

Clinical Policy: Brolucizumab-dbl (Beovu)

Reference Number: CP.PHAR.445

Effective Date: 03.01.20

Last Review Date: 02.20

Line of Business: Commercial, HIM, Medicaid,

[Coding Implications](#)[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Brolucizumab-dbl (Beovu[®]) is a vascular endothelial growth factor (VEGF) inhibitor.

FDA Approved Indication(s)

Beovu is indicated for the treatment of patients with neovascular (wet) age-related macular degeneration (AMD).

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 health plans affiliated with Centene Corporation[®] that Beovu is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria**A. Neovascular (Wet) AMD (must meet all):**

1. Diagnosis of neovascular (wet) AMD;
2. Prescribed by or in consultation with an ophthalmologist;
3. Age \geq 18 years;
4. Failure of intravitreal bevacizumab, unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization may be required for bevacizumab*
5. Dose does not exceed 6 mg (1 vial) every 4 weeks for the first 3 months.

Approval duration: 4 months (3 loading doses only)

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid

II. Continued Therapy**A. Neovascular (Wet) AMD (must meet all):**

1. Currently receiving medication via Centene 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. Member meets one of the following (a or b):
 - a. Dose does not exceed 6 mg (1 vial) every 12 weeks;
 - b. If request is for a dose increase, both of the following (i and ii):
 - i. Documentation supports evidence of continued disease activity;
 - ii. 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. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid

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 – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AMD: age-related macular degeneration

FDA: Food and Drug Administration

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 for all relevant lines of business and may require prior authorization.

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|--------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|-----------------------------|
| Avastin [®] (bevacizumab), Mvasi [™] (bevacizumab-awwb), Zirabev [™] (bevacizumab-bvzr) | 1.25 to 2.5 mg administered by intravitreal injection every 4 weeks | 2.5 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.

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 6mg demonstrated non-inferiority to aflibercept 2mg 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 |
|-----------------------|--------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| Neovascular (wet) AMD | 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 (total volume 0.05 mL): 6 mg/0.05 mL, 120 mg/mL

VII. References

1. Beovu Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals, Inc.; October 2019. Available at: <https://www.beovuhcp.com>. Accessed October 23, 2019.
2. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern[®] Guidelines. Age-related macular degeneration. San Francisco, CA: American Academy of Ophthalmology; 2015. Available at: www.aao.org/ppp.
3. 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. Presented at: the American Academy of Ophthalmology Annual Meeting, Nov 11-14, 2017, New Orleans, LA. Accessed: 23 Oct. 2019. [https://www.aaojournal.org/article/S0161-6420\(18\)33018-5/](https://www.aaojournal.org/article/S0161-6420(18)33018-5/)

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-dbl, 1mg |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|--------------------------------------------------------------------------|-------------|------------------------------|
| Policy created | 11.26.19 | 02.20 |
| Finalize HIM line of business per March SDC and prior clinical guidance. | 03.03.20 | |

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. The Health Plan 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. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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