| | |
|---|---|
| **Approved by:**<br>Optum Medical and Pharmacy Subcommittee | **Effective Date:**<br>06/10//26 |
| **Clinical Policy Document:**<br>Specialty Medical Injectable Drug | **Date Approved:**<br>06/10/26 |
| **Reference #:**<br>MC/PC062 | **Replaces Effective Clinical Policy Dated**:<br>03/15/2026 |

## TABLE OF CONTENTS


Plans In Scope ..... 1

Purpose: ..... 1

Coverage Indications: ..... 1

Exclusions ..... 2

Medical Records Documentation ..... 2

Policy/Revision History ..... 2

References: ..... 2


## PLANS IN SCOPE

Aspirus Health Plan

## PURPOSE:

The intent of this policy is to provide coverage guidelines for specialty medical injectable drugs where a current policy does not exist.

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.

## COVERAGE INDICATIONS:

This policy provides parameters for coverage of medically injectable medications.

For consideration of coverage, the following must apply:

1. The medication is ordered by a licensed provider
2. A medication specific policy is not available
3. Step therapy options have been explored, as applicable
4. The medication must be provider administered or administration of the specialty drug must be supervised by a provider
5. The medication is approved by the FDA
6. The medication requested aligns with all FDA label indications for use
7. The requested medication dosing and frequency aligns with the FDA label recommended dosing and frequency

## Exclusions

The following services are excluded from this policy:

- Medications that can be self-administered
- Medications that are considered experimental and/or investigational
- Off label medication use
- Unproven medication indications

## Medical Records Documentation

Benefit coverage is determined by review of member specific benefit plan information and all applicable laws. Medical records documentation may be required to assess if the member meets criteria; however, provision of records does not guarantee coverage.

## POLICY/REVISION HISTORY

| Date | Summary of Changes | Approval By |
|---|---|---|
| 03/11/26 | Initial Policy Development | Optum Medical and Pharmacy Subcommittee |
| 06/10/26 | Policy update: removed term “all” from policy and clarified investigational language | Optum Medical and Pharmacy Subcommittee |

## REFERENCES:


National Library of Medicine (n.d.) Dailymed. Accessed 6/08/26. DailyMed

U.S. Food & Drug Administration (n.d.) Drugs@FDA: FDA-Approved drugs. Accessed 06/08/26. Drugs@FDA: FDA-Approved Drugs

U.S. Food and Drug Administration (n.d.) FDA label. Accessed 06/08/26. https://nctr-crs.fda.gov/fdalabel/ui/search

U.S. Food and Drug Administration (07/01/25) FDA’s labeling resources for human prescription drugs: For industry. Accessed 06/08/26. https://www.fda.gov/drugs/laws-acts-and-rules/fdas-labeling-resources-human-prescription-drugs

# 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 اعلى رقم الهاتف1-800-332-6501(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 zurVerfügung. 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_ध 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 numer1-800-332-6501 (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 al1-800-332-6501 (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 Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

**Lao**: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).

70021 07-24 ©2024 Aspirus Health Plan, Inc. All rights reserved.