LOUISIANA BLUE

Bevacizumab Products

Policy # 00817
Original Effective Date: 12/12/2022
Current Effective Date: 05/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider bevacizumab-awwb (Mvasi®)‡ and bevacizumab-bvzr (Zirabev™)‡ to be **eligible for coverage.****

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of bevacizumab (Avastin®)‡, bevacizumab-maly (Alymsys®)‡, bevacizumab-tnjn (Avzivi®)‡ and bevacizumab-adcd (Vegzelma®)‡ to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for the use of bevacizumab (Avastin), bevacizumab-maly (Alymsys), bevacizumab-tnjn (Avzivi), and bevacizumab-adcd (Vegzelma) will be considered when the following criterion is met:

- Patient has tried and failed (e.g., intolerance or inadequate response) BOTH bevacizumab-awwb (Mvasi) AND bevacizumab-bvzr (Zirabev) unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of bevacizumab (Avastin), bevacizumab-maly (Alymsys), bevacizumab-tnjn (Avzivi), and bevacizumab-adcd (Vegzelma) when the patient selection criterion is not met to be **not medically necessary.****

Background/Overview

The bevacizumab products (Avastin, Mvasi, Zirabev, Alymsys, Avzivi, and Vegzelma) are approved by the Food and Drug Administration for a variety of oncolytic conditions. They also have off-label, yet acceptable, guideline driven uses.

Biosimilar products are biological products that are highly similar to and have no clinically meaningful differences from an existing FDA-approved reference product. In the case of the bevacizumab products, Avastin is the FDA-approved reference product and Mvasi, Zirabev, Alymsys, Avzivi, and Vegzelma are biosimilar products. As biosimilars, these products have been determined to have no clinically meaningful differences from Avastin.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The patient selection criterion in this policy takes into account clinical evidence or patient history that suggests the non-preferred bevacizumab products will be ineffective or cause an adverse reaction to the patient. Based on review of available data, in the absence of this caveat, there is no advantage of using the non-preferred bevacizumab products over the preferred products.

References

1. Avastin [package insert]. Genentech, Inc. South San Francisco, California. September 2022.
2. Mvasi [package insert]. Amgen, Inc. Thousand Oaks, California. November 2021.
3. Zirabev [package insert]. Pfizer, Inc. New York, New York. May 2021.
4. Alymsys [package insert]. Amneal Pharmaceuticals, LLC. April 2022.
5. Vegzelma [package insert]. Celltrion USA, Inc. Jersey City, NJ. February 2023.
6. Primer on Biosimilars and Interchangeability. IPD Analytics. Updated October 2022.
7. Avzivi [package insert]. Bio-Thera Solutions, Ltd. Guangdong Province, China. Updated December, 2023.

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Policy History

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11/03/2022	Medical Policy Committee review
11/09/2022	Medical Policy Implementation Committee approval. New policy.
11/02/2023	Medical Policy Committee review
11/08/2023	Medical Policy Implementation Committee approval. Added new product, Vegzelma.
04/04/2024	Medical Policy Committee review
04/10/2024	Medical Policy Implementation Committee approval. Updated policy to require trial of Mvasi and Zirabev prior to the use of other products. Added new product, Avzivi.
04/03/2025	Medical Policy Committee review
04/09/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 04/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

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Codes used to identify services associated with this policy may include (but may not be limited to) githe following:

Code Type	Code
CPT	No codes
HCPCS	J3490, J3590, J9035, Q5107, Q5118, Q5126, Q5129
ICD-10 Diagnosis	All related diagnoses

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.