

Jurisdiction Specific Medicare Part B Lucentis and Biosimilars

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lucentis	ranibizumab
Byooviz	ranibizumab-nuna
Cimerli	ranibizumab-eqrn

Covered Uses

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-labeled indications and recognized compendial (off-label) uses:

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

Compendial uses- ICD-10 codes supported by the Medicare Administrative Contractor

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Neovascular (Wet) Age-Related Macular Degeneration¹⁻⁶

Authorization of 12 months may be granted for treatment of neovascular (wet) age-related macular degeneration.

Macular Edema Following Retinal Vein Occlusion¹⁻⁶

Authorization of 12 months may be granted for treatment of macular edema following retinal vein occlusion (RVO).

Diabetic Macular Edema^{1-4,6}

Authorization of 12 months may be granted for treatment of diabetic macular edema (DME).

Diabetic Retinopathy^{1-4,6}

Authorization of 12 months may be granted for treatment of diabetic retinopathy (DR).

Myopic Choroidal Neovascularization¹⁻⁶

Authorization of 12 months may be granted for treatment of myopic choroidal neovascularization (mCNV).

Retinopathy of prematurity^{1-3,7}

Authorization of 12 months may be granted for the treatment of retinopathy of prematurity.

All Other Indications¹⁻³

Authorization of 12 months may be granted for treatment of all other approvable indications listed in LCA A52451.

Dosage and Administration

Approvals may be subject to administration and dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

References

1. Drugs and Biologicals LCD (L33394) Version R16. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed February 15, 2024.
2. Billing and Coding: Ranibizumab and biosimilars, Aflibercept, Aflibercept HD, Brolucizumab-dbl, and Faricimab-svoa (A52451) Version R20. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed February 14, 2025.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R9. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed February 15, 2024.
4. Lucentis [package insert]. South San Francisco, CA: Genentech, Inc.; February 2024.
5. Byooviz [package insert]. Cambridge, MA: Biogen, Inc.; October 2023.
6. Cimerli [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; June 2024.
7. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com/>. Accessed February 14, 2025.