

Approved by: Optum Medical and Pharmacy Subcommittee	Effective Date: 10/01/2026
Clinical Policy Document: Step Therapy for Provider- Administered Biologic Medications	Date Approved: 10/01/2026
Reference #: MC/PC 063	Replaces Effective Clinical Policy Dated: N/A

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PLANS IN SCOPE

Aspirus Health Plan

BACKGROUND & PURPOSE:

Step therapy is a utilization management approach that establishes an order in which clinically appropriate therapies are accessed. For provider-administered medications, including biologics and other complex therapies, direct comparative clinical evidence supporting mandatory sequencing between reference products is often limited. Nevertheless, step therapy frameworks are widely implemented across commercial markets to promote clinically appropriate use, encourage adoption of lower-cost therapeutic alternatives such as FDA-approved biosimilars or generics when available, and support operational consistency.

Clinical practice guidelines and professional society recommendations describe evidence-based treatment strategies within specific therapeutic areas, including initiation, escalation, and switching of therapies based on clinical response and patient-specific factors. These guidelines

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inform standards of care and clinical appropriateness but are not intended to dictate payer coverage, formulary placement, or utilization management requirements.

FDA-approved biosimilars are highly similar to their respective reference products and have no clinically meaningful differences in safety, purity, or potency. Available clinical and postmarketing evidence supports comparable safety and effectiveness, including when clinically appropriate transitions occur between reference products and their biosimilars. FDA-approved generic drugs contain the same active ingredient as the corresponding reference listed drug and are required to meet applicable FDA standards for pharmaceutical equivalence and bioequivalence.

At the same time, professional societies and other stakeholders have expressed concern regarding insurer-mandated non-medical switching, particularly for patients who are stable on established therapy. These concerns highlight the importance of preserving prescriber and patient decision-making, ensuring continuity of care, and providing access to medical necessity exceptions.

The purpose of this policy is to define principles, safeguards, and delegation standards for applying step therapy to provider-administered medications while preserving clinical flexibility, continuity of care, and compliance with applicable state and federal requirements.

POLICY STATEMENT:

Step therapy may be applied to provider-administered biologic medications when clinically appropriate and operationally supported.

Step therapy must:

- Be applied to new starts only
- Allow for medical necessity exceptions
- Preserve continuity of care for members stable on established therapy
- Align with FDA-approved labeling and recognized standards of care

Step therapy must not:

- Require switching of members who are stable on established therapy solely due to non-clinical preferences
- Override documented contraindications or intolerance
- Delay medically necessary or urgent treatment

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STEP THERAPY FRAMEWORK

Preferred and Biosimilar Medications

Preferred agents, biosimilars, and step-through requirements for provider-administered biologics are determined by Optum Rx medical policies adopted by Aspirus Health Plan, as published and maintained in the plan's medical policy repository.

These policies are incorporated by reference and may be updated independently of this framework policy.

Default Biosimilar / Generic-First Application

For provider-administered biologic medications not explicitly addressed in the Optum Rx / Aspirus medical policy framework:

FDA-approved biosimilars or generics should be used prior to reference biologic products when clinically appropriate.

This approach applies to new starts only.

Requests for reference products may be approved based on documented medical necessity.

This default sequencing reflects commonly adopted utilization management practices in the commercial market and evidence that FDA-approved biosimilars are highly similar to their reference products with no clinically meaningful differences in safety, purity, or potency. It does not require switching stable patients already receiving a clinically effective therapy.

Exceptions and Overrides

Exceptions to step therapy requirements may be granted when one or more of the following apply:

- Contraindication to the preferred or step-through agent
- Documented intolerance or adverse reaction
- Prior inadequate response to the required step agent
- Member is stable on established therapy
- Urgent or emergent clinical circumstances where delay would risk harm

Exception requests are evaluated through standard prior authorization processes.

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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.

LIMITATIONS

- This policy does not establish disease-specific or drug-specific sequencing requirements.
- Detailed step therapy criteria are delegated to UM tools and drug-specific policies.
- This policy does not supersede FDA labeling, clinical judgment, or applicable regulatory requirements.
- Specialty society guidelines are referenced for clinical appropriateness but are not used as coverage mandates.

DEFINITIONS

Provider-Administered Biologic Medication

A biologic drug administered by a healthcare professional and reimbursed under the medical benefit.

Step Therapy

A utilization management protocol requiring the use of one therapy before another therapy may be covered.

Biosimilar

An FDA-approved biologic product demonstrated to be highly similar to a reference biologic with no clinically meaningful differences in safety, purity, or potency.

New Start A member who has not received the requested medication within the applicable continuity/lookback period established for the member's line of business. The applicable lookback period and any continuity-of-care requirements must be applied in accordance with the governing benefit, utilization-management criteria, and applicable federal or state requirements.

APPLICABLE CODES

Applicable HCPCS, CPT, and J-codes are determined operationally and are not exhaustively listed in this policy.

REGULATORY AND LEGAL CONSIDERATIONS

This policy is intended to comply with applicable federal and state step therapy requirements. Coverage determinations remain subject to benefit plan terms, ERISA considerations, and jurisdiction-specific regulations.

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POLICY/REVISION HISTORY

Date	Summary of Changes	Approval By
10/01/2026	Initial Policy Development	Optum Medical and Pharmacy Subcommittee

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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 mitaus 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).