

Beovu® (brolucizumab-dbli) (Intravitreal)

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I. Length of Authorization

Coverage will be provided annually and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- 6 mg single-use vial for injection: 1 vial per eye every 25 days

B. Max Units (per dose and over time) [HCPCS Unit]:

Diagnosis	MU for Initial Dosing	MU for Maintenance Dosing
Neovascular age-related macular degeneration (AMD)	12 billable units every 25 days x 3 doses	12 billable units every 56-84 days

(Max units are based on administration to both eyes)

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patients must have an inadequate response to an adequate trial of, or contraindication or intolerance to bevacizumab prior to initiating therapy with brolucizumab; **AND**
- Patient is at least 18 years of age; **AND**
- Patient has baseline measurement of the best corrected visual acuity (BCVA); **AND**

Universal Criteria ¹

- Patient is free of ocular and/or 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, pegaptanib, bevacizumab, etc.) ; **AND**
- Patient has a definitive diagnosis of the following:

Neovascular (Wet) Age-Related Macular Degeneration (AMD) † ¹

† FDA Approved Indication(s)

IV. Renewal Criteria ¹

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and indication-specific relevant criteria as identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: endophthalmitis and retinal detachment, increase in intraocular pressure, arterial thromboembolic events, retinal vasculitis and/or retinal vascular occlusion; **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

V. Dosage/Administration ^{1,2}

Indication	Dose
AMD	The recommended dose for Beovu is 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection monthly (approximately every 25-31 days) for the first three doses, followed by 6 mg (0.05 mL) by intravitreal injection once every 8-12 weeks. – <i>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.</i>

- 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:
 - Decrease in BCVA of ≥ 5 letters compared to baseline; **OR**
 - Decrease in BCVA of ≥ 3 letters and central subfield thickness $\geq 75 \mu\text{m}$ compared with week 12; **OR**
 - Decrease in BCVA of ≥ 5 letters due to neovascular AMD disease activity compared with week 12; **OR**
 - New or worsening intra-retinal cysts or fluid compared with week 12

VI. Billing Code/Availability Information

HCPCS:

J0179 – Injection, brolucizumab-dblb, 1 mg; 1 mg = 1 billable unit

NDC:

Beovu 6 mg/0.05 mL Solution for Injection, single-use vial: 00078-0827-xx

VII. References

1. Beovu [package insert]. East Hanover, NJ; Novartis Pharmaceuticals, Inc.; June 2020. Accessed September 2020.
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>.
9. National Government Services, Inc. Local Coverage Article: Billing and Coding: Ranibizumab, Aflibercept and Brolucizumab-dbl (A52451). Centers for Medicare & Medicaid Services, Inc. Updated on 12/20/2019 with effective date of 01/01/2020. Accessed September 2020.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
H35.3210	Exudative age-related macular degeneration, right eye, stage unspecified
H35.3211	Exudative age-related macular degeneration, right eye, with active choroidal neovascularization
H35.3212	Exudative age-related macular degeneration, right eye, with inactive choroidal neovascularization
H35.3213	Exudative age-related macular degeneration, right eye, with inactive scar
H35.3220	Exudative age-related macular degeneration, left eye, stage unspecified
H35.3221	Exudative age-related macular degeneration, left eye, with active choroidal neovascularization
H35.3222	Exudative age-related macular degeneration, left eye, with inactive choroidal neovascularization
H35.3223	Exudative age-related macular degeneration, left eye, with inactive scar

ICD-10	ICD-10 Description
H35.3230	Exudative age-related macular degeneration, bilateral, stage unspecified
H35.3231	Exudative age-related macular degeneration, bilateral, with active choroidal neovascularization
H35.3232	Exudative age-related macular degeneration, bilateral, with inactive choroidal neovascularization
H35.3233	Exudative age-related macular degeneration, bilateral, with inactive scar
H35.3290	Exudative age-related macular degeneration, unspecified eye, stage unspecified
H35.3291	Exudative age-related macular degeneration, unspecified eye, with active choroidal neovascularization
H35.3292	Exudative age-related macular degeneration, unspecified eye, with inactive choroidal neovascularization
H35.3293	Exudative age-related macular degeneration, unspecified eye, with inactive scar
H35.81	Retinal edema

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

Jurisdiction(s): 6, K	NCD/LCD Document (s): A52451
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52451&bc=gAAAAAAAAAAAA	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

