Reference number(s)
3831-A

JURISDICTION SPECIFIC MEDICARE PART B

LUCENTIS (ranibizumab)
BYOOVIZ (ranibizumab-nuna)
CIMERLI (ranibizumab-eqrn)

POLICY

I. 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.

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. The FDA-labeled indications are listed below:

A. Neovascular (wet) age-related macular degeneration (AMD)
B. Macular edema following retinal vein occlusion (RVO)
C. Myopic choroidal neovascularization (mCNV)

Lucentis and Cimerli are also indicated for:
A. Diabetic macular edema (DME)
B. Diabetic retinopathy (DR)

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

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
A. Relevant medical history, physical examination, results of pertinent diagnostic tests or procedures
B. Medical record with name of drug administered, route of administration, dosage, duration of the administration.

III. CRITERIA FOR APPROVAL

A. Neovascular (Wet) Age-Related Macular Degeneration (AMD)
Authorization of 12 months may be granted for treatment of neovascular (wet) age-related macular degeneration (AMD).

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B. Macular Edema Following Retinal Vein Occlusion (RVO)
Authorization of 12 months may be granted for treatment of macular edema following retinal vein occlusion (RVO).

C. Diabetic Macular Edema (DME)[1-4,6]
Authorization of 12 months may be granted for treatment of diabetic macular edema (DME).

D. Diabetic Retinopathy (DR)[1-4,6]
Authorization of 12 months may be granted for treatment of diabetic retinopathy (DR).

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

IV. DOSAGE AND ADMINISTRATION

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

V. REFERENCES

1. Drugs and Biologicals LCD (L33394) Version R14. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed October 12, 2022.
2. Billing and Coding: Ranibizumab, Aflibercept and Brolucizumab-dbll (A52451) Version R15. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed October 12, 2022.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R8. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed October 12, 2022.
4. Lucentis [package insert]. South San Francisco, CA: Genentech, Inc.; October 2020.
5. Byooviz [package insert]. Cambridge, MA: Biogen, Inc.; September 2021.
6. Cimerli [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; August 2022