BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 04/01/23**
SECTION: SPECIALTY MEDICAL DRUGS	**LAST REVIEW DATE: 05/16/24**
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Non-Discrimination Statement is located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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Criteria:

Refer to FDA website for current indications and dosage.

- **Criteria for initial therapy:** Biosimilar medication or brand reference biologic will be approved when **ALL** of the following criteria are met:

  1. BCBSAZ review has determined the medication is ***medically necessary***, determined by **ONE** of the following*:*

     - Medical necessity is determined by applying criteria found in separate Evidence-Based Criteria (EBC), EviCore clinical guidelines, or Pharmacy Coverage Guidelines (PCG).
     - If separate EBC, EviCore clinical guidelines, or PCG does not exist for the medication, BCBSAZ will review the request to determine if the medication has been approved by the Food and Drug Administration (FDA) for that specific indication.

  2. **For non-preferred biosimilar medication:** Individual has failure after adequate trial, contraindication per FDA label or intolerance to **ALL** of the preferred biosimilar medications and brand reference biologic (See Table 1 in Definitions Section) [Note: Failure, contraindication or intolerance to any biosimilar should be reported to the FDA] (see Definitions section)

  Initial approval duration: Refer to EBC, EviCore clinical guidelines or PCG. If guidelines do not exist, initial approval duration is 12 months.

- **Criteria for continuation of coverage (renewal request):** Biosimilar medication or brand reference biologic will be approved when **ALL** of the following criteria are met:

  1. Individual has met **ALL** the initial criteria for biosimilar medication or brand reference biologic

  Renewal duration: 12 months

- Biosimilar medication or brand reference biologic is considered ***experimental or investigational*** and will not be covered when any **ONE** or more of the following criteria are met:

  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

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Including, *but are not limited to*:

- Treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, or duration.

Definitions:

Biologic: Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. For the purposes of this policy, biologics refers to FDA approved medications comprised of genetically engineered proteins produced by living cells.

Brand reference biologic: A reference product is the single biological product against which a proposed biological (biosimilar) product is evaluated. The reference product is usually the first or original branded product available on the market. For example, Remicade is the reference biologic and Avsola, Inflectra and Renflexis are biosimilars to Remicade.

Biosimilar: A biosimilar product is a biologic product that is FDA approved based on demonstrating that it is highly similar to a reference biologic and has no clinically meaningful differences in terms of safety and effectiveness from the reference biologic. Only minor differences in clinically inactive components are allowable in biosimilar products. Biosimilars must utilize the same mechanism of action (MOA), route of administration, dosage form and strength as the reference product. Unlike generic medications, biosimilars may not be substituted for reference biologic or another biosimilar without intervention of the physician that prescribed the reference product.

Medication failure is defined as disease progression despite maximally tolerated dose (≥3 months use) as appropriate for disease state being treated. Experience of common side effects of medication will **not** be considered medication failure for the purpose of this review.

Adverse reaction reporting:
U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Table 1: Preferred and Non-preferred biologics and biosimilars

Medication	Product	Code(s)	Preferred Status
Bevacizumab	Avastin*	J9035	Preferred
	Mvasi	Q5107	Preferred
	Alymsys	Q5126	Non-preferred
	Vegzelma	Q5129	Non-preferred
	Zirabev	Q5118	Non-preferred
Filgrastim	Neupogen*	J1442	Preferred
	Nivestym	Q5110	Preferred

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	Granix	J1447	Non-preferred
	Releuko	Q5125	Non-preferred
	Zarxio	Q5101	Non-preferred
Infliximab	Avsola	Q5121	Preferred
	Infliximab (Unbranded)	J1745	Preferred
	Remicade*	J1745	Preferred
	Renflexis	Q5104	Preferred
	Inflectra	Q5103	Non-preferred
Pegfilgrastim	Fulphila	Q5108	Preferred
	Neulasta*/Neulasta Onpro	J2506	Preferred
	Fylnetra	Q5130	Non-preferred
	Nyvepria	Q5122	Non-preferred
	Stimufend	Q5127	Non-preferred
	Udenyca/Udenyca Onbody	Q5111	Non-preferred
	Ziextenzo	Q5120	Non-preferred
Rituximab	Rituxan*	J9312	Preferred
	Ruxience	Q5119	Preferred
	Riabni	Q5123	Non-preferred
	Truxima	Q5115	Non-preferred
Trastuzumab	Herceptin*	J9355	Preferred
	Kanjinti	Q5117	Preferred
	Ogivri	Q5114	Preferred
	Herzuma	Q5113	Non-preferred
	Ontruzant	Q5112	Non-preferred
	Trazimera	Q5116	Non-preferred

*Brand reference biologic (first to market and product to which biosimilars are compared)

History:	**Date:**	**Activity:**
Pharmacy and Therapeutics Committee	05/16/24	Review with revisions: criteria, resources
Pharmacy and Therapeutics Committee	11/16/23	Revision to criteria
Pharmacy and Therapeutics Committee	08/17/23	Review with revisions: criteria, resources
Pharmacy and Therapeutics Committee	05/18/23	Review with revisions: criteria, resources
Pharmacy and Therapeutics Committee	03/23/23	Approved guideline
Clinical Pharmacist	03/01/23	Development

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Coding:

HCPCS: C9399, J1442, J1447, J1745, J2506, J3590, J9035, J9312, J9355, Q5101, Q5103, Q5104, Q5107, Q5108, Q5110, Q5111, Q5112, Q5113, Q5114, Q5115, Q5116, Q5117, Q5118, Q5119, Q5120, Q5121, Q5122, Q5123, Q5125, Q5126, Q5127, Q5129, Q5130

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Resources:

Literature reviewed 05/16/24. We do not include marketing materials, poster boards and non-published literature in our review.

1. Alymsys (bevacizumab-maly) product information, revised by Amneal Pharmaceuticals LLC 04/2022, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 4, 2024.

2. Avastin (bevacizumab) product information, revised by Genentech, Inc. 09/2022, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 4, 2024.

3. Avsola (infliximab-axxq) product information, revised by Amgen Inc 09/2021, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 4, 2024.

4. Biologics. U.S. Food and Drug Administration. March 01, 2023. Accessed March 7, 2023. https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars

5. Fulphila (pegfilgrastim-jmdb) product information, revised by Mylan Pharmaceuticals Inc. 06/2023, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 6, 2024.

6. Fylnetra (pegfilgrastim-pbbk) product information, revised by Amneal Pharmaceuticals LLC 05/2022, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 6, 2024.

7. Granix (tbo-filgrastim) product information, revised by Cephalon, LLC 11/2023, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 4, 2024.

8. Herceptin (trastuzumab) product information, revised by Genentech, Inc. 02/2021, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 6, 2024.

9. Herzuma (trastuzumab-pkrb) product information, revised by Cephalon, Inc. 05/2019, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 4, 2024.

10. Inflectra (infliximab-dyyb) product information, revised by Pfizer Laboratories Div Pfizer Inc 04/2023, at DailyMed http://dailymed.nlm.nih.gov. Accessed March 4, 2024.

11. Infliximab (infliximab) product information, revised Janssen Biotech, Inc 10/2021, at DailyMed http://dailymed.nlm.nih.gov. Accessed March 4, 2024.

12. Kanjinti (trastuzumab-anns) product information, revised by Amgen Inc. 10/2022, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 6, 2024.

13. Mvasi (bevacizumab-awwb) product information, revised by Amgen Inc. 02/2023, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 4, 2024.

14. Neulasta (pegfilgrastim) product information, revised by Amgen, Inc. 02/2021, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 6, 2024.

15. Neupogen (filgrastim) product information, revised by Amgen Inc 04/2023, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 4, 2024.

16. Nivestym (filgrastim-aafi) product information, revised by Pfizer Laboratories Div Pfizer Inc 02/2024, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 4, 2024.

17. Nyvepria (pegfilgrastim-apgf) product information, revised by Pfizer Laboratories Div Pfizer Inc 03/2023, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 6, 2024.

18. Ogivri (trastuzumab-dkst) product information, revised by Biocon Biologics Inc. 07/2023, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 6, 2024.

19. Ontruzant (trastuzumab-dttb) product information, revised by Organon LLC 06/2021, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 6, 2024.

20. Releuko (filgrastim-ayow) product information, revised by Amneal Pharmaceuticals LLC 08/2023, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 4, 2024.

21. Remicade (infliximab) product information, revised by Janssen Biotech, Inc 10/2021, at DailyMed http://dailymed.nlm.nih.gov. Accessed March 4, 2024.

22. Renflexis (infliximab-abda) product information, revised by Merck Sharp & Dohme Corp. 01/2023, at DailyMed http://dailymed.nlm.nih.gov. Accessed March 4, 2024.

23. Riabni (rituximab-arrx) product information, revised by Amgen Inc 06/2022, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 6, 2024.

24. Rituxan (rituximab) product information, revised by Genentech, Inc. 12/2021, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 6, 2024.

25. Ruxience (rituximab-pvvr) product information, revised by Pfizer Laboratories Div Pfizer Inc 10/2023, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 6, 2024.

26. Stimufend (pegfilgrastim-fpjk) product information, revised by Fresenius Kabi USA, LLC 09/2023, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 6, 2024.

27. Trazimera (trastuzumab-qyyp) product information, revised by Pfizer Laboratories Div Pfizer Inc 11/2020, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 6, 2024.

28. Truxima (rituximab-abbs) product information, revised by Cephalon, Inc. 11/2023, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 6, 2024.

29. Udenyca (pegfilgrastim-cbqv) product information, revised by Coherus BioSciences Inc 12/2023, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 6, 2024.

30. Vegzelma (bevacizumab-adcd) product information, revised by Celltrion USA, Inc. 02/2023, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 4, 2024.

31. Zarxio (filgrastim-sndz) product information, revised by Sandoz Inc. 01/2024, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 4, 2024.

32. Ziextenzo (pegfilgrastim-bmez) product information, revised by Sandoz Inc. 03/2021, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 6, 2024.

33. Zirabev (bevacizumab-bvzr) product information, revised by Pfizer Laboratories Div Pfizer Inc. 02/2023, at DailyMed https://dailymed.nlm.nih.gov/dailymed/. Accessed March 4, 2024.

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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ 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: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights 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, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html