

UTILIZATION MANAGEMENT MEDICAL POLICY

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

- Byooviz® (ranibizumab-nuna intravitreal injection – Biogen)
- Cimerli™ (ranibizumab-eqrn intravitreal injection – Coherus)
- Lucentis® (ranibizumab intravitreal injection – Genentech)

REVIEW DATE: 11/12/2025

OVERVIEW

Ranibizumab is a vascular endothelial growth factor (VEGF) inhibitor.¹⁻³ Ophthalmic ranibizumab products (Lucentis, Byooviz, and Cimerli) are given intravitreally for the treatment of ophthalmic conditions. Byooviz and Cimerli are interchangeable biosimilars to Lucentis, indicating no clinically meaningful differences in safety and effectiveness and the same mechanism of action, route of administration, and dosage form as Lucentis. However, minor differences in clinically inactive components are allowed.

Intravitreal ranibizumab injection is indicated for the following uses:^{1,3}

- **Diabetic macular edema.**
- **Diabetic retinopathy.**
- **Macular edema following retinal vein occlusion.**
- **Myopic choroidal neovascularization.**
- **Neovascular (wet) age-related macular degeneration (AMD).**

The recommended dosing of intravitreal ranibizumab injection for each of the indication is as follows:¹⁻³

- **Diabetic macular edema:** 0.3 mg administered by intravitreal injection once every month (approximately 28 days).
- **Diabetic retinopathy:** 0.3 mg administered by intravitreal injection once every month (approximately 28 days).
- **Macular edema following retinal vein occlusion:** 0.5 mg administered by intravitreal injection once every month (approximately 28 days).
- **Neovascular (wet) AMD:** 0.5 mg administered by intravitreal injection once every month (approximately 28 days).
- **Myopic choroidal neovascularization:** 0.5 mg administered by intravitreal injection once every month (approximately 28 days) for up to 3 months; patients may be retreated if needed.

Other Uses with Supportive Evidence

VEGF is a protein that plays a key role in retinal physiology and pathology.⁴ 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 neovascularopathy, 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 intravitreal ranibizumab injection. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. 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 ranibizumab products as well as the monitoring required for adverse events and long-term efficacy, approval requires the intravitreal ranibizumab products to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of the intravitreal ranibizumab injection products is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. Diabetic Macular Edema. Approve for 1 year if administered by or under the supervision of an ophthalmologist.

Dosing. Approve if the dose meets BOTH of the following (A and B):

A) The dose is 0.3 mg administered by intravitreal injection for each eye being treated; AND
B) The dosing interval is not more frequent than once every month (approximately 28 days) for each eye being treated.

2. Diabetic Retinopathy. Approve for 1 year if administered by or under the supervision of an ophthalmologist.

Dosing. Approve if the dose meets BOTH of the following (A and B):

A) The dose is 0.3 mg administered by intravitreal injection for each eye being treated; AND
B) The dosing interval is not more frequent than once every month (approximately 28 days) for each eye being treated.

3. Macular Edema Following Retinal Vein Occlusion. Approve for 1 year if administered by or under the supervision of an ophthalmologist.

Dosing. Approve if the dose meets BOTH of the following (A and B):

A) The dose is 0.5 mg administered by intravitreal injection for each eye being treated; AND
B) The dosing interval is not more frequent than once every month (approximately 28 days) for each eye being treated.

4. Myopic Choroidal Neovascularization. Approve for 1 year if administered by or under the supervision of an ophthalmologist.

Dosing. Approve if the dose meets BOTH of the following (A and B):

- A)** The dose is 0.5 mg administered by intravitreal injection for each eye being treated; AND
- B)** The dosing interval is not more frequent than once every month (approximately 28 days) for each eye being treated.

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

Dosing. Approve if the dose meets BOTH of the following (A and B):

- A)** The dose is 0.5 mg administered by intravitreal injection for each eye being treated; AND
- B)** The dosing interval is not more frequent than once every month (approximately 28 days) for each eye being treated.

Other Uses with Supportive Evidence

6. 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 angioid streaks, iris neovascularization, neovascular glaucoma, pachychoroid neovasculopathy, polypoidal choroidal vasculopathy, and presumed ocular histoplasmosis syndrome.

Dosing. Approve if the dose meets BOTH of the following (A and B):

- A)** The dose is 0.5 mg administered by intravitreal injection for each eye being treated; AND
- B)** The dosing interval is not more frequent than once every month (approximately 28 days) for each eye being treated.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of the intravitreal ranibizumab injection products is not recommended in the following situations:

1. Concomitant Use with Another Intravitreal Vascular Endothelial Growth Factor Inhibitor (Except Susvimo [ranibizumab intravitreal injection via ocular implant]).

There is no evidence to support concomitant use of intravitreal ranibizumab injection (Lucentis and biosimilars) with another intravitreal vascular endothelial growth factor inhibitor. Some patients who are receiving Susvimo may require supplemental treatment with intravitreal ranibizumab injection.⁵

Note: Intravitreal vascular endothelial growth factor inhibitors are: bevacizumab intravitreal injection (compounded from Avastin® [bevacizumab, injection, for intravenous use] or its biosimilars; off-label use), afibercept intravitreal injection (Eylea®/biosimilars, Eylea® HD), Beovu® (brolucizumab-dbll intravitreal injection), 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. Lucentis® intravitreal injection [prescribing information]. South San Francisco, CA: Genentech; February 2024.
2. Byooviz™ intravitreal injection [prescribing information]. Cambridge, MA: Biogen; August 2025.
3. Cimerli™ intravitreal injection [prescribing information]. Redwood City, CA: Coherus; May 2024.
4. 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.
5. Susvimo™ intravitreal injection via ocular implant [prescribing information]. South San Francisco, CA: Genentech; May 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	For all indications/uses, the dosing interval was changed from “not more frequent than once every 25 days for each eye being treated” to “not more frequent than once every 28 days for each eye being treated”; the 28 days aligns with the prescribing information.	11/15/2023
Annual Revision	No criteria changes.	11/20/2024
Annual Revision	Other Neovascular Diseases of the Eye: The Note of examples of other neovascular diseases was revised to remove sickle cell neovascularization and choroidal neovascular conditions and the following examples were added: angioid streaks, iris neovascularization, pachychoroid neovasculopathy, polypoidal choroidal vasculopathy, and presumed ocular histoplasmosis. Conditions Not Recommended for Approval: “Concomitant Use with Another Intravitreal Vascular Endothelial Growth Factor Inhibitor (Except Susvimo [ranibizumab injection via ocular implant])” was added.	11/12/2025