POLICY: Ophthalmology – Vascular Endothelial Growth Factor Inhibitors – Beovu Utilization Management Medical Policy

- Beovu® (brolucizumab for intravitreal injection – Novartis)

EFFECTIVE DATE: 1/1/2022
LAST REVISION DATE: 09/16/2024

COVERAGE CRITERIA FOR: UCare Medicaid and Exchange Plans Only (PMAP, Connect, MSC+, MnCare, all Individual and Family Plans)

OVERVIEW

Beovu, a vascular endothelial growth factor (VEGF) inhibitor, is indicated for the following uses:[1]

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

For DME, the recommended dose for Beovu is 6 mg administered by intravitreal (IVT) injection every six weeks (every 39 to 45 days) for the first 5 doses, followed by 6 mg IVT injection once every 8 to 12 weeks. For nAMD, the recommended dose for Beovu is 6 mg administered by IVT injection every month (every 25 to 31 days) for the first 3 doses, followed by 6 mg IVT injection once every 8 to 12 weeks.

Other Uses with Supportive Evidence

Overproduction of VEGF may lead to other eye conditions, including neovascular glaucoma, retinopathy of prematurity, and other retinal and choroidal neovascular conditions affecting the eye, the VEGF inhibitors also have the potential to be used off-label and reduce vision loss associated with other eye conditions related to increased VEGF production.[2,3] The use of anti-VEGF agents have been shown to stop the angiogenic process and maintain visual acuity and improve vision in patients with certain neovascular ophthalmic conditions; therefore, research is rapidly evolving on the use of VEGF inhibitors in other neovascular ophthalmic conditions which threaten vision.[4,5] Anti-VEGF therapy has the potential to be used off-label in other neovascular conditions affecting the eye and may prevent or slow visual impairment.[2,4,5]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Beovu. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Beovu as well as the monitoring required for adverse events and long-term

efficacy, approval requires Beovu to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Beovu is recommended for requests meeting both the step therapy requirements and indication requirements:

Step Therapy Requirements (New Starts Only)

Criteria. *The patient must meet the following criteria (A or B):*

A) For patients new to Beovu therapy only, must have a trial of repackaged Avastin prior to approval of Beovu. New starts to therapy defined as no use of Beovu within the past 180 days for Medicaid and Commercial patients and includes use in either eye.

B) Patient has a contraindication or other clinical reason why repackaged Avastin cannot be tried before Beaovu.

Note: Step therapy only required for indications FDA-Approved for both Beovu and Avastin.

FDA-Approved Indications

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1. **Diabetic Macular Edema.** Approve for 1 year if administered by or under the supervision of an ophthalmologist.

   Dosing. Approve if the requested dosing meets the following (A and B):

   A) The dose is 6 mg administered by intravitreal injection for each eye being treated; AND

   B) The dosing interval is not more frequent than once every 39 days for five doses, followed by not more frequently than once every 8 weeks for each eye being treated.

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2. **Neovascular (Wet) Age-Related Macular Degeneration.** Approve for 1 year if administered by or under the supervision of an ophthalmologist.

   Dosing. Approve if the requested dosing meets the following (A and B):

   A) The dose is 6 mg administered by intravitreal injection for each eye being treated; AND

   B) The dosing interval is not more frequent than once every 25 days for three doses, followed by not more frequently than once every 8 weeks for each eye being treated.

Other Uses with Supportive Evidence

3. Other Neovascular Diseases of the Eye. Approve for 1 year if administered by or under the supervision of an ophthalmologist.
Note: Examples of other neovascular diseases of the eye include neovascular glaucoma, retinopathy of prematurity, sickle cell neovascularization, choroidal neovascular conditions.

Dosing. Approve if the requested dosing meets the following (A and B):
A) The dose is 6 mg administered by intravitreal injection for each eye being treated; AND
B) The dosing interval is not more frequent than once every 25 days for three doses, followed by not more frequently than once every 8 weeks for each eye being treated.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Beovu is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Beovu® [prescribing information]. Hanover, NJ: Novartis; May 2022.
2. Barakat MR, Kaiser PK. VEGF inhibitors for the treatment of neovascular age-related macular degeneration. *Expert Opin Investig Drugs*. 2009;18(5):637-646.
3. Tolentino M. Systemic and ocular safety of intravitreal anti-VEGF therapies for ocular neovascular disease. *Surv Ophthalmol*. 2011;56(2):95-113.
4. Kinnunen K, Ylä-Herttuala S. Vascular endothelial growth factors in retinal and choroidal neovascular diseases. *Ann Med*. 2012;44(1):1-17.
5. Horsley MB, Kahook MY. Anti-VEGF therapy for glaucoma. *Curr Opin Ophthalmol*. 2010;21(2):112-117.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/04/2020
Annual Revision	**Neovascular (Wet) Age-Related Macular Degeneration:** To align with the FDA-approved dosing, the dose was changed from "≤ 6 mg" to "is 6 mg". **Other Neovascular Diseases of the Eye:** Examples of other neovascular diseases of the eye were moved to a Note. To align	11/10/2021

	with the FDA-approved dosing, the dose was changed from "≤ 6 mg" to "is 6 mg".	
Selected Revision	**Diabetic Macular Edema:** This indication and associated criteria were added to the policy.	06/08/2022
UCare Revision	Clarified that continuation of therapy is acceptable if the requested product has been used in either eye.	10/7/2022
Annual Revision	No criteria changes.	11/15/2023
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024