Clinical Policy Document: Off-label Drug Use	Replaces Effective Policy Dated: 2/4/2022
Reference #: PP/O001	Page: 2 of 4

PROCEDURE:

Initiation of an *off-label drug use* request:

- I. The member's prescribing provider must submit a written request for an *off-label drug use* on behalf of the member. This can be initiated by:
 - A. Completing the Infusion Prior Authorization Form for drugs under the medical benefit; or
 - B. Completing the [Medication Request Form](https://www.preferredone.com/providers/pharmacy-resources.aspx) which can be found at <https://www.preferredone.com/providers/pharmacy-resources.aspx>; or
 - C. Calling the Customer Service telephone number listed on the member's insurance card; or
- II. The member's prescribing provider must include all patient-specific clinical information supporting the request for the off-label use of the drug and should include any available *medical literature* supporting the *off-label drug use*.
- III. Requests for exception for *off-label drug use* will be reviewed on a case-by-case basis.
- IV. Timeframes for completion and notification of an *off-label drug use* request for all groups:
 - A. An urgent concurrent request will be completed within 24 hours of receipt of complete information.
 - B. An urgent preservice request will be completed within 48 hours (and must include at least one business day) of receipt of complete information.
 - C. A non-urgent preservice request will be completed within 5 business days of receipt of complete information.
 - D. Postservice decisions are made within 30 calendar days of receipt of complete information.
- V. Notification method and process after completion of a *quantity limit* override request:
 - A. If an *off-label drug use* request is approved:
 1. PreferredOne will notify the provider and member by electronic or written notification.
 2. For PIC and PAS Non-ERISA members, PreferredOne will also notify the provider telephonically or by facsimile.
 2. Coverage of the approved *off-label drug use* includes coverage of medically necessary services directly related to and required for appropriate administration of the drug.
 3. Coverage is not subject to any greater copayment, coinsurance, deductible, or other member out of pocket costs.
 - B. If an *off-label drug use* request is not approved:
 1. PreferredOne will notify the provider of the denial and appeal rights by electronic or written notification.

PreferredOne®

Department of Origin: Pharmacy	Date approved: 1/19/2023
Approved by: Chief Medical Officer	Effective Date: 1/23/2023
Pharmacy Clinical Policy Document: Off-label Drug Use	Replaces Effective Policy Dated: 2/4/2022
Reference #: PP/O001	Page: 3 of 4

2. PreferredOne will notify the member of the denial and appeal rights by letter.
3. For PIC and PAS Non-ERISA members, the attending provider (and hospital, as applicable) will be notified by telephone, facsimile to a verified number or by electronic mail to a secure electronic mailbox.

EXCLUSIONS (not limited to):

Refer to member's Certificate of Coverage or Summary Plan Description

DEFINITIONS:

Authoritative Compendia:

American Hospital Formulary Service- Drug Information (AHFS-DI), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Micromedex DrugDex, Clinical Pharmacology, and Lexi-Drugs

Medical Literature:

Articles from major peer reviewed medical journals that have recognized the drug or combination of drugs' safety and effectiveness for treatment of the indication for which it has been prescribed. Each article shall meet the uniform requirements for manuscripts submitted to biomedical journals established by the International Committee of Medical Journal Editors, or be published in a journal specified by the United States Secretary of Health and Human Services pursuant to United States Code, title 42, section 1395x, paragraph (t), clause (2), item (B), as amended, as acceptable peer review medical literature. Each article must use generally acceptable scientific standards and must not use case reports to satisfy this criterion.

Off-label Drug Use:

Drugs prescribed for the treatment of a condition, at a dosage or a mode of delivery that has not been approved by the Federal Food and Drug Administration (FDA).

Reliable Evidence:

PreferredOne 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.

Department of Origin: Pharmacy	Date approved: 1/19/2023
Approved by: Chief Medical Officer	Effective Date: 1/23/2023
Pharmacy Clinical Policy Document: Off-label Drug Use	Replaces Effective Policy Dated: 2/4/2022
Reference #: PP/O001	Page: 4 of 4

Standard Reference Compendia

Any authoritative compendia as identified by the Medicare program for use in the determination of a medically accepted indication of drugs and biologicals used off-label.

Prior Authorization: Yes, per network provider agreement

REFERENCES:

1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy: MP/C008 Clinical Trials
3. Clinical Policy: MP/C009 Coverage Determination Guidelines
4. Clinical Policy: MP/L004 Levels Evidence and the Evaluation of Health Care Services
5. Minnesota Statute 62Q.525 Coverage for Off-Label Drug use
6. Minnesota Statute 151.375 Right to Try Act
7. Minnesota Statute 62M.05 Procedures for Review Determination
8. Medicare Benefit Policy Manual. Chapter 15, 50.4.5 – Covered Medical and Other Health Services. Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen. (Rev. 10880, Issued: 08-06-21, Effective: 08-06-21, Implementation: 11-08-21). Retrieved from <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>. Accessed 01-18-23.
9. NCQA 2021 HP Standards and Guidelines
 - UM 5: Timeliness of UM Decisions
 - UM 11: Procedures for Pharmaceutical Management

DOCUMENT HISTORY:

Created Date: 02/02
Reviewed Date: 10/19/07, 08/13/08, 12/21/10, 12/07/11, 12/06/12, 12/06/13, 12/04/14, 12/04/15, 10/31/16, 10/31/17, 10/31/18, 01/14/19, 01/03/20, 12/31/20, 12/27/21, 11/30/22
Revised Date: 10/05/04, 11/16/05, 11/15/06, 10/01/07, 08/05/09, 10/22/09, 12/22/09, 2/27/12, 02/11/16, 10/31/16, 01/29/18, 03/21/18, 01/23/19, 01/08/21

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, taiaa jiila qarqaarsa 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, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, 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- နမၤကတိၤ ကသီၤ ကျိၣ်အယိၣ်, နမၤနီၣ် ကျိၣ်အတၢ်မၤစၢၤလၢ တလၢကတၢၢ်လၢကတၢၢ် နီၣ်တမံၤဘၣ်သ့န့ၣ်လီၤ. 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 ដោយមិនគិតល្បួល គឺអាចមានសំរាប់បំរើអ្នក។ ចរ 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).

XIYEEFFANNAA: 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).

បំពេញ: ប្រសិនបើ អ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 1.800.940.5049 (TTY: 763.847.4013)។

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፡ በነጻ ሊያገኙበት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (ማስማት ለተሳናቸው: 763.847.4013)፡፡

ဟံသာဝတီ: နမူနာတို့ ကညီ ကျိအသိ, နမူနာ ကျိအတိအကျတို့ တလက်ကွက်လက်စွာ နှိတ်မိသည့်သို့လည်း 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: បើសិនជាអ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 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).