

PHARMACY POLICY STATEMENT

North Carolina Marketplace

DRUG NAME	Ranibizumab (Lucentis, Byooviz, Cimerli)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Lucentis was approved by the FDA in 2006. It is indicated for the treatment of several ophthalmic conditions. Lucentis is a vascular endothelial growth factor (VEGF) inhibitor for intravitreal use. VEGF inhibitors suppress endothelial cell proliferation, neovascularization, and vascular permeability.

There are 2 forms of age-related macular degeneration (AMD), dry and wet (neovascular). Lucentis is approved for the treatment of Wet AMD which is less common but progresses more quickly. Neovascular in the context of AMD means growth of new blood vessels under the macula which can lead to loss of central vision.

Diabetic eye disease includes diabetic retinopathy (DR) and diabetic macular edema (DME). DR affects blood vessels in the retina at the back of the eye. DME is a consequence of DR that occurs in about half of DR patients. It causes fluid build-up in the macula part of the retina.

Retinal Vein Occlusion (RVO) occurs when there is a partial or complete obstruction of a retinal vein. Macular edema is a complication of RVO and can lead to vision loss. It is treated first-line with anti-VEGF drugs.

Myopia (nearsightedness) occurs when the eyeball becomes elongated. In pathological myopia, progressive elongation can cause a weakened sclera to bulge at the posterior of the eye which can lead to thinning of the retina and growth of new blood vessels. This can result in vision loss if not treated.

Two biosimilar products have also been approved, Byooviz and Cimerli. Cimerli is interchangeable with Lucentis but Byooviz is not.

Ranibizumab will be considered for coverage when the following criteria are met:

Retinal Disease

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an ophthalmologist; AND
3. Member has a confirmed diagnosis of one of the following conditions:
 - a) Neovascular (Wet) Age-Related Macular Degeneration (AMD)
 - b) Macular Edema Following Retinal Vein Occlusion (RVO)
 - c) Diabetic Macular Edema (DME) [Lucentis or Cimerli only]
 - d) Diabetic Retinopathy (DR) [Lucentis or Cimerli only]
 - e) Myopic Choroidal Neovascularization (mCNV); AND
4. Member has tried and failed bevacizumab intravitreal injection; AND
5. Documentation of best-corrected visual acuity (BCVA); AND
6. Member does NOT have active infection or inflammation in or around the eye(s) to be treated.
7. **Dosage allowed/Quantity limit:**
 - AMD: 0.5 mg every 28 days (may extend to every 3 months after 4 monthly doses).
 - RVO: 0.5 mg every 28 days
 - DME or DR: 0.3 mg every 28 days
 - CNV: 0.5 mg every 28 days for up to 3 months. Re-treat if needed.

If all the above requirements are met, the medication will be approved for 6 months (3 months for mCNV).

For **reauthorization**:

1. Chart notes must include documentation of improved or stabilized visual acuity.

If all the above requirements are met, the medication will be approved for an additional 12 months (3 months for mCNV).

CareSource considers Ranibizumab not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/26/2021	New policy for Lucentis created.
04/07/2023	Changed policy name to Ranibizumab and added biosimilars.

References:

1. Lucentis [prescribing information]. Genentech, Inc.; 2018.
2. Byooviz [prescribing information]. Biogen, Inc.; 2022.
3. Cimerli [prescribing information]. Coherus BioSciences, Inc.; 2022.
4. Flaxel CJ, Adelman RA, Bailey ST, et al. Age-Related Macular Degeneration Preferred Practice Pattern® [published correction appears in Ophthalmology. 2020 Sep;127(9):1279]. *Ophthalmology*. 2020;127(1):P1-P65. doi:10.1016/j.ophtha.2019.09.024
5. Solomon SD, Lindsley K, Vedula SS, Krzystolik MG, Hawkins BS. Anti-vascular endothelial growth factor for neovascular age-related macular degeneration. *Cochrane Database Syst Rev*. 2019;3(3):CD005139. Published 2019 Mar 4. doi:10.1002/14651858.CD005139.pub4
6. Holekamp, Nanvy M. Review of Neovascular Age-Related Macular Degeneration Treatment Options. *Am J Manag Care*. July 2019; 25:-S0
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9. Flaxel CJ, Adelman RA, Bailey ST, et al. Diabetic Retinopathy Preferred Practice Pattern® [published correction appears in Ophthalmology. 2020 Sep;127(9):1279]. *Ophthalmology*. 2020;127(1):P66-P145. doi:10.1016/j.ophtha.2019.09.025
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12. Pham B, Thomas SM, Lillie E, et al. Anti-vascular endothelial growth factor treatment for retinal conditions: a systematic review and meta-analysis. *BMJ Open*. 2019;9(5):e022031. Published 2019 May 28. doi:10.1136/bmjopen-2018-022031

Effective date: 10/01/2023

Revised date: 04/07/2023