Effective Date: 02/2012
Last P&T Approval/Version: 10/27/2021
Next Review Due By: 11/2022
Policy Number: C10417-A

Lucentis (ranibizumab)

PRODUCTS AFFECTED

Lucentis (ranibizumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:
Diabetic macular edema, Neovascular (wet or exudative) age-related macular degeneration, Macular edema following retinal vein occlusion, Diabetic retinopathy or Myopic choroidal neovascularization

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. FOR ALL INDICATIONS:
1. Documented diagnosis of ANY of the following: Neovascular (Wet) age-related macular degeneration, Macular edema following retinal vein occlusion, Diabetic macular edema, Diabetic retinopathy, or Myopic choroidal neovascularization
   AND

2. Documentation that member is free of ocular and/or peri-ocular infections
   AND
3. Documentation of trial/failure or contraindication to bevacizumab (10, 11,12,13)
   AND
4. Documentation of baseline visual status with notation of eye(s) being treated
   AND
5. Lucentis (ranibizumab) is prescribed as monotherapy (no other anti-VEGF) medications.
   AND
6. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted forreview [Contraindications to Lucentis (ranibizumab) include: ocular or periocular infections, known hypersensitivity to ranibizumab or any of the excipients in Lucentis]

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:

1. Documentation of improvement or stabilization of disease state and visual status that has been submitted
   AND
2. Documentation of administration records showing dates and eye(s) administered, along with documentation of member compliance with treatment plan
   NOTE: Therapy may be discontinued due to poor adherence upon recommendation of the Molina Medical Director when adherence < 85% has been demonstrated in at least two months during the course of therapy
   AND
3. Documentation of absence of unacceptable toxicity from the drug (i.e.. endophthalmitis and retinal detachments; increase in intraocular pressure or arterial thromboembolic events)
   AND
4. Lucentis (ranibizumab) is being prescribed as monotherapy: Member is not on additional anti-VEGF medications [i.e., bevacizumab (Avastin), pegaptanib (Macugen), and aflibercept (Eylea)]

DURATION OF APPROVAL:

Initial: 6 months, Continuation: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified ophthalmologist, ophthalmic surgeon or retinal specialist. [If prescribed in consultation, consultation notes must be submitted within initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

Age-related macular degeneration (AMD), neovascular (wet): One eye: ONE injection per month; Up to TWELVE vials per year, Both eyes: TWO injections per month; Up to TWENTY-FOUR vials per year J2778 – 5 units/eye (0.5 mg) every 30 days

Diabetic macular edema (DME): Intravitreal: 0.3 mg once a month (approximately every 28 days);J2778 – 3 units/eye (0.3 mg) every 30 days

Diabetic retinopathy: Intravitreal: 0.3 mg once a month (approximately every 28 days); J2778 – 3 units/eye (0.3 mg) every 30 days

Myopic choroidal neovascularization: One eye: ONE injection per month; Up to TWELVE vials per year, Both eyes: TWO injections per month; Up to TWENTY-FOUR vials per year J2778 – 5 units/eye (0.5 mg) every 30 days

Macular edema following retinal vein occlusion: One eye: ONE injection per month; Up to TWELVE vials per year, Both eyes: TWO injections per month; Up to TWENTY-FOUR vials per yearJ2778 – 5 units/eye (0.5mg) every 30 days

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the intravitreal injectable products be administered in a place of service that is a non- hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravitreal injection

DRUG CLASS:
Vascular endothelial growth factor (VEGF) antagonists

FDA-APPROVED USES:
Lucentis is indicated for the treatment of members with: Neovascular
(Wet) age-related macular degeneration, Macular edema following retinal vein occlusion, Diabetic macular edema, Diabetic retinopathy and myopic choroidal neovascularization

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Lucentis (ranibizumab) that are not an FDA-approved indication or not included in the 'Coverage Criteria 'section of this policy is considered experimental/investigational or not a covered benefit of this policy. Other contraindications include ocular or periocular infection and Concurrent use of other VEGF products.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J2778	Injection, ranibizumab, 0.1 mg

AVAILABLE DOSAGE FORMS:
Intraocular Solution: 0.3 MG/0.05 ML, 0.5 MG/0.05 ML

REFERENCES

1. Lucentis [package insert]. South San Francisco, CA: Genentech, Inc.; March 2018
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4. Zhang G, Yang M, Zeng J, et al: Comparison of intravitreal injection of ranibizumab versus laser therapy for zone II treatment-requiring retinopathy of prematurity. Retina 2017; 37(4):710-717.
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6. Kabatas EU, Kurtul BE, Altiaylik Ozer P, et al: Comparison of intravitreal bevacizumab, intravitreal ranibizumab and laser photocoagulation for treatment of type 1 retinopathy of prematurity in Turkish preterm children. Curr Eye Res 2017; 42(7):1054-1058.
7. Rich RM, Rosenfeld PJ, Puliafito CA, et al. Short-term safety and efficacy of intravitreal bevacizumab (Avastin) for neovascular age-related macular degeneration. Retina 2006; 26:495-511.
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11. Rajendram R, Fraser-Bell S, Kaines A, et al: A 2-year prospective randomized controlled trial of intravitreal bevacizumab or laser therapy (BOLT) in the management of diabetic macular edema: 24-month data: report 3. Arch Ophthalmol 2012; 130(8):972-979.
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13. Iacono P, Parodi MB, Papayannis A, et al: Intravitreal ranibizumab versus bevacizumab for treatment of myopic choroidal neovascularization. Retina 2012; 32(8):1539-1546.