

# Beovu® (brolucizumab-dbll) (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	12 billable units every 25 days x 3	12 billable units every 56-84 days
degeneration (AMD)	doses	
Diabetic Macular Edema (DME)	12 billable units every 6 weeks x 5	12 billable units every 56-84 days
	doses	

(Max units are based on administration to both eyes)

# III. Initial Approval Criteria <sup>1</sup>

Coverage is provided in the following conditions:

- Patient must try and have an inadequate response (defined as 3 injections in either eye with minimal to no improvement), clinically significant adverse effects, or contraindication to Avastin (bevacizumab) prior to consideration of a non-preferred product. Documentation of contraindication, adverse events, or date(s) of failed therapy to Avastin (bevacizumab) required; AND
- Patient is at least 18 years of age; AND



#### Universal Criteria <sup>1</sup>

- 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 (e.g., aflibercept, ranibizumab, 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 Criteria 1,12

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) <sup>2</sup>

- 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:
  - o Decrease in BCVA of  $\geq 5$  letters compared to baseline; **OR**
  - Decrease in BCVA of  $\geq$  3 letters and central subfield thickness (CST) increase  $\geq$  75  $\mu m$  compared with week 12; **OR**
  - o Decrease in BCVA of  $\geq$  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  $\geq 5$  letters compared to baseline; **AND**
  - Increase in central subfield thickness compared to baseline

#### Dosage/Administration 1,2,10 V.

Indication	Dose
Neovascular (Wet) Age-Related Macular Degeneration (AMD)	Administer 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection per affected eye monthly (approximately every 25-31 days) for the first three doses, followed by 6 mg (0.05 mL) once every 8-12 weeks*.
Diabetic Macular Edema (DME)	Administer 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection per affected eye every 6 weeks (approximately every 39-45 days) for the first five doses, followed by 6 mg (0.05 ml) once every 8-12 weeks*.
* For many patients, every 12 weeks frequency is sufficient. For some patients who show continued	

disease activity, increasing the frequency to every 8 weeks may be considered

#### VI. **Billing Code/Availability Information**

#### HCPCS:

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

#### NDC(s):

- 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

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  Retina/Vitreous Committee, Hoskins Center for Quality Eye Care. Age-Related Macular
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- 13. National Government Services, Inc. Local Coverage Article: Billing and Coding: Ranibizumab and biosimilars, Aflibercept, Brolucizumab-dbll and Faricimab-svoa (A52451). Centers for Medicare & Medicaid Services, Inc. Updated on 03/24/2023 with effective date of 04/01/2023. Accessed September 2023.
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# **Appendix 1 – Covered Diagnosis Codes**

ICD-10	ICD-10 Description
E08.311	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with
200.011	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
E00.0410	with macular edema, right eye
E08.3412	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy
E08.3413	with macular edema, left eye  Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy
EU0.5415	with macular edema, bilateral
E08.3419	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy
100.5415	with macular edema, unspecified eye
E08.3511	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with
200.0011	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
F00 0010	with macular edema, right eye
E09.3212	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy
E00 2012	with macular edema, left eye
E09.3213	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy
E09.3219	with macular edema, bilateral  Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy
E05.5415	with macular edema, unspecified eye
E09.3311	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic
700.0011	retinopathy with macular edema, right eye
E09.3312	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic
100.0012	retinopathy with macular edema, left eye
E09.3313	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic
E09.5515	Dide of chemical madeca alabetes membas with moderate nombrotherative alabetes



ICD-10	ICD-10 Description
E09.3319	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic
E09.5519	retinopathy with macular edema, unspecified eye
E09.3411	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy
200.0111	with macular edema, right eye
E09.3412	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy
200.0112	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,
210.0211	right eye
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
P100110	edema, right eye
E10.3412	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular
E10.0410	edema, left eye
E10.3413	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular
F10 2410	edema, bilateral
E10.3419	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular
E10.3511	edema, unspecified eye  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,
210.0010	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



ICD-10	ICD-10 Description
E11.3212	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema,
111.0212	left eye
E11.3213	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema,
211.0210	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
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,
E11.5515	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
E12 2010	Other provided dishetes mellitus with wild recognificanting dishet is not in such a with an order
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
E15.5215	edema, bilateral
E13.3219	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular
210.0210	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



ICD-10	ICD-10 Description
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
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):

Proprietary Information. Restricted Access – Do not disseminate or copy

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%2CMC		
<u>D%2C6%2C3%2C5%2C1%2CF%2CP</u>		



without approval.

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 &	Novitas Solutions, Inc.	
	Fairfax counties and the city of Alexandria in VA)		
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)	
15	KY, OH	CGS Administrators, LLC	

