POLICY Document for BEOVU (brolucizumab-dbll)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

CAREFIRST: EXCEPTIONS CRITERIA
VEGF INHIBITORS FOR OCULAR INDICATIONS

PRIMARY PREFERRED PRODUCT: AVASTIN

SECONDARY PREFERRED PRODUCTS: BYOOVIZ, CIMERLI, VABYSMO

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the VEGF inhibitors for ocular indications specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. VEGF inhibitors for ocular indications

	Product(s)
Primary Preferred	• **Avastin** (bevacizumab)
Secondary Preferred	• **Byooviz** (ranibizumab-nuna) • **Cimerli** (ranibizumab-eqrn) • **Vabysmo** (faricimab-svoa)
Targeted	• **Beovu** (brolucizumab-dbll) • **Lucentis** (ranibizumab) • **Susvimo** (ranibizumab injection)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

Coverage for a secondary preferred product is provided when EITHER of the following criteria are met:

A. Member has a documented inadequate response, contraindication, or intolerable adverse event to Avastin.
B. Member is in an active treatment plan with the requested product.

Coverage for Beovu product is provided when EITHER of the following criteria are met:

A. Member is in an active treatment plan with the requested product.
B. Member meets ALL the following:
   1. Member has a documented inadequate response, contraindication, or intolerable adverse event to Avastin.
   2. Member has a documented inadequate response, contraindication, or intolerable adverse event to Byooviz, Cimerli, and Vabysmo.

Coverage for Lucentis and Susvimo is provided when EITHER of the following criteria are met:

A. Member is in an active treatment plan with the requested product.
B. Member meets ALL the following:
   1. Member has a documented inadequate response, contraindication, or intolerable adverse event to Avastin.
   2. Member has a documented inadequate response, contraindication, or intolerable adverse event to Vabysmo.
   3. Member has a documented inadequate response, contraindication, or intolerable adverse event to Byooviz and Cimerli AND adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar).

Section 2: Clinical Criteria

SPECIALTY GUIDELINE MANAGEMENT

BEOVU (brolucizumab-dbll)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Beovu is indicated for:
1. Neovascular (wet) age-related macular degeneration
2. Diabetic macular edema

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Neovascular (Wet) Age-Related Macular Degeneration
Authorization of 6 months may be granted for treatment of neovascular (wet) age-related macular degeneration.

B. Diabetic Macular Edema
Authorization of 6 months may be granted for treatment of diabetic macular edema.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when the member has demonstrated a positive clinical response to therapy (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss).

REFERENCES:

SECTION 1

1. Avastin [package insert]. South San Francisco, CA: Genentech, Inc.; January 2021.
2. Beovu [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2022.
3. Byooviz [package insert]. Cambridge, MA: Biogen, Inc.; June 2022.
4. Cimerli [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; November 2022.
5. Eylea [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; June 2021.
6. Eylea HD [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; August 2023.
7. Lucentis [package insert]. San Francisco, CA: Genentech, Inc.; October 2020.
8. Susvimo [package insert]. San Francisco, CA: Genentech, Inc.; April 2022.
9. Vabysmo [package insert]. San Francisco, CA: Genentech, Inc.' January 2023.

SECTION 2

1. Beovu [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2023.
2. 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; 127:72-84.