Drug Coverage Policy

Effective Date 3/1/2026
Coverage Policy Number.....IP0543
Policy Title..... Ranibizumab Products

Ophthalmology – Vascular Endothelial Growth Factor Inhibitors – Ranibizumab Products

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

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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 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.

Coverage Policy

Coverage for Ranibizumab Products (Byooviz, Cimerli, and Lucentis) varies across plans and requires the use of preferred products in addition to the criteria listed below. Refer to the customer's benefit plan document for coverage details.

POLICY STATEMENT

Prior Authorization is required for 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.

Intravitreal ranibizumab injection products are considered medically necessary when the following criteria are met (1, 2, 3, 4, 5 or 6):

FDA-Approved Indications

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1. **Diabetic Macular Edema.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A.** Medication is administered by, or under the supervision of an ophthalmologist; AND
   - **B.** Preferred product criteria are met for the product(s) as listed in the below table(s).

   Dosing. Approve if the dose meets BOTH of the following (i and ii):
   - **i.** The dose is 0.3 mg administered by intravitreal injection for each eye being treated; AND
   - **ii.** The dosing interval is not more frequent than once every month (approximately 28 days) for each eye being treated.

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2. **Diabetic Retinopathy.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A.** Medication is administered by, or under the supervision of an ophthalmologist; AND
   - **B.** Preferred product criteria are met for the product(s) as listed in the below table(s).

   Dosing. Approve if the dose meets BOTH of the following (i and ii):
   - **i.** The dose is 0.3 mg administered by intravitreal injection for each eye being treated; AND
   - **ii.** The dosing interval is not more frequent than once every month (approximately 28 days) for each eye being treated.

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3. **Macular Edema Following Retinal Vein Occlusion.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A.** Medication is administered by, or under the supervision of an ophthalmologist; AND
   - **B.** Preferred product criteria are met for the product(s) as listed in the below table(s).

   Dosing. Approve if the dose meets BOTH of the following (i and ii):
   - **i.** The dose is 0.5 mg administered by intravitreal injection for each eye being treated; AND
   - **ii.** The dosing interval is not more frequent than once every month (approximately 28 days) for each eye being treated.

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4. **Myopic Choroidal Neovascularization.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A.** Medication is administered by, or under the supervision of an ophthalmologist; AND
   - **B.** Preferred product criteria are met for the product(s) as listed in the below table(s).

Dosing. Approve if the dose meets BOTH of the following (i and ii):

i. The dose is 0.5 mg administered by intravitreal injection for each eye being treated; AND

ii. The dosing interval is not more frequent than once every month (approximately 28 days) for each eye being treated.

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5. Neovascular (Wet) Age-Related Macular Degeneration. Approve for 1 year if the patient meets BOTH of the following (A and B):

A. Medication is administered by, or under the supervision of an ophthalmologist; AND

B. Preferred product criteria are met for the product(s) as listed in the below table(s).

Dosing. Approve if the dose meets BOTH of the following (i and ii):

i. The dose is 0.5 mg administered by intravitreal injection for each eye being treated; AND

ii. The dosing interval is not more frequent than once every month (approximately 28 days) for each eye being treated.

Other Uses with Supportive Evidence

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6. Other Neovascular Diseases of the Eye. Approve for 1 year if the patient meets BOTH of the following (A and B):

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.

A. Medication is administered by, or under the supervision of an ophthalmologist; AND

B. Preferred product criteria are met for the product(s) as listed in the below table(s).

Dosing. Approve if the dose meets BOTH of the following (i and ii):

i. The dose is 0.5 mg administered by intravitreal injection for each eye being treated; AND

ii. The dosing interval is not more frequent than once every month (approximately 28 days) for each eye being treated.

Employer and Individual and Family Plan:

Product	Criteria
Byooviz (ranibizumab-nuna) for intravitreal injection	**ONE** of the following (A or B): A. Patient is currently receiving therapy with Byooviz; OR B. Patient meets ONE of the following (i, ii, iii, or iv): i. Patient meets BOTH of the following [a and b]: a. Patient has previously tried repackaged bevacizumab; AND b. Either inadequate efficacy or intolerability was demonstrated; OR ii. Patient has diabetic retinopathy (without diabetic macular edema); OR iii. In the professional opinion of the prescriber, the safety of using repackaged bevacizumab is of significant concern; OR iv. In the professional opinion of the prescriber, the supplier of repackaged bevacizumab is of significant concern.
Cimerli (ranibizumab-eqrn) for	**ONE** of the following (A or B): A. Patient is currently receiving therapy with Cimerli; OR B. Patient meets ONE of the following (i, ii, iii, or iv):

intravitreal injection	i. Patient meets BOTH of the following [a and b]: a. Patient has previously tried repackaged bevacizumab; AND b. Either inadequate efficacy or intolerability was demonstrated; OR ii. Patient has diabetic retinopathy (without diabetic macular edema); OR iii. In the professional opinion of the prescriber, the safety of using repackaged bevacizumab is of significant concern; OR iv. In the professional opinion of the prescriber, the supplier of repackaged bevacizumab is of significant concern.
Lucentis (ranibizumab) for intravitreal injection	**ONE** of the following (A or B): A. Patient is currently receiving therapy with Lucentis; OR B. Patient meets ONE of the following (i, ii, iii, or iv): i. Patient meets BOTH of the following [a and b]: a. Patient has previously tried repackaged bevacizumab; AND b. Either inadequate efficacy or intolerability was demonstrated; OR ii. Patient has diabetic retinopathy (without diabetic macular edema); OR iii. In the professional opinion of the prescriber, the safety of using repackaged bevacizumab is of significant concern; OR iv. In the professional opinion of the prescriber, the supplier of repackaged bevacizumab is of significant concern.

Conditions Not Covered

Intravitreal ranibizumab injection for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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), aflibercept intravitreal injection (Eylea®/biosimilars, Eylea® HD), Beovu® (brolucizumab-dbll intravitreal injection), and Vabysmo® (faricimab-svoa intravitreal injection).

Coding Information

Note:
1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J2778	Injection, ranibizumab, 0.1 mg
Q5124	Injection, ranibizumab-nuna, biosimilar, (Byooviz), 0.1 mg
Q5128	Injection, ranibizumab-eqrn (Cimerli), biosimilar, 0.1 mg

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.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	For all indications/uses, the dosing interval was changed from 25 days to 28 days to align with the prescribing information.	5/1/2024
Annual Revision	No criteria changes.	3/1/2025
Annual Revision	For all uses, the dosing interval was changed **from** "once every 28 days" **to** "once every month (approximately 28 days)." **Employer and Individual and Family Plan: Updated from** "ONE of the following: 1. Currently receiving Cimerli, Byooviz, or Lucentis 2. ONE of the following: a. Documentation of failure, contraindication, or intolerance to repackaged bevacizumab b. If, in the professional opinion of the prescriber, the safety of using the repackaged bevacizumab or the supplier of the repackaged bevacizumab is of significant concern 3. Diabetic retinopathy" **to** "**ONE** of the following (A, B, or C): A. Patient has tried either Eylea or Pavblu **[may require prior authorization];** OR	3/1/2026

	B. Patient with myopic choroidal neovascularization (mCNV); OR C. Patient is currently receiving therapy with" respective product for Byooviz, Cimerli, and Lucentis. **Conditions Not Recommended for Approval:** "Concomitant Use with Another Intravitreal Vascular Endothelial Growth Factor Inhibitor (Except Susvimo [ranibizumab injection via ocular implant])" was added.	

The policy effective date is in force until updated or retired.