

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]:

Neovascular age-related macular degeneration (AMD):

- 6 mg single-dose vial or pre-filled syringe for injection: 1 vial/syringe per eye every 25 days for three doses initially, then 1 vial/syringe every 8 weeks

Diabetic Macular Edema (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

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
Diabetic Macular Edema (DME)	12 billable units every 6 weeks x 5 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 an alternative agent; **AND**
- Patient is at least 18 years of age; **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, faricimab-svoa, etc.); **AND**

- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; **AND**
- Patient has a definitive diagnosis of the following:

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

Diabetic Macular Edema (DME) †¹

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); **Φ** Orphan Drug

IV. Renewal Criteria¹

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: endophthalmitis and retinal detachment, increase in intraocular pressure, arterial thromboembolic events, retinal vasculitis and/or retinal vascular occlusion, etc.; **AND**
- Continued administration is necessary for the maintenance treatment of the condition; **AND**

Neovascular (Wet) Age-Related Macular Degeneration (AMD)²

- Patient has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity (BCVA), etc.); **AND**
- Decreasing the interval of maintenance doses from 12-weeks to 8-weeks will be allowed if the patient has received all 3 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 ≥ 75 μm 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

Diabetic Macular Edema (DME)¹⁰

- Patient has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity (BCVA), etc.); **AND**
- Decreasing the interval of maintenance doses from 12-weeks to 8-weeks will be allowed if the patient has received all 5 loading doses and has evidence of disease activity, indicated by one of the following, at (or beyond) treatment-week 28:
 - Decrease in BCVA of ≥ 5 letters compared to baseline; **AND**

- Increase in central subfield thickness compared to baseline

V. Dosage/Administration ^{1,2,10}

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. <ul style="list-style-type: none"> – <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>
DME	The recommended dose for Beovu is 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 6 weeks (approximately every 39-45 days) for the first five doses, followed by 6 mg (0.05 mL) by intravitreal injection once every 8-12 weeks. <ul style="list-style-type: none"> – <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>

VI. Billing Code/Availability Information

HCPCS:

- J0179 – Injection, brolocizumab-dbl, 1 mg; 1 mg = 1 billable unit

NDC:

- Beovu 6 mg/0.05 mL single-dose vial kit with injection components: 00078-0827-xx
- Beovu 6 mg/0.05 mL single-dose pre-filled syringe: 00078-0827-xx

VII. References

1. Beovu [package insert]. East Hanover, NJ; Novartis Pharmaceuticals, Inc.; May 2022. Accessed September 2022.
2. Dugel PU, Koh A, Ogura Y, et al. HAWK and HARRIER: Phase 3, Multicenter, Randomized, Double-Masked Trials of Brolocizumab 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. Brolocizumab 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 Committee, Hoskins Center for Quality Eye Care. Diabetic Retinopathy PPP – Update 2019. Oct 2019.

6. American Academy of Ophthalmology-Preferred Practice Patterns (AAO-PPP) Retina/Vitreous Committee, Hoskins Center for Quality Eye Care. Retinal Vein Occlusions PPP – Update 2019. Oct 2019.
7. American Academy of Ophthalmology-Preferred Practice Patterns (AAO-PPP) Retina/Vitreous Committee, Hoskins Center for Quality Eye Care. Age-Related Macular Degeneration PPP – Update 2019. Oct 2019.
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. Garweg J. A Randomized, Double-Masked, Multicenter, Phase III Study Assessing the Efficacy and Safety of Brolucizumab versus Aflibercept in Patients with Visual Impairment due to Diabetic Macular Edema (KITE). *Klin Monbl Augenheilkd*. 2020 Apr;237(4):450-453. doi: 10.1055/a-1101-9126. Epub 2020 Mar 4.
10. Brown D, Emanuelli A, Bandello F, et al. KESTREL and KITE: 52-Week Results From Two Phase III Pivotal Trials of Brolucizumab for Diabetic Macular Edema. *Am J Ophthalmol* 2022 Jun;238:157-172. doi: 10.1016/j.ajo.2022.01.004. Epub 2022 Jan 14.
11. National Government Services, Inc. Local Coverage Article: Billing and Coding: Ranibizumab, Aflibercept and Brolucizumab-dbl and Faricimab-svoa (A52451). Centers for Medicare & Medicaid Services, Inc. Updated on 06/24/2022 with effective date of 07/01/2022. Accessed September 2022.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
E08.311	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema
E08.3211	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, right eye
E08.3212	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, left eye
E08.3213	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E08.3219	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E08.3311	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E08.3312	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E08.3313	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E08.3319	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E08.3411	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, right eye

ICD-10	ICD-10 Description
E08.3412	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, left eye
E08.3413	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E08.3419	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E08.3511	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, right eye
E08.3512	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, left eye
E08.3513	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, bilateral
E08.3519	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, unspecified eye
E09.311	Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with macular edema
E09.3211	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E09.3212	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E09.3213	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E09.3219	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E09.3311	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E09.3312	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E09.3313	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E09.3319	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E09.3411	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E09.3412	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E09.3413	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E09.3419	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E09.3511	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E09.3512	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E09.3513	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E09.3519	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.3211	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye

ICD-10	ICD-10 Description
E10.3212	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E10.3213	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3219	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E10.3311	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E10.3312	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E10.3313	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3319	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E10.3411	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E10.3412	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E10.3413	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3419	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E10.3511	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E10.3512	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E10.3513	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E10.3519	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E11.3211	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E11.3212	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E11.3213	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3219	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E11.3311	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E11.3312	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E11.3313	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3319	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E11.3411	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E11.3412	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E11.3413	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral

ICD-10	ICD-10 Description
E11.3419	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E11.3511	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E11.3512	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E11.3513	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E11.3519	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye
E13.311	Other specified diabetes mellitus with unspecified diabetic retinopathy with macular edema
E13.3211	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E13.3212	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E13.3213	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E13.3219	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E13.3311	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E13.3312	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E13.3313	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E13.3319	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E13.3411	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E13.3412	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E13.3413	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E13.3419	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E13.3511	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E13.3512	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E13.3513	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E13.3519	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye
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

ICD-10	ICD-10 Description
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
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

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: <https://www.cms.gov/medicare-coverage-database/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/new-search/search-results.aspx?keyword=a52451&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMD%2C6%2C3%2C5%2C1%2CF%2CP	

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

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
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