

Department of Origin: Pharmacy	Effective Date: 09/17/2024
Approved by: Chief Medical Officer	Approved Date: 09/08/2024
Pharmacy Clinical Policy Document: Off-label Drug Use for Business Process Outsourced (BPO) Clients	Replaces Effective Policy Dated: 1/23/2023
Reference #: PP/O002	Page: 1 of 3

PURPOSE:

The intent of this pharmacy clinical policy is to provide coverage guidelines for 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:

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. 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
- 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

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:

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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 be 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:

We 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.

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 biologics used off-label.

Prior Authorization: Yes, per network provider agreement - initial authorize for up to 12 months. This is subject to the member's contract benefits.

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REFERENCES:

1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy: MP/C009 Coverage Determination Guidelines
3. Clinical Policy: MP/L004 Levels of Evidence and the Evaluation of Health Care Services
4. 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 <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>
Accessed 10/31/2023.
5. NCQA 2021 HP Standards and Guidelines
 - UM 5: Timeliness of UM Decisions
 - UM 11: Procedures for Pharmaceutical Management

DOCUMENT HISTORY:

Created Date: 12/1/2020
Reviewed Date: 11/29/2021, 11/29/2022, 10/24/2023
Revised Date:

Nondiscrimination & Language Access Policy



Discrimination is Against the Law. 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, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:

Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services 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 assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If you need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If you believe that Aspirus Health Plan, Inc. 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:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
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>. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1-800-332-6501 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن أعلى رقم الهاتف 1-800-332-6501 (رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: यान द : य द आप िहंदी बोलते ह तो आपके िलए मु त म भाषा सहायता सेवाएं उपल थ ह 1-800-332-6501 (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 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1-800-332-6501 (TTY: 711) 번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (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 1-800-332-6501 (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 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deutsch (Pennsylvania German / Dutch) schwetzscht, kannst du mitaue Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາໂດຍບໍ່ເສັຽຄ່າ, ຄວນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1-800-332-6501 (TTY: 711).