PART B DRUG MEDICAL/PHARMACY	ASPIRE HEALTH	Effective Date January 1, 2024	
		Policy # Beovu (brolucizumab)	
	BEOVU (BROLUCIZUMAB)	**Review Date** 09/27/2023	**Applicable to:** ☑ Medicare Advantage ☐ Commercial ☐ Elevance Health HMO ☐ Blue Shield Trio
	Approver's Name & Title QI & UM Drug Subcommittee		

Aspire Health Plan applies medical drug clinical criteria as a reference for medical policy information only. Federal and state laws or requirements, contract language, and Plan benefit may take precedence over the application of these clinical criteria. Please consult the applicable certificate or contract for benefit details. This policy is subject to revision at the discretion of the Plan and is therefore subject to change. Refer to the disclaimer section below for more information.

POLICY

This policy addresses the coverage of intravitreal Beovu (brolucizumab) for ophthalmic use.

APPLICABLE HCPCS

J0179: Injection, brolucizumab-dbll, 1 mg

Available as:
Beovu (brolucizumab-dbll) 6 mg/0.05 mL single-dose Vial Kit
Beovu (brolucizumab-dbll) 6 mg/0.05 mL single-dose Prefilled Syringe

CLINICAL CRITERIA

A. INITIAL CRITERIA

Beovu (brolucizumab-dbll) may be authorized when **ALL** of the following are present:

1. Clinical diagnosis of **ONE** of the following:
    a. Neovascular (wet, or exudative) age-related macular degeneration (AMD); **OR**
    b. Diabetic Macular Edema.

AND

2. No active intraocular inflammation; **AND**
3. No concurrent ocular or periocular infection; **AND**

4. Best corrected visual acuity (BCVA) is assessed prior to treatment and will be assessed periodically during treatment; AND

5. Beovu (brolucizumab-dbll) is being prescribed as monotherapy: Member is not on additional ophthalmic vascular endothelial growth factor (VEGF) inhibitors (i.e., aflibercept, ranibizumab, pegaptanib, bevacizumab).

B. REAUTHORIZATION / CONTINUATION OF THERAPY CRITERIA

Beovu (brolucizumab-dbll) may be authorized for continuation of thereapy when **ALL** of the following are met:

1. Member continues to meet the initial therapy criteria (as stated above); **AND**

2. Absence of adverse events from intravitreal injections of Beovu (brolucizumab-dbll) (e.g., endophthalmitis and retinal detachments, increase in intraocular pressure, arterial thromboembolic events); **AND**

3. Positive response to therapy (e.g., improvement or maintenance in BCVA or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss) and continued administration is necessary for the maintenance treatment of the condition; **AND**

4. Documentation of administration records showing dates and eye(s) administered, along with documentation of member compliance with treatment plan.

STEP THERAPY

Step therapy criteria do not apply for members who are currently being treated with the requested medications. Step therapy is only applied for members that are new to therapy (have not received the requested drug in the last 365 days.

A. **PREFERRED PRODUCT(S): AVASTIN (no step therapy required)**

B. NONPREFERRED PRODUCT, Beovu (brolucizumab-dbll), may be authorized when all of the clinical criteria above are met **AND** the member meets the following criteria for a non-preferred intravitreal VEGF antagonist:

1. Inadequate response to a trial of the *preferred agent, bevacizumab (Avastin); **or**

2. History of contraindication or adverse event(s) to Avastin (bevacizumab); **or**

3. Member has been on the requested agent within the past 365 days.

DOSAGE AND AUTHORIZATION TIMEFRAMES

1. Recommended Dosage

Indication	Initial / Maintenance Dosing
Neovascular AMD	Initial dosage: 6 mg by intravitreal injection once per month (approximately every 25 to 31 days) for 3 months. Maintenance dosage: 6 mg by intravitreal injection once every 8 to 12 weeks.
Diabetic Macular Edema	Initial dosage: 6 mg by intravitreal injection every 6 weeks (approximately every 39 to 45 days) for 5 doses. Maintenance dosage: 6 mg by intravitreal injection once every 8 to 12 weeks

2. Quantity

    a. Neovascular AMD: 6 mg single-dose vial or pre-filled syringe for injection: 1 vial/syringe per eye every 25 days for three doses initially, then 1 vial/syringe every 8 weeks.

    b. Diabetic Macular Edema: 6 mg single-dose vial or pre-filled syringe for injection: 1 vial/syringe per eye every 6 weeks for five doses initially, then 1 vial/syringe every 8 weeks.

3. Authorization Period

    a. May be authorized for 12 months and reauthorized with continuation of therapy criteria.

    b. Frequency is regarded as excessive when services are performed more frequently than indicated on the FDA-approved labeling or generally accepted by guidelines or consensus, and a rationale for the additional services is not documented. Dosage and frequency should be in accordance with the FDA label or CMS-recognized compendia (for off-label use). Services rendered in excess of the established standard of care may be subjected to review.

4. Limitations

    a. It is not reasonable and necessary to inject more than one anti-VEGF medication (e.g., aflibercept, pegaptanib, brolucizumab, bevacizumab, ranibizumab, faricimab-svoa, etc.) in the same eye during the same treatment session. It is not typical to inject one anti-VEGF medication in one eye and another in the other eye. If different medications are injected into each eye during the same date of service, the rationale for this therapy must be documented in the medical record and the billing modifier [right (RT) and left (LT) modifiers] must be appended to the correct drug. Intravitreal injection for the treatment of macular edema more frequently than every 4 weeks regardless of which drug is used for any given injection i.e. alternating drugs every 2 weeks will not be covered.

    b. Concurrent use of more than one VEGF inhibitor in the same eye: The safety and effectiveness of combinational use of VEGF inhibitors for ocular indications has not been established and is currently not the standard of care according to clinical evidence and guidelines.

DRUG INFORMATION

PHARMACOLOGIC CATEGORY: Ophthalmic Agent; Vascular Endothelial Growth Factor (VEGF) Inhibitor

ROUTE OF ADMINISTRATION: Intravitreal Injection

FDA-APPROVED INDICATIONS

1. Neovascular (wet) AMD
    - Initial dosage: 6 mg by intravitreal injection once per month (approximately every 25 to 31 days) for 3 months.
    - Maintenance dosage: 6 mg by intravitreal injection once every 8 to 12 weeks.

2. Diabetic Macular Edema
    - Initial dosage: 6 mg by intravitreal injection every 6 weeks (approximately every 39 to 45 days) for 5 doses.
    - Maintenance dosage: 6 mg by intravitreal injection once every 8 to 12 weeks.

COMPENDIAL APPROVED (OFF-LABELED) USES: NONE

CONTRAINDICATIONS: Hypersensitivity (e.g., rash, pruritus, urticaria, erythema, severe intraocular inflammation) to brolucizumab or any component of the formulation; ocular or periocular infections; active intraocular inflammation.

OTHER CONSIDERATIONS:

Monitoring Parameters
Intraocular pressure (via tonometry) and optic nerve head perfusion immediately following administration; symptoms of endophthalmitis and retinal detachment; symptoms of retinal vasculitis and retinal vascular occlusion (especially in patients with intraocular inflammation), vision changes.

CLINICAL SUMMARY / APPENDIX

Brolucizumab-dbll provides an additional treatment option for patients with neovascular (wet) AMD. It appears to offer efficacy comparable to current therapies for neovascular AMD, with the additional benefit of fewer injections and an individualized treatment regimen. Brolucizumab-dbll is a monoclonal single-chain antibody fragment, and its smaller size may provide more effective tissue penetration and faster systemic exposure. Common adverse reactions reported with brolucizumab-dbll included blurred vision, cataract, conjunctival hemorrhage, eye pain, and vitreous floaters.

REFERENCES

Government Agency

Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (no National Coverage Determination identified; no applicable LCD identified). Available from CMS.

Prescribing Information

Beovu (brolucizumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2022.

Peer-reviewed Literature, Guidelines, and Consensus

1. Brolucizumab (Beovu) for age-related macular degeneration. Medical Letter on Drugs and Therapeutics 2020;62(1591):23-24.
2. Brown DM, et al. KESTREL and KITE: 52-week results from two phase III pivotal trials of brolucizumab for diabetic macular edema. American Journal of Ophthalmology 2022;238:157-172. DOI: 10.1016/j.ajo.2022.01.004.

3. Dugel PU, et al. HAWK and HARRIER: phase 3, multicenter, randomized, double-masked trials of rolucizumab for neovascular age-related macular degeneration. Ophthalmology 2020;127(1):72-84. DOI: 10.1016/j.ophtha.2019.04.017.
4. Milliman Care Guidelines (MCG). Ambulatory Care 27th Edition. ACG: A-1026 (AC). 2023.

IMPORTANT REMINDER

This Medicare Part B Step Therapy Medical Necessity Guideline is provided for informational purposes only and neither constitutes nor replaces professional medical advice. Physicians, hospitals, and other providers are expected to administer or use drugs/biologicals in the most effective and clinically appropriate manner. Treating physicians and other health care providers are solely responsible for all medical care decisions. In accordance with the member's Evidence of Coverage (EOC), every benefit plan has its own coverage provisions, limitations, and exclusions. In the event of a conflict between this policy and the member's EOC, the member's EOC provisions will take precedence.

Aspire Health Plan (AHP) adheres to Medicare guidelines, including National Coverage Determination (NCD), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and other relevant Medicare manuals established by CMS. Compliance with these guidelines is required when applicable. Refer to the CMS website at http://www.cms.hhs.gov. For the most up-to-date Medicare policies and coverage, please search the Medicare Coverage Database. All LCDS are the same for each state within a Jurisdiction. Medicare Part B Administrative Contractor (MAC) for CA [Jurisdiction E (1)]: Active LCDs - JE Part B – Noridian (noridianmedicare.com). In the event of a discrepancy between this policy and the Medicare NCD or LCD, the Medicare NCD/LCD will govern.

This policy is utilized by AHP to determine coverage in the absence of applicable CMS Medicare guidelines. Please refer to the links provided in the References section to access the Medicare source materials that were used for developing this resource document. This document does not serve as a substitute for the official Medicare source materials that provide detailed information on Medicare coverage requirements. In the event of a conflict between this document and Medicare source materials, the Medicare source materials will take precedence.

The inclusion of a code in this policy does not imply that the health service it describes is covered or not covered. Benefit coverage for health services is determined by the member-specific plan document and applicable laws that may mandate coverage for a particular service. Inclusion of a code does not imply or guarantee reimbursement or payment of a claim. Other Policies and Standards may also apply. Providers are expected to retain or have access to the necessary documentation when requested in order to support coverage.

POLICY HISTORY

Version	Date	Revision Author/Title	Summary of Changes
1	9/27/2023		New Policy