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		
Revision Date:	1/29/2020, 5/20/2021, 10/21/2021		

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.

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, ranibizumab, bevacizumab, etc.); AND
- Must have a definitive diagnosis of Neovascular (wet) age related macular degeneration (AMD); AND
- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; AND
- The patient must have an adequate trial, intolerance or contraindication to treatment with bevacizumab; OR
- 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 include the following: 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; AND

Coverage durations:

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

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

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	<u>Initial dosing:</u> ▪ 12 units every 28 days x 3 doses <u>Maintenance dosing:</u> ▪ 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.; June 2020. Accessed September2021.
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.