ranibizumab

Medicare Part B Drug Policy

- Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category).
- Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50, describes national policy regarding Medicare guidelines for coverage of drugs and biologicals.
- Blue Shield of California (BSC) follows Medicare statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and policy articles for determining coverage for Part B drug requests when applicable.
- BSC Medicare Part B Drug Policies will be used when coverage criteria are not fully established or there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs.

Drug Details

USP Category: OPHTHALMIC AGENTS
Mechanism of Action: a recombinant humanized IgG1 kappa isotype monoclonal antibody fragment designed for intraocular use. Ranibizumab binds to and inhibits the biologic activity of human vascular endo
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
How Supplied:
Byooviz
2 mL single-dose vial
Single-dose glass vial provides 0.05 mL for intravitreal injections: 10 mg/mL solution (0.5 mg dose)

Cimerli
0.3 mg (Single-use vial)
0.5 mg (Single-use vial)

Lucentis
0.3 mg (Single-use syringe)
0.5 mg (Single-use syringe)

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

- Diabetic Macular Edema (DME) or Diabetic Retinopathy
- Macular Edema Secondary to Retinal Vein Occlusion
- Myopic Choroidal Neovascularization
- Neovascular (Wet) Age-Related Macular Degeneration (AMD)

Any request for a condition not listed in policy must meet the definition of a medically accepted indication. Section 1861(t)(2)(B) of the Act defines "medically-accepted indication," as any use of a prescription drug or biological product which is approved under the Federal Food, Drug, and

Cosmetic Act, or the use of which is supported by one or more citations included (or approved for inclusion) in one or more of the CMS approved compendia.

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.

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

Diabetic Macular Edema (DME) or Diabetic Retinopathy
Meets medical necessity if all the following are met:
1. Request is for Cimerli or Lucentis

Covered Doses:
Up to 0.3 mg once a month injected into affected eye

Coverage Period:
Yearly, based on continued response to therapy

ICD-10:
(X= 0-9) E08.3XXX, E09.3XXX, E10.3XXX, E11.3XXX, E13.3XXX

Macular Edema Secondary to Retinal Vein Occlusion
Meets medical necessity if all the following are met:

Covered Doses:
Up to 0.5 mg once a month injected into affected eye

Coverage Period:
Yearly, based on continued response to therapy

ICD-10:
H34.8110-8112, H34.8120-8122, H34.8130- 8132, H34.8190-8192, H34.8310-8312, H34.8320-8322, H34.8330- 8332, H34.8390-8392

Myopic Choroidal Neovascularization
Meets medical necessity if all the following are met:

Covered Doses:
Up to 0.5 mg once a month injected into affected eye

Coverage Period:
Yearly, based on continued response to therapy

ICD-10:
H35.059

Neovascular (Wet) Age-Related Macular Degeneration (AMD)
Meets medical necessity if all the following are met:

Covered Doses:
Up to 0.5 mg once a month injected into affected eye

Coverage Period:
Yearly, based on continued response to therapy

ICD-10:
H35.3210-3213 H35.3220-3223 H35.3230-3233 H35.3290-3293

Additional Information

Summary of Evidence

The contents of this policy were created after examining the following resources:

1. The prescribing information for Byooviz, Cimerli, and Lucentis
2. CMS approved compendium in accordance with the accepted compendia ratings listed:
   a. Micromedex DrugDex - Class I, Class IIa, of Class IIb
   b. American Hospital Formulary Service-Drug Information (AHFS-DI) - supportive narrative text

Explanation of Rationale:

- Support for FDA-approved indications can be found in the manufacturer's prescribing information.

References

1. CMS Benefit Policy Manual. Chapter 15; § 50 Drugs and Biologicals
2. Medicare Coverage Database. Available at https://www.cms.gov/Medicare-Coverage-Database/search.aspx
3. Social Security Act (Title XVIII) Standard References, Sections: 1862(a)(1)(A) Medically Reasonable & Necessary; 1862(a)(1)(D) Investigational or Experimental; 1833(e) Incomplete Claim; 1861(t) (1) Drugs and Biologicals
4. AHFS. Available by subscription at http://www.lexi.com
5. Byooviz (ranibizumab-nuna) Prescribing Information. Biogen Inc., Cambridge, MA: 8/2025.
6. Cimerli (ranibizumab-eqrn) Prescribing Information. Coherus Biosciences, Inc., Redwood City, CA: 5/2025.
7. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
8. Lucentis (ranibizumab) Prescribing Information. Genentech, Inc., South San Francisco, CA: 2/2024.

Review History

Date of Last Annual Review: 1Q2026
Changes from previous policy version:

- No clinical changes following annual review

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

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