CARECONTINUUM™

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: 11/20/2024

OVERVIEW

Ranibizumab is a vascular endothelial growth factor (VEGF) inhibitor.[1-3] There are two interchangeable biosimilars to Lucentis: Byooviz and Cimerli.

Lucentis and Cimerli are 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**.

Byooviz is indicated for the following uses:[2]
- **Macular edema following retinal vein occlusion**.
- **Myopic choroidal neovascularization**.
- **Neovascular (wet) age-related macular degeneration**.

The recommended dosing for each of the indication is as follows:[1-3]
- **Diabetic macular edema, diabetic retinopathy:** 0.3 mg administered by intravitreal injection once every month (approximately 28 days) [Cimerli and Lucentis]
- **Macular edema following retinal vein occlusion, neovascular (wet) age-related macular degeneration:** 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

Overproduction of VEGF may lead to other eye conditions, including neovascular glaucoma, retinopathy of prematurity, and other retinal and choroidal neovascular conditions affecting the eye.[4,5] The VEGF inhibitors have the potential to be used off-label to reduce or slow visual impairment or vision loss associated with other eye conditions related to increased VEGF production.[4,6,7] The use of VEGF inhibitors have been shown to stop the angiogenic process, maintain visual acuity, and improve vision in patients with certain neovascular ophthalmic conditions. Therefore, research is rapidly evolving on the use of VEGF inhibitors in other neovascular ophthalmic conditions that threaten vision.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of ranibizumab products. 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 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 ranibizumab products is recommended in those who meet one of the following criteria:

FDA-Approved Indications

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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 28 days for each eye being treated.

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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 28 days for each eye being treated.

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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 28 days for each eye being treated.

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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 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 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 neovascular glaucoma, retinopathy of prematurity, sickle cell neovascularization, choroidal neovascular conditions.

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 28 days for each eye being treated.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

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

1. 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; October 2023.
3. Cimerli™ intravitreal injection [prescribing information]. Redwood City, CA: Coherus; May 2024.
4. Barakat MR, Kaiser PK. VEGF inhibitors for the treatment of neovascular age-related macular degeneration. *Expert Opin Investig Drugs*. 2009;18(5):637-646.
5. Tolentino M. Systemic and ocular safety of intravitreal anti-VEGF therapies for ocular neovascular disease. *Surv Ophthalmol*. 2011;56(2):95-113.
6. Kinnunen K, Ylä-Herttuala S. Vascular endothelial growth factors in retinal and choroidal neovascular diseases. *Ann Med*. 2012;44(1):1-17.
7. Horsley MB, Kahook MY. Anti-VEGF therapy for glaucoma. *Curr Opin Ophthalmol*. 2010;21(2):112-117.

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