

Department of Origin: Pharmacy	Effective Date: 09/17/2024
Approved by: Chief Medical Officer	Date Approved: 09/08/2024
Pharmacy Clinical Policy Document: Therapeutic Equivalence	Replaces Effective Policy Dated: 8/8/2022
Reference #: PP/T002	Page: 1 of 3

PURPOSE:

The intent of this Therapeutic Equivalence Pharmacy Clinical Policy is to provide coverage guidelines for medications and products that the FDA has determined are *therapeutically equivalent* and therefore approved as a *generic* or *biosimilar*.

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:

As part of the medication utilization management tools and cost-effective determination, the Plan may designate a preferred medication(s) that is *therapeutically equivalent* to a non-preferred medication(s).

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. Provider-administered medications or products

- A. A preferred medication(s) or product may be required to be trialed before a non-preferred medication(s) when the medication(s) or product is *therapeutically equivalent* and when there is a lower net cost in comparison to its *biosimilar, brand, generic, or reference product*.
- B. Treatment naive members may be required to complete a *standard dosing cycle* of the preferred medication(s), where applicable.
- C. Approval of a non-preferred medication(s) or product will require documentation of the following:
 - 1 or 2, and 3
 1. Evidence of inadequate clinical response to preferred therapy and residual disease activity as demonstrated by a disease or condition specific scale or measurement; or
 2. Evidence of intolerance to or adverse event with the preferred medication(s); and
 3. Physician attestation that a superior clinical response would be expected with a non-preferred medication(s) or product, based on any of the following: a – c
 - a. A clinical practice guideline; or
 - b. A systematic evidence review; or
 - c. A high-quality clinical trial.

II. Continuity of Care – Transition of Care for Provider-administered medications or products – continuation of a non-preferred medication or product may be authorized to allow for transition to a preferred medication or product.

Department of Origin: Pharmacy	Effective Date: 09/17/2024
Approved by: Chief Medical Officer	Date Approved: 09/08/2024
Pharmacy Clinical Policy Document: Therapeutic Equivalence	Replaces Effective Policy Dated: 8/8/2022
Reference #: PP/T002	Page: 2 of 3

DEFINITIONS:

Biologic (BLA):

Biologic agents are derived from natural sources (human, animal, microorganisms); these are large complex proteins applicable to the prevention, treatment, or cure of a disease or condition of human beings. Given the complexity of the drug and the difficulty to characterize a biologic, the manufacturing process is proprietary. Licensed by the Public Health Services Act (PHS) (section 351), the 351(a) pathway is utilized for the approval of biologics. Examples of biologics include: vaccine, blood products, antitoxin, allergy shots and cellular therapies.

Biosimilar ("abbreviated" BLA):

A biosimilar is a biological product that is highly similar to the reference or innovator product, notwithstanding minor differences in clinically inactive components; and there are no clinically meaningful differences between biological the product and the reference product in terms of the safety, purity, and potency of the product. Created by the Biologics Price Competition and Innovation Act (BPCIA), the 351(k) pathway streamlined the licensure of biologics demonstrated to be biosimilar to a reference product with intentions of creating a low-cost alternative to innovator biologics. A list of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations care be viewed in the Purple Book.

Brand and generic (NDA, ANDA):

Small molecule drugs, or conventional drugs, are pure chemical substances with a unique chemical structure. Licensed by the Food, Drug, and Cosmetic Act (FD&C Act) (section 505), conventional drug approvals occur via either NDA or ANDAs. To better illustrate the differences in each pathway, please note the following examples:

- 505(b)1: Traditional development path for brand name drugs whose active ingredient has not previously been FDA approved
- 505(b)2: Drugs with a new indication, change in dosage form, and combination products of previously FDA approved drugs
- 505(j): Generic version of a previously FDA approved drug with the same dosage form, strength, route of administration, quality, active ingredient, and intended use. Approved drug products with therapeutic equivalence evaluations can be viewed in the Orange Book.

Follow-On Biologic (NDA):

Follow-on biologic agents are highly similar to innovator biologic drugs, where the innovator biologic drug was approved via section 505 of the FD&C Act, and not through the 351(a) pathway. For example, historically hormones (ie, insulins) have been regulated as drugs, under section 505 of the FD&C Act, and not as biologics under the PHS Act. Once BPCIA phase-in is complete, this pathway will no longer exist.

Interchangeable:

Interchangeable products are both biosimilar to an FDA-approved reference product, and can be expected to produce the same clinical result as the reference product in any given patient. An interchangeable product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

Reference product:

The single biological product licensed by the FDA under section 351(a) of the PHS Act, against which a proposed biosimilar biological product is evaluated in its biosimilar application.

Department of Origin: Pharmacy	Effective Date: 09/17/2024
Approved by: Chief Medical Officer	Date Approved: 09/08/2024
Pharmacy Clinical Policy Document: Therapeutic Equivalence	Replaces Effective Policy Dated: 8/8/2022
Reference #: PP/T002	Page: 3 of 3

Standard Dosing Cycle:

A period of dosing, including induction (higher dose and/or at closer intervals), and at least one maintenance (repeated on a regular schedule) and as described in the prescribing information on the package insert.

Therapeutically Equivalent:

Medications that produce the same or comparable therapeutic outcome and adverse event profile.

REFERENCES:

1. Medical Management Process Manual UR015 Use of Medical Policy and Criteria
2. Clinical Policy: MP/C009 Coverage Determination Guidelines
3. FDA/Vaccines, Blood and Biologics main page. Food and Drug Administration Web site. <http://www.fda.gov/BiologicsBloodVaccines/default.htm>. Accessed 04-19-2024.
4. Richardson, E. Biosimilars. Health Policy Briefs. 10/10/13. Retrieved from http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=100. Accessed 04-19-2024.
5. US Food and Drug Administration. New Drug Application (NDA). Content current as of 01/21/22. Retrieved from <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm>. Accessed 04-19-2024.
6. US Food and Drug Administration. Abbreviated New Drug Application: Generics (ANDAs). Content current as of 12/16/22. Retrieved from <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm>. Accessed 04-19-2024.
7. US Food and Drug Administration. Therapeutic Biologics Application (BLA). Content current as of 02/24/20. Retrieved from <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/default.htm>. Accessed 04-19-2024.
8. US Food and Drug Administration. Biosimilars. Content current as of 03/01/23. Retrieved from <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/default.htm>. Accessed 04-19-2024.
9. US Food and Drug Administration. Draft Guidance Document. Applications Covered by Section 505(b)(2). December 1999. Content current as of 04/27/20. Retrieved from <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm079345.pdf>. Accessed 04-19-2024..
10. US Food and Drug Administration. Guidance Document. Considerations in Demonstrating Interchangeability with a Reference Product Guidance for the Industry. May 2019. Content current as of 05/06/20. Retrieved from <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537135.pdf>. Accessed 04-19-2024.

DOCUMENT HISTORY:

Created Date: 04/18/19
Reviewed Date: 04/07/20, 04/07/21, 04/07/22, 2/27/2023, 04/15/2024
Revised Date: 08/05/22, 4/19/2024

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).