

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)

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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.

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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.

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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:

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Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity. We do not exclude people or treat them differently because of race, color, national origin, age, disability, sex, sexual orientation, or gender identity.

We will:

Provide 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)

Provide 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 us at the phone number shown on the inside cover of this contract, your id card, or aspirushealthplan.com.

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

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
Phone: 1.866.631.5404 (TTY: 711)
Fax: 763.847.4010
Email: customerservice@aspirushealthplan.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Nondiscrimination Grievance Coordinator 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

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1.866.631.5404 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلی رقم الهاتف 1.866.631.5404 (رقم هاتف الصم والبك : 711)

French: ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelezle 1.866.631.5404 (ATS : 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.866.631.5404 (TTY: 711).

Hindi: _यान द_ : य_द आप िहंदी बोलते ह_ तो आपके िलए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_। 1.866.631.5404 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.866.631.5404 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 711)

Traditional Chinese: 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 1.866.631.5404 (TTY: 711)。

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 711).

Lao: ໄປດຊາຍ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.866.631.5404 (TTY: 711).