Utilization Review Policy 268A

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

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

EFFECTIVE DATE: 1/1/2022
LAST REVISION DATE: 09/16/2024

COVERAGE CRITERIA FOR: UCare Medicaid and Exchange Plans Only (PMAP, Connect, MSC+, MnCare, all Individual and Family Plans)

OVERVIEW

Lucentis and Cimerli (biosimilar to Lucentis), a vascular endothelial growth factor (VEGF) inhibitor, is indicated for the following uses:[1]

- **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:[6]

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

The recommended dose for Lucentis and Cimerli 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, Cimerli, 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.[2,3] 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.[4,5] 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.[2,4,5]

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 Lucentis, Cimerli or Byooviz is recommended for requests meeting both the step therapy requirements and indication requirements:

Step Therapy Requirements (New Starts Only)

Criteria. *The patient must meet the following criteria (A, B, or C):*

A) For patients new to Lucentis, Cimerli or Byooviz therapy only, must have a trial of repackaged Avastin prior to approval of Lucentis, Cimerli or Byooviz. New starts to therapy defined as no use of Lucentis, Cimerli or Byooviz within the past 180 days for Medicaid and Commercial patients and includes use in either eye.

B) Patient has diabetic retinopathy (without diabetic macular edema).

C) Patient has a contraindication or other clinical reason why repackaged Avastin cannot be tried before Lucentis, Cimerli or Byooviz.

Note: Step therapy only required for indications compendia supported for both Lucentis, Cimerli or Byooviz and Avastin.

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 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 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 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 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 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 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 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 requested dosing meets 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 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 28 days for each eye being treated.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Lucentis 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.
7. Cimerli™ intravitreal injection [prescribing information]. Redwood City, CA: Coherus; August 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	11/14/2018
Annual Revision	The dosing in the approval conditions for **Neovascular (Wet) Age-Related Macular Degeneration, Macular Edema Following Retinal Vein Occlusion, Myopic Choroidal Neovascularization, and Other Neovascular Ophthalmic Conditions** was changed from "the dose is 0.5 mg" to "The dose is ≤ 0.5 mg". The dosing in the approval conditions for **Diabetic Macular Edema** and **Diabetic Retinopathy** was changed from "the dose is 0.3 mg" to "The dose is ≤ 0.3 mg".	11/06/2019
Annual Revision	No criteria changes.	11/04/2020
Annual Revision	**Macular Edema Following Retinal Vein Occlusion, Myopic Choroidal Neovascularization,** and **Neovascular (Wet) Age-Related Macular Degeneration:** To align with the FDA-approved dosing, the dose was changed from "≤ 0.5 mg" to "is 0.5 mg". **Diabetic Macular Edema** and **Diabetic Retinopathy:** To align with the FDA-approved dosing, the dose was changed from "≤ 0.3 mg" to "is 0.3 mg".	11/10/2021

	Other Neovascular Ophthalmic Conditions: 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".	
Selected Revision	**Product:** Byooviz was added to the same conditions for approval as for Lucentis.	06/08/2022
Selected Revision	**Product:** Cimerli was added to the same conditions for approval as for the other ranibizumab products.	08/10/2022
UCare Revision	Clarified that continuation of therapy is acceptable if the requested product has been used in either eye.	10/7/2022
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
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024