Policy Title:	Beovu (brolucizumab)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	1/15/2020, 1/29/2020, 5/20/2021, 10/21/2021, 05/26/2022, 10/06/2022, 7/27/2023, 12/07/2023, 01/04/2024		

Purpose: To support safe, effective, and appropriate use of Beovu (brolucizumab).

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Policy Statement:

Beovu (brolucizumab) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Beovu (brolucizumab) will be reviewed prospectively via the prior authorization process based on criteria below.

Summary of Evidence

Beovu is indicated for neovascular (wet) age related macular degeneration (nAMD) and diabetic macular edema (DME). Clinical trials evaluating the efficacy and safety of Beovu in patients with nAMD have demonstrated its effectiveness in improving visual outcomes and reducing disease activity. Key findings from pivotal trials, such as HAWK and HARRIER, have shown that Beovu achieves superior visual gains compared to aflibercept. Beovu met its primary endpoints in these trials, demonstrating non-inferiority and, in some cases, superiority in visual acuity outcomes at various time points. Adverse events associated with Beovu include intraocular inflammation, retinal vascular occlusion, and vision-related adverse events; however, these are generally manageable and do not outweigh the benefits of treatment.

Initial Criteria:

- Patient is at least 18 years of age or older; AND
- Prescribed by or in consultation with Retina Specialist; AND
- Patient is free of ocular and peri-ocular infections; AND
- Patient does not have active intraocular inflammation; AND
- Therapy will not be used with other ophthalmic VEGF inhibitors (i.e., aflibercept, bevacizumab, pegaptanib, faricimab, ranibizumab, ranibizumab via ocular implant etc.); AND
- Must have a definitive diagnosis of Neovascular (wet) age related macular degeneration (AMD) or Diabetic Macular Edema (DME); AND

- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; AND
- For patients with AMD, the patient must have an inadequate treatment response, intolerance or contraindication to treatment with bevacizumab or ranibizumab (Byooviz); OR
- For patients with DME and baseline visual acuity of 20/50 or worse, they must have an inadequate treatment response, intolerance or contraindication to treatment with bevacizumab or ranibizumab (Lucentis); OR
- For patients with DME and baseline visual acuity better than 20/50, the patient must have an inadequate treatment response with bevacizumab; AND
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

***Continuation of Therapy* coverage**:

- Patient meets all initial criteria; AND
- Patient is tolerating treatment with absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity: endophthalmitis and retinal detachments; increase in intraocular pressure; arterial thromboembolic events; AND
- Patient has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity (BCVA), etc.) and continued administration is necessary for the maintenance treatment of the condition

Coverage Durations:

- Initial coverage: 6 months
- Renewal coverage: 12 months

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale:
Beovu was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Beovu according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

Dosage/Administration:

Indication	Dose	Maximum Dose* (1 billable unit = 1 mg)
AMD	▪ 6 mg monthly for the first three doses, followed by 6 mg once every 8-12 weeks. • Decreasing the interval of maintenance doses from 12-weeks to 8-weeks will be allowed if the patient has received all three loading doses and has evidence of disease activity, indicated by one of the following, at (or beyond) treatment-week 16: o Decrease in BCVA of ≥ 5 letters compared to baseline; **OR** o Decrease in BCVA of ≥ 3 letters and central subfield thickness ≥ 75 μm compared with week 12; **OR** o Decrease in BCVA of ≥ 5 letters due to neovascular AMD disease activity compared with week 12; **OR** o New or worsening intra-retinal cysts or fluid compared with week 12	Initial dosing: ▪ 12 units every 28 days x 3 doses Maintenance dosing: ▪ 12 units every 56-84 days
DME	▪ 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 ▪ For many patients, dosing at the every 12 week frequency is sufficient. For some patients who show continued disease activity, increasing the frequency to every 8 weeks may be considered.	Initial dosing: ▪ 12 units every 6 weeks x 5 doses Maintenance dosing: ▪ 12 units every 56-84 days

*based on administration to both eyes

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J0179	Injection, brolucizumab-dbll, 1mg

References:

1. Beovu [package insert]. East Hanover, NJ; Novartis Pharmaceuticals, Inc.; September2023. Accessed October2023.
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. 2019 Apr 12. pii: S0161-6420(18)33018-5.
3. Dugel PU, Jaffe GJ, Sallstig P, et al. Brolucizumab versus aflibercept in participants with neovascular age-related macular degeneration: a randomized trial. Ophthalmology. 2017;124:1296e1304.
4. Solomon SD, Chew E, Duh EJ, et al. Diabetic Retinopathy: A Position Statement by the American Diabetes Association. Diabetes Care. 2017 Mar; 40(3):412-418.
5. American Academy of Ophthalmology-Preferred Practice Patterns (AAO-PPP) Retina/Vitreous Panel, Hoskins Center for Quality Eye Care. Diabetic Retinopathy PPP – Update 2017. Nov 2017
6. American Academy of Ophthalmology-Preferred Practice Patterns (AAO-PPP) Retina/Vitreous Panel, Hoskins Center for Quality Eye Care. Retinal Vein Occlusions PPP – Update 2017. Nov 2017.
7. American Academy of Ophthalmology-Preferred Practice Patterns (AAO-PPP) Retina/Vitreous Panel, Hoskins Center for Quality Eye Care. Age-Related Macular Degeneration PPP – Update 2017. Nov 2017.
8. Royal College of Ophthalmologists. Clinical Guidelines – Retinal Vein Occlusion (RVO) Guidelines – July 2015. Accessed at https://www.rcophth.ac.uk/standards-publications-research/clinical-guidelines.