UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Ophthalmology – Vascular Endothelial Growth Factor Inhibitors – Lytenava Utilization Management Medical Policy

- Lytenava™ (bevacizumab-vikg intravitreal injection – Outlook Therapeutis)

REVIEW DATE: 08/26/2026

OVERVIEW

Lytenava, a vascular endothelial growth factor (VEGF) inhibitor, is given intravitreally for the treatment of **neovascular (wet) age-related macular degeneration (AMD)**.[1]

The recommended dosing for neovascular AMD is 1.25 mg administered by intravitreal injection once a month (approximately every 28 days).[1]

Other Uses with Supportive Evidence

VEGF is a protein that plays a key role in retinal physiology and pathology.[2] Overexpression of VEGF may result in retinal and choroidal neovascularization and vascular leakage, which can contribute to vision loss associated with common retinal disorders. Intravitreal VEGF inhibitors are highly effective in reducing ocular neovascularization, macular edema, and exudation that can result in vision impairment and/or loss. Intravitreal VEGF inhibitors have been used off-label to manage eye conditions related to increased VEGF production. In addition to the labeled indications for the intravitreal VEGF inhibitors (e.g., neovascular AMD, diabetic macular edema, diabetic retinopathy), examples of other neovascular diseases of the eye that can potentially be treated with intravitreal VEGF inhibitors are angioid streaks, iris neovascularization, neovascular glaucoma, pachychoroid neovasculopathy, polypoidal choroidal vasculopathy, and presumed ocular histoplasmosis syndrome. Of note, angioid streaks can occur secondary to systemic conditions such as pseudoxanthoma elasticum, Paget's disease of bone, and sickle cell disease. Research is ongoing and rapidly evolving on the use of intravitreal VEGF inhibitors in other neovascular eye disorders.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Lytenava. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Lytenava as well as the monitoring required for adverse events and long-term efficacy, approval requires Lytenava to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Lytenava is recommended in those who meet one of the following criteria:

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FDA-Approved Indication

1. **Neovascular (Wet) Age-Related Macular Degeneration.** Approve for 1 year if administered by or under the supervision of an ophthalmologist.

   Dosing. Approve if the requested dosing meets BOTH of the following (A and B):
   A) The dose is 1.25 mg administered by intravitreal injection for each eye being treated; AND
   B) The dosing interval is not more frequent than once every 28 days for each eye being treated.

Other Uses with Supportive Evidence

2. **Other Neovascular Diseases of the Eye.** Approve for 1 year if administered by or under the supervision of an ophthalmologist.
   Note: Examples of other neovascular diseases of the eye include diabetic macular edema, diabetic retinopathy, macular edema following retinal vein occlusion, angioid streaks, iris neovascularization, neovascular glaucoma, pachychoroid neovasculopathy. polypoidal choroidal vasculopathy, and presumed ocular histoplasmosis syndrome.

   Dosing. Approve if the requested dosing meets BOTH of the following (A and B):
   A) The dose is 1.25 mg administered by intravitreal injection for each eye being treated; AND
   B) The dosing interval is not more frequent than once every 28 days for each eye being treated.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Lytenava is not recommended in the following situations:

1. **Concomitant Use with Another Intravitreal Vascular Endothelial Growth Factor Inhibitor.** There is no evidence to support concomitant use of Lytenava with another intravitreal VEGF inhibitor.
   Note: Intravitreal VEGF inhibitors are: bevacizumab intravitreal injection (compounded/repackaged from Avastin® [bevacizumab injection, for intravenous use] or its biosimilars; off-label use), aflibercept intravitreal injection (Eylea®/biosimilars, Eylea® HD), Beovu® (brolucizumab intravitreal injection), ranibizumab intravitreal injection (Lucentis®/biosimilars), Susvimo® (ranibizumab intravitreal injection via ocular implant), and Vabysmo® (faricimab-svoa intravitreal injection).

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Lytenava™ intravitreal injection [prescribing information]. Iselin, NJ: Outlook Therapeutics; July 2026.
2. Hang A, Feldman S, Amin AP, et al. Intravitreal anti-vascular endothelial growth factor therapies for retinal disorders. *Pharmaceuticals*. 2023;16:1140. Doi.org/10.3390/ph16081140.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/26/2026

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