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 Medicare Plans Only (UCare Medicare, EssentiaCare, Group Plans, MSHO, Connect + Medicare, UCare Your Choice)

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 indication(s). All approvals are provided for the duration noted below.

This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents

are cited in the References section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Reference section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage.

Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.

Indications with a ^ below are also covered (and, if applicable, further detailed/referenced) in the corresponding Commercial Care Continuum (CC) Policy. Note: Additional criteria requirements for coverage of the same indication as outlined in the Commercial CC Policy and this Medicare Advantage CC Policy may NOT be the same.

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 365 days for Medicare 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 compendia supported for both Beovu and Avastin.

FDA-Approved Indications

1. Diabetic Macular Edema. ^

Criteria. Approve for 1 year.

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.

2. Neovascular (Wet) Age-Related Macular Degeneration. ^

Criteria. Approve for 1 year.

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. ^
Note: Examples of other neovascular diseases of the eye include neovascular glaucoma, retinopathy of prematurity, sickle cell neovascularization, choroidal neovascular conditions.

Criteria. Approve for 1 year.

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.
6. Centers for Medicare and Medicaid Services, National Government Services, Inc, Local Coverage Determination (LCD): Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394) [original date 10/01/2015; revision effective date 11/7/2019]. Accessed on June 29, 2022.
7. Centers for Medicare and Medicaid Services, National Government Services, Inc, Local Coverage Article (LCA): Billing and Coding: Ranibizumab, Aflibercept and Brolucizumab-dbll (A52451) [original date 10/01/2015; revision effective date 04/21/2022]. Accessed on June 29, 2022.

HISTORY

Type of Revision	Summary of Changes*	Date
Policy created	New Medicare Advantage Medical Policy	02/05/2020
Policy revision	*Added the following to the Policy Statement "Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles." *Updated references	08/07/2020
Policy 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 with the FDA-approved dosing, the dose was changed from "≤ 6 mg" to "is 6 mg".	12/20/2021
Policy revision	**Diabetic Macular Edema:** This indication was added to the policy.	06/29/2022
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