Ranibizumab (Lucentis®)	Place of Service Office Administration Outpatient FacilityAdministration Infusion Center Administration HCPCS: J2778 per 0.1 mg

Condition(s) listed in policy (*see 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 (nAMD)

AHFS therapeutic class: EENT Drugs, Miscellaneous

Mechanism of action: Ranibizumab is a recombinant humanized IgG1 kappa isotype monoclonal antibody fragment designed for intraocular use. Ranibizumab binds to and inhibits the biologic activity of human vascular endothelial growth factor A (VEGF-A)

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Lucentis® (ranibizumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Diabetic macular edema (DME) or diabetic retinopathy

1. Diagnosis, **AND**
2. ***Effective 1/30/2023 and after***: Intolerable side effect with preferred ranibizumab product, Cimerli, that is not expected with Lucentis, or contraindication to Cimerli

Covered Doses
Up to 0.3 mg (3 units) once a month injected into affected eye

Coverage Period
Yearly

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

Macular edema secondary to retinal vein occlusion

1. Intolerable side effect with a preferred ranibizumab product, Byooviz or Cimerli, that is not expected with Lucentis, or contraindication to both preferred products

Covered Doses
Up to 0.5 mg (5 units) once a month injected into affected eye

Coverage Period
Yearly

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

1. Intolerable side effect with a preferred ranibizumab product, Byooviz or Cimerli, that is not expected with Lucentis, or contraindication to both preferred products

Covered Doses
Up to 0.5 mg (5 units) once a month injected into affected eye

Coverage Period
Yearly

ICD-10:
H35.051-H35.053
H35.059
H44.21-H44.23

Neovascular (Wet) age-related macular degeneration (nAMD)

1. Intolerable side effect with a preferred ranibizumab product, Byooviz or Cimerli, that is not expected with Lucentis, or contraindication to both preferred products

Covered Doses
Up to 0.5 mg (5 units) once a month injected into affected eye

Coverage Period
Yearly

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

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for Lucentis® (ranibizumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)
Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Combination with Verteporfin

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
0.3 mg (Single-use vial)
0.5 mg (Single-use vial)

0.3 mg (Single-use pre-filled syringe)
0.5 mg (Single use pre-filled syringe)

Per prescribing information, proper aseptic injection technique should always be used when administering Lucentis intravitreal injection. Monitoring for elevation in intraocular pressure and endophthalmitis is recommended.

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Lucentis® (ranibizumab) [Prescribing information]. South San Francisco, CA: Genentech, Inc., 3/2018.

(7) Policy Update

Date of last revision: 4Q2023
Date of next review: 1Q2024

Changes from previous policy version:
- No clinical change to policy following revision.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee