

Specialty Guideline Management

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

Indications

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

FDA-approved Indications^{1,5,6}

Lucentis, Byooviz and Cimerli are indicated for:

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

Lucentis and Cimerli are also indicated for:

- Diabetic macular edema
- Diabetic retinopathy

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Diabetic Macular Edema^{1,3,6}

Authorization of 6 months may be granted for treatment of diabetic macular edema.

Neovascular (Wet) Age-Related Macular Degeneration^{1,2,5,6}

Authorization of 6 months may be granted for treatment of neovascular (wet) age-related macular degeneration.

Macular Edema Following Retinal Vein Occlusion^{1,4,5,6}

Authorization of 6 months may be granted for treatment of macular edema following retinal vein occlusion.

Diabetic Retinopathy^{1,3,6}

Authorization of 6 months may be granted for treatment of diabetic retinopathy.

Myopic Choroidal Neovascularization^{1,5,6}

Authorization of 6 months may be granted for treatment of myopic choroidal neovascularization.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the criteria coverage section when the member has demonstrated a positive clinical response to therapy (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss).

References

1. Lucentis [package insert]. South San Francisco, CA: Genentech, Inc.; February 2024.
2. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: <https://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp>.

Reference number(s)
1976-A

3. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Diabetic Retinopathy. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: <https://www.aao.org/preferred-practice-pattern/diabetic-retinopathy-ppp>.
4. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Retinal Vein Occlusions. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: <https://www.aao.org/preferred-practice-pattern/retinal-vein-occlusions-ppp>.
5. Byooviz [package insert]. Cambridge, MA: Biogen, Inc.; October 2023.
6. Cimerli [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; June 2024.