Lytenava™ (bevacizumab-vikg)
(Intravitreal)

Document Number: IC-0876

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 12 months (365 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

II. Dosing Limits

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

- 2.5 mg per 28 days

(Max units are based on administration to both eyes)

III. Initial Approval Criteria [1-6]

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**

Universal Criteria

- Member does NOT have any FDA labeled contraindications to the requested agent (e.g., ocular and/or peri-ocular infection, active intraocular inflammation, hypersensitivity to any bevacizumab product); **AND**
- Member intraocular pressure will be monitored prior to and following each intravitreal injection, and managed appropriately; **AND**
- Therapy will not be used concomitantly with other ophthalmic vascular endothelial growth factor (VEGF) inhibitors*; **AND**
- Member must have a contraindication, intolerance, or failure to at least one compounded ophthalmic bevacizumab product [e.g., J9035, 5107, Q5118, Q5126, Q5129, Q5160, C9257, etc.] prior to the consideration of Lytenava (bevacizumab-vikg); **AND**
- Member's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; **AND**

Neovascular (Wet) age-related macular degeneration (nAMD) †

- Member has a definitive diagnosis of neovascular (Wet) age-related macular degeneration (nAMD)

***Note:** Use as part of an alternating treatment regimen with other ophthalmic vascular endothelial growth factor (VEGF) inhibitors is generally not permitted and will be reviewed on a case-by-case basis.*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1-27]

Prior authorization validity can be renewed based upon the following criteria:

- Member continues to meet universal and indication specific criteria as identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: endophthalmitis, retinal detachment, severe increases in intraocular pressure, arterial thromboembolic events (ATEs), etc.; **AND**
- Member has had a beneficial response to therapy (e.g., improvement in best corrected visual acuity (BCVA) from baseline, etc.) and continued administration is necessary for the maintenance treatment of the condition

V. Dosage/Administration

Indication	Dose
Neovascular (wet) age-related macular degeneration (nAMD)	1.25 mg intravitreally into the affected eye(s) once monthly (approximately 28 days)

VI. Billing Code/Availability Information

HCPCS code:

- J3590 – Unclassified biologics

NDC:

- Lytenava 1.25 mg solution in a single-dose vial for injection: 82491-0025-xx

VII. References

1. Lytenava [package insert]. Iselin, NJ; Outlook Therapeutics, Inc.; July 2026. Accessed July 2026.
2. Rich RM, Rosenfeld PJ, Puliafito CA, et al. Short-term safety and efficacy of intravitreal bevacizumab (Avastin) for neovascular age-related macular degeneration. Retina 2006;26:495-511.
3. Avery RL, Pieramici DJ, Rabena MD, et al. Intravitreal bevacizumab (Avastin) for neovascular age-related macular degeneration. Ophthalmol 2006;113:363-72.
4. The CATT Research Group. Ranibizumab and Bevacizumab for Neovascular Age-Related Macular Degeneration. N Engl J Med 2011; 364:1897-1908
5. American Academy of Ophthalmology-Preferred Practice Patterns (AAO-PPP) Retina/Vitreous Committee, Hoskins Center for Quality Eye Care. Age-Related Macular Degeneration PPP – Update 2024. Feb 2025.

6. Chandra S, McKibbin M, Mahmood S, et al; AMD Commissioning Guidance Development Group. The Royal College of Ophthalmologists Commissioning guidelines on age macular degeneration: executive summary. Eye (Lond). 2022 Nov;36(11):2078-2083. doi: 10.1038/s41433-022-02095-2. Epub 2022 May 27. PMID: 35624304; PMCID: PMC9582190.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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
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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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