Clinical Policy: Brolucizumab-dbll (Beovu)

Reference Number: LA.PHAR.445
Effective Date: 09.29.23
Last Review Date: 02.24.25
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

Description

Brolucizumab-dbll (Beovu®) is a vascular endothelial growth factor (VEGF) inhibitor.

FDA Approved Indication(s)

Beovu is indicated for the treatment of:

- Neovascular (wet) age-related macular degeneration (nAMD)
- Diabetic macular edema (DME)

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections® that Beovu is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Ophthalmic Disease (must meet all)**:**

1. Diagnosis of one of the following (a or b):
   a. nAMD;
   b. DME;
2. Prescribed by or in consultation with an ophthalmologist;
3. Age ≥ 18 years;
4. Failure of bevacizumab intravitreal solution, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for bevacizumab intravitreal solution. Requests for IV formulations of Avastin, Mvasi, and Zirabev will not be approved*
5. Dose does not exceed (a or b):
   a. nAMD: 6 mg (1 vial) every 4 weeks for the first 3 doses, then every 8 to 12 weeks thereafter;
   b. DME: 6 mg (1 vial) every 6 weeks for the first 5 doses, then every 8 to 12 weeks thereafter.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. LA.PMN.53.

II. Continued Therapy

A. Ophthalmic Disease (must meet all)**:**

1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy as evidenced by one of the following (a, b, c, or d):
   a. Detained neovascularization;
   b. Improvement/stabilization in visual acuity;
   c. Maintenance of corrected visual acuity from prior treatment;
   d. Supportive findings from optical coherence tomography or fluorescein angiography;
3. If request is for a dose increase, both of the following (a and b):
   a. Documentation supports evidence of continued disease activity;
   b. New dose does not exceed 6 mg (1 vial) every 8 weeks.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – LA.PMN.53.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
DME: diabetic macular edema
FDA: Food and Drug Administration
nAMD: neovascular (wet) age-related macular degeneration
VEGF: vascular endothelial growth factor

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
bevacizumab (Avastin®)†	1.25 mg administered by intravitreal injection every 4 weeks	1.25 mg/month

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
†Off-label

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Ocular or periocular infections
  - Active intraocular inflammation
  - Known hypersensitivity to Beovu or any of the excipients
- Boxed warning(s): none reported

Appendix D: General Information

- In the HAWK study, brolucizumab 3 mg and 6 mg groups demonstrated non-inferiority to aflibercept 2 mg in terms of mean best corrected visual acuity (BCVA) to week 48 with respective least squares mean changes in BCVA from baseline being: 6.1, 6.6, and 6.8. Similar results were seen in HARRIER, in which brolucizumab 6 mg demonstrated non-inferiority to aflibercept 2 mg with a least squares mean change in BCVA from baseline being 6.9 and 7.6 respectively.
- Disease activity was assessed 8 weeks after the loading phase period, revealing a formal demonstration of superiority versus aflibercept in the HAWK study regarding duration of effect. Additionally, in both studies, this advantage of brolucizumab 6 mg v. aflibercept was reflected in anatomic assessment; similar results were observed at Week 16 and Week 48.
- Based on observations from the HAWK and HARRIER studies, it was estimated that for brolucizumab-treated eyes, the probabilities for exclusively maintaining q12w dosing after loading through Week 48 were 49.4% and 55.6% in HAWK for 3 mg and 6 mg respectively and 51% in HARRIER. Time-to-event analyses revealed that most q8w treatment needed was identified during the first q12w interval (at Weeks 16 and 20).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
nAMD	6 mg (1 vial) via intravitreal injection every 4 weeks for the first 3 months, then every 8 or 12 weeks thereafter	6mg (1 vial) every 2 months after loading period

VI. Product Availability

- Single-dose vial: 6 mg/0.05 mL (120 mg/mL solution in 0.05 mL total volume)
- Single-dose, preservative free, pre-filled syringe: 6 mg/0.05 mL (120 mg/mL solution in 0.05 mL total volume)

VII. References

1. Beovu Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals, Inc.; July 2024. Available at: https://www.novartis.com/us-en/sites/novartis_us/files/beovu.pdf. Accessed November 15, 2024.
2. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-related macular degeneration. San Francisco, CA: American Academy of Ophthalmology; October 2019. Available at: www.aao.org/ppp. Accessed November 15, 2024.
3. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Diabetic Retinopathy. San Francisco, CA: American Academy of Ophthalmology; September 2019. Available at: www.aao.org/ppp. Accessed November 15, 2024.
4. Dugel PA, 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. doi: 10.1016/j.ophtha.2019.04.017.
5. Brown DM, Emanuelli A, Bandelleo F, et al. KESTREL and KITE: 52-week results from two phase III pivotal trials of brolucizumab for diabetic macular edema. *Am J Ophthalmol*. 2022 Jun;238:157-172. doi: 10.1016/j.ajo.2022.01.004..

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0179	Injection, brolucizumab-dbll, 1mg

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Policy created	05.09.23	08.28.23
Annual review: no significant changes; references reviewed and updated.	03.21.24	05.23.24
Annual review: revised initial approval duration to 6 months for all indications; revised initial criteria maximum dosage to include dosing schedule after loading doses; revised continued therapy to only apply to requests for dose increase; in Appendix B per Clinical	02.24.25	

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Pharmacology, updated dosing regimens and clarified off-label indications; references reviewed and updated.		

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.