Medical benefit drug policies are a source for WyoBlue Advantage 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

Beovu® (brolucizumab-dbll)

HCPCS: J0179

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
   d. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in WyoBlue Advantage'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. Beovu is an anti-VEGF currently indicated for the treatment of neovascular (wet) age-related macular degeneration (AMD) and diabetic macular edema (DME).

- 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 2022 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.

References:

1. Beovu [prescribing information]. East Hanover, NJ: Novartis Pharmaceutical Corp.; July 2024.
2. Avastin [prescribing information]. South San Francisco, CA: Genentech, Inc.; September 2022.
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. Dugel PU, Koh A, Ogura Y, et al. HAWK and HARRIER: phase 3, multicenter, randomized, double-masked trials of brolucizumab for neovascular age-related macular degeneration. Ophthalmology. 2020 Jan; 127 (1): 72-84.
6. 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.
7. Solomon SD, Lindsley K, Vedula SS, et al. Anti-vascular endothelial growth factor for neovascular age-related macular degeneration. The Cochrane database of systematic reviews. 2019 Mar 4; 3: CD005139. PMID: 30834517.
8. Jhaveri CD, Glassman AR, Ferris FL, et al. Aflibercept monotherapy or bevacizumab first for diabetic macular edema. NEJM. 2022 Aug 25; 387: 692 – 703.

9. Flaxel CJ, Adelman RA, Bailey ST, et al. Diabetic retinopathy preferred practice pattern. Ophthalmology. 2020 Jan (March 2022); 127 (1): P66 - P145.

Policy History		
#	Date	Change Description
1.0	Initial Effective Date: 01/01/2026	New policy

** 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.*