ranibizumab

Medical Benefit Drug Policy

Place of Service

Office Administration
Outpatient FacilityAdministration

Drug Details

USP Category: OPHTHALMIC AGENTS
Mechanism of Action: A recombinant humanized IgG1 kappa isotype monoclonal antibody fragment
HCPCS:
J2778:Injection, ranibizumab, 0.1 mg
Q5124:Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg
Q5128:Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg
Q5168:Injection, ranibizumab-leyk (nufymco), biosimilar, 0.1 mg
How Supplied:

- Lucentis: 0.3 mg, 0.5 mg (Single-use syringe)
- Byooviz: 2 mL single-dose vial. Single-dose glass vial provides 0.05 mL for intravitreal injections: 10 mg/mL solution (0.5 mg/0.05 ml dose).
- Cimerli or Nufymco: 0.3 mg, 0.5 mg (Single-dose glass vial)

Condition(s) listed in policy *(see coverage criteria for details)*

- Diabetic Macular Edema (DME) or Diabetic Retinopathy (DR)
- Macular Edema Following Retinal Vein Occlusion (RVO)
- Myopic Choroidal Neovascularization (mCNV)
- Neovascular (Wet) Age-Related Macular Degeneration (AMD)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Diabetic Macular Edema (DME) or Diabetic Retinopathy (DR)

Meets medical necessity if all the following are met:

Initial

1. Request is for Lucentis, Cimerli, or Nufymco
2. If request is for Lucentis: Intolerable side effect with preferred ranibizumab products (e.g., Cimerli, Nufymco) that is not expected with Lucentis, or contraindication to all preferred products

Reauthorization

1. Patient is responding to therapy
   .1

Covered Doses:

Up to 0.3 mg (3 units) given intravitreally once monthly into the affected eye

Coverage Period:

Yearly

ICD-10:

E08.31-E08.3599, E09.31-E09.3599, E10.31-E10.3599, E11.31-E11.3599, E13.31-E13.3599

Macular Edema Following Retinal Vein Occlusion (RVO)

Meets medical necessity if all the following are met:

Initial

1. Request is for Lucentis, Byooviz, Cimerli, or Nufymco
2. If request is for Lucentis: Intolerable side effect with preferred ranibizumab products (e.g., Byooviz, Cimerli, and Nufymco) that is not expected with Lucentis, or contraindication to all preferred products

Reauthorization

1. Patient is responding to therapy

Covered Doses:

Up to 0.5 mg (5 units) given as an intravitreal injection once a month into the affected eye

Coverage Period:

Yearly

ICD-10:

H34.81, H34.811, H34.8110, H34.8111, H34.8112, H34.812, H34.8120, H34.8121, H34.8122, H34.813, H34.8130, H34.8131, H34.8132, H34.819, H34.8190, H34.8191, H34.8192, H34.83, H34.831, H34.8310, H34.8311, H34.8312, H34.832, H34.8320, H34.8321, H34.8322, H34.833, H34.8330, H34.8331, H34.8332, H34.839, H34.8390, H34.8391, H34.8392

Myopic Choroidal Neovascularization (mCNV)

Meets medical necessity if all the following are met:

Initial

1. Request is for Lucentis, Byooviz, Cimerli, or Nufymco
2. If request is for Lucentis: Intolerable side effect with preferred ranibizumab products (e.g., Byooviz, Cimerli, and Nufymco) that is not expected with Lucentis, or contraindication to all preferred products

Reauthorization

1. Patient is responding to therapy

Covered Doses:

Up to 0.5 mg (5 units) given as an intravitreal injection once monthly into the affected eye

Coverage Period:

Yearly

ICD-10:

H35.05, H35.051, H35.052, H35.053, H35.059, H44.2A, H44.2A1, H44.2A2, H44.2A3, H44.2A9

Neovascular (Wet) Age-Related Macular Degeneration (AMD)

Meets medical necessity if all the following are met:

Initial

1. Request is for Lucentis, Byooviz, Cimerli, or Nufymco
2. If request is for Lucentis: Intolerable side effect with preferred ranibizumab products (e.g., Byooviz, Cimerli, and Nufymco) that is not expected with Lucentis, or contraindication to all preferred products

Reauthorization

1. Patient is responding to therapy

Covered Doses:

Up to 0.5 mg (5 units) given as an intravitreal injection once monthly into the affected eye

Coverage Period:

Yearly

ICD-10:

H35.32, H35.321, H35.3210, H35.3211, H35.3212, H35.3213, H35.322, H35.3220, H35.3221, H35.3222, H35.3223, H35.323, H35.3230, H35.3231, H35.3232, H35.3233, H35.329, H35.3290, H35.3291, H35.3292, H35.3293

References

1. AHFS. Available by subscription at http://www.lexi.com
2. Byooviz (ranibizumab-nuna) Prescribing Information. Biogen Inc., Cambridge, MA: 8/2025.
3. Cimerli (ranibizumab-eqrn) Prescribing Information. Coherus Biosciences, Inc., Redwood City, CA: 5/2025.
4. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
5. Lucentis (ranibizumab) Prescribing Information. Genentech, Inc., South San Francisco, CA: 2/2024.
6. Nufymco (ranibizumab-leyk) Prescribing information. Zydus Pharmaceuticals (USA) Inc., Pennington, NJ: 6/2026.

Review History

Date of Last Annual Review: 1Q2026

Changes from previous policy version:

- Added new drug Nufymco for (1) neovascular (wet) age-related macular degeneration; (2) macular edema following retinal vein occlusion; (3) diabetic macular edema; (4) diabetic retinopathy; (5) myopic choroidal neovascularization (Rationale: FDA approval)
- Nufymco will be a preferred ranibizumab product (Rationale: cost effective biosimilar)

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee