



## UTILIZATION MANAGEMENT MEDICAL POLICY

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

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

**REVIEW DATE:** 11/10/2021; selected revision 06/08/2022

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### OVERVIEW

Lucentis, a vascular endothelial growth factor (VEGF) inhibitor, is indicated for the following uses:<sup>1</sup>

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

Byooviz, a biosimilar to Lucentis, is indicated for the following uses:<sup>6</sup>

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

The recommended dose for Lucentis in diabetic macular edema and diabetic retinopathy is 0.3 mg administered by intravitreal injection once every month (approximately 28 days). The recommended dose for Byooviz and Lucentis in neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, and myopic choroidal neovascularization is 0.5 mg administered by intravitreal injection once every month (approximately 28 days).

### 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, the VEGF inhibitors also have the potential to be used off-label and reduce vision loss associated with other eye conditions related to increased VEGF production.<sup>2,3</sup> The use of anti-VEGF agents have been shown to stop the angiogenic process and 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 which threaten vision.<sup>4,5</sup> Anti-VEGF therapy has the potential to be used off-label in other neovascular conditions affecting the eye and may prevent or slow visual impairment.<sup>2,4,5</sup>

### 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 criteria (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 25 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 criteria (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 25 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 criteria (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 25 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 criteria (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 25 days for each eye being treated.

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**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 criteria (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 25 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 criteria (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 25 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; March 2018.
2. Barakat MR, Kaiser PK. VEGF inhibitors for the treatment of neovascular age-related macular degeneration. *Expert Opin Investig Drugs.* 2009;18(5):637-646.
3. Tolentino M. Systemic and ocular safety of intravitreal anti-VEGF therapies for ocular neovascular disease. *Surv Ophthalmol.* 2011;56(2):95-113.
4. Kinnunen K, Ylä-Herttuala S. Vascular endothelial growth factors in retinal and choroidal neovascular diseases. *Ann Med.* 2012;44(1):1-17.
5. Horsley MB, Kahook MY. Anti-VEGF therapy for glaucoma. *Curr Opin Ophthalmol.* 2010;21(2):112-117.
6. Byooviz™ intravitreal injection [prescribing information]. Cambridge, MA: Biogen; September 2021.

**HISTORY**

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/04/2020
Annual Revision	<b>Macular Edema Following Retinal Vein Occlusion, Myopic Choroidal Neovascularization, and Neovascular (Wet) Age-Related Macular Degeneration:</b> To align with the FDA-approved dosing, the dose was changed from “≤ 0.5 mg” to “is 0.5 mg”. <b>Diabetic Macular Edema and Diabetic Retinopathy:</b> To align with the FDA-approved dosing, the dose was changed from “≤ 0.3 mg” to “is 0.3 mg”. <b>Other Neovascular Ophthalmic Conditions:</b> Examples of other neovascular diseases of the eye were moved to a Note. To align with the FDA-approved dosing, the dose was changed from “≤ 0.5 mg” to “is 0.5 mg”.	11/10/2021
Selected Revision	<b>Title:</b> The name was changed by replacing “Lucentis” with “Ranibizumab Products”. Now reads, Ophthalmology – Vascular Endothelial Growth Factor Inhibitors – Ranibizumab Products Utilization Management Medical Policy. <b>Product:</b> Byooviz was added to the same conditions for approval as for Lucentis.	06/08/2022