Blue Cross Blue Shield Blue Care Network of Michigan

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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 06/05/2025

Vabysmo™ (faricimab-svoa)

HCPCS: J2777

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved indication
   b. FDA approved age
   c. Treatment with bevacizumab or a bevacizumab biosimilar has been ineffective, not tolerated or contraindicated
      i. Trial and failure of bevacizumab is NOT required for those with a diagnosis of diabetic macular edema when visual acuity in the affected eye(s) is less than or equal to 20/50
   d. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: For at least 60 days and up to one year at a time
   c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Intravitreal injections of anti-vascular endothelial growth factor (VEGF) have been widely used by ophthalmologists to treat a variety of ocular diseases. They are injected directly into the eye to prevent the formation of new blood vessels and reduce blood vessel leakage and inflammation. Vabysmo is an anti-VEGF therapy indicted for neovascular (wet) age related macular degeneration (AMD), diabetic macular edema (DME), and macular edema following retinal vein occlusion (RVO).

- Age-related Macular Degeneration

    - Age-related macular degeneration is a degenerative disease of the macula that results primarily in loss of central vision. Wet AMD is characterized by growth of abnormal vessels into the subretinal space. These abnormal blood vessels leak leading to collections of subretinal fluid and/or blood beneath the retina. The 2022 American Academy of Ophthalmologists (AAO) Age-Related Macular Degeneration Preferred Practice Pattern Guidelines recommend observation and early detection, antioxidant vitamin and mineral supplements, and intravitreal injections of anti-VEGF agents for the management of wet AMD. Guidelines recommend Eylea™, Avastin®, Vabysmo, or Lucentis® for treatment. The guidelines have not been updated with Beovu®, Byooviz™, and Susvimo™.

- Diabetic Macular Edema

    - Diabetic retinopathy and DME are common complications and the ocular manifestations of end-organ damage in diabetes mellitus. The 2025 AAO Diabetic Retinopathy Preferred Practice Pattern Guidelines state the goals of therapy for DR and DME include improvement or stabilization of visual function, improvement in vision-related quality of life, and optimal control of blood glucose, blood pressure, and other metabolic risk factors. Patients should always be treated with anti-VEGF therapy if they have severe non-proliferative DR or proliferative DR with center-involved macular edema. In cases of mild to moderate non-proliferative DR with center-involved macular edema, patients should also receive intravitreal injections. The guidelines support the use of Lucentis, Eylea, Vabysmo, and Avastin. AAO recommendations were based on trials comparing Eylea, Avastin, and Lucentis to focal laser treatment. All trials showed that treatment with VEGF inhibitors resulted in statistically and clinically significant improvements in visual acuity in patients with DME after one to two years compared to laser treatment.

- Retinal Vein Occlusion

    - Retinal vein occlusion occurs when there is partial or complete obstruction of a retinal vein. Vision loss can occur with RVO and is associated with macular ischemia or edema, retinal hemorrhages, vitreous hemorrhage, or epiretinal membrane formation. The 2025 AAO Retinal Vein Occlusions Preferred Practice Pattern Guidelines recommend anti-VEGF therapy as first-line treatment for macular edema caused by RVO. The guidelines support the use of Lucentis, Eylea, and Avastin. The guidelines state VEGF inhibitors, Eylea, Avastin, and Lucentis, are more effective than sham injection or laser therapy in maintaining or improving visual acuity in patients with macular edema secondary to RVO.

- There are very few randomized control trials that assess the efficacy of one anti-VEGF therapy over another. Of the two that are available, Avastin, Eylea, and Lucentis were all shown to be non-inferior to each other, and because of this, choice of therapy should be based on patient characteristics, side effect profiles, cost, and availability. However, a 2015 study conducted by Wells, et al. did show Eylea was superior to Avastin therapy when patients had a visual acuity of less than or equal to 20/50. In addition, a subcohort analysis of the YOSEMITE AND RHINE trials showed Vabysmo demonstrated BCVA gains similar to aflibercept, while demonstrating numerically greater improvements in anatomic outcomes at years 1 and 2. Therefore, in these scenarios Avastin should not be used prior to Eylea or Vabysmo.

References:

1. Avastin [prescribing information]. South San Francisco, CA: Genentech, Inc.; January 2021.
2. Vabysmo [prescribing information]. South San Francisco, CA: Genentech, Inc.; July 2024.
3. Flaxel CJ, Adelman RA, Bailey ST, et al. Age-related macular degeneration preferred practice pattern. Ophthalmology. 2020 Jan (updated March 2022); 127 (1): P1 - P65.
4. Tufail A, Patel PJ, Egan C, et al. Bevacizumab for neovascular age related macular degeneration (ABC Trial): multicentre randomized double masked study. BMJ. 2010; 340: c2459.
5. Michaelides M, Kaines A, Hamilton R, et al. A prospective randomized trial of intravitreal bevacizumab or laser therapy in the management of diabetic macular edema (BOLT Study). Amer Acad Ophth. 2010 Mar; 117 (6): 1078 – 86.
6. Wells JA, Glassman AR, Ayala AR, et al. Aflibercept, bevacizumab, or ranibizumab for diabetic macular edema. NEJM. 2015 March 26; 372 (13): 1193 – 203.
7. Vedula SS & Krzystolik MG. Antiangiogenic therapy with anti-vascular endothelial growth factor modalities for neovascular age-related macular degeneration. The Cochrane database of systematic reviews. 2008(2):CD005139. PMID: 18425911 6.
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12. Flaxel CJ, Adelman RA, Bailey ST, et al. Retinal vein occlusions preferred practice pattern. Feb 2025. Available at: https://www.aao.org/education/preferred-practice-pattern/retinal-vein-occlusions-ppp. Accessed on March 27, 2025.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>1.6</td><td>Effective Date: 06/05/2025</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>1.5</td><td>Effective Date: 06/06/2024</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>1.4</td><td>Effective Date: 06/08/2023</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>1.3</td><td>Effective Date: 04/06/2023</td><td>New policy. This policy replaces previously approved criteria that was embedded in the Intravitreal Injections for Retinal Conditions Policy which is being split into individual drug policies and retired. The authorization period was updated from up to 1 year to at least 60 days and up to 1 year</td></tr>
<tr><td>1.2</td><td>Effective Date: 03/07/2022</td><td>UM medical management system update for MAPPO and BCNA
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<tr><td>1.1</td><td>Effective Date: 02/24/2022</td><td>UM medical management system update for BCBSM and BCN
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*