

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Beovu (brolucizumab)
BILLING CODE	J0179
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient Hospital
STATUS	Prior Authorization Required

Beovu was approved by the FDA in 2019 for the treatment of neovascular (wet) age-related macular degeneration (AMD). There are 2 forms of AMD, dry and wet (neovascular). Wet AMD is less common but progresses more quickly. Neovascular in the context of AMD means growth of new blood vessels under the macula which can lead to loss of central vision. The goal of AMD treatment is to preserve visual function. Beovu is a vascular endothelial growth factor (VEGF) inhibitor administered by intravitreal injection. VEGF inhibitors suppress endothelial cell proliferation, neovascularization, and vascular permeability. In the Phase 3 studies HAWK and HARRIER, Beovu was noninferior to another VEGF inhibitor, Eylea (aflibercept), in the primary endpoint measuring change in best corrected visual acuity (BCVA). In 2022, Beovu gained an additional indication for diabetic macular edema (DME). DME occurs in many patients with diabetic retinopathy and causes fluid build-up in the macula part of the retina. In the KITE and KESTREL clinical trials, Beovu was noninferior to Eylea.

Beovu (brolucizumab) will be considered for coverage when the following criteria are met:

Retinal Disease

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an ophthalmologist; AND
3. Member has a diagnosis of one of the following conditions:
 - a) Neovascular (wet) age-related macular degeneration (AMD)
 - b) Diabetic Macular Edema (DME); AND
4. Member has tried and failed bevacizumab intravitreal injection; AND
5. Documentation of best-corrected visual acuity (BCVA); AND
6. Member does NOT have any of the following:
 - a) Active infection or inflammation around or in the affected eye(s)
 - b) Uncontrolled glaucoma
 - c) Recent eye surgery
 - d) Concurrent use with another vascular endothelial growth factor (e.g., Eylea, Avastin, Lucentis)
7. **Dosage allowed/Quantity limit:**
 AMD: 6 mg by intravitreal injection monthly for the first 3 doses, then 6 mg once every 8-12 weeks.
 DME: 6 mg by intravitreal injection every 6 weeks for the first 5 doses, then 6 mg every 8-12 weeks.
 (Note: Each single dose vial provides 6 mg of drug).

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must include documentation of improved or stabilized visual acuity.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Beovu (brolucizumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/24/2020	New policy for Beovu created.
10/20/2021	Transferred to new template. Updated references. Added baseline BCVA. Specified visual acuity in renewal criteria.
06/13/2022	Added new indication DME.

References:

1. Beovu [prescribing information]. Novartis Pharmaceuticals Corporation; 2022.
2. Dugel, Pravin U. et al. HAWK and HARRIER: Phase 3, Multicenter, Randomized, Double-Masked Trials of Brolucizumab for Neovascular Age-Related Macular Degeneration. *Ophthalmology*, Volume 127, Issue 1, 72 – 84
3. Holekamp, Nanvy M. Review of Neovascular Age-Related Macular Degeneration Treatment Options. *Am J Manag Care*. July 2019; 25:-S0
4. Flaxel CJ, Adelman RA, Bailey ST, et al. Age-Related Macular Degeneration Preferred Practice Pattern® [published correction appears in *Ophthalmology*. 2020 Sep;127(9):1279]. *Ophthalmology*. 2020;127(1):P1-P65. doi:10.1016/j.ophtha.2019.09.024
5. Solomon SD, Lindsley K, Vedula SS, Krzystolik MG, Hawkins BS. Anti-vascular endothelial growth factor for neovascular age-related macular degeneration. *Cochrane Database Syst Rev*. 2019;3(3):CD005139. Published 2019 Mar 4. doi:10.1002/14651858.CD005139.pub4
6. Flaxel CJ, Adelman RA, Bailey ST, et al. Diabetic Retinopathy Preferred Practice Pattern® [published correction appears in *Ophthalmology*. 2020 Sep;127(9):1279]. *Ophthalmology*. 2020;127(1):P66-P145. doi:10.1016/j.ophtha.2019.09.025
7. Virgili G, Parravano M, Evans JR, Gordon I, Lucenteforte E. Anti-vascular endothelial growth factor for diabetic macular oedema: a network meta-analysis. *Cochrane Database Syst Rev*. 2018;10(10):CD007419. Published 2018 Oct 16. doi:10.1002/14651858.CD007419.pub6

Effective date: 01/01/2023

Revised date: 06/13/2022