Original Effective Date: 02/2012
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Policy Number: C10417-A

Ranibizumab and Biosimilars (Lucentis, Byooviz, Cimerli)

PRODUCTS AFFECTED

Byooviz (ranibizumab-nuna), Cimerli (ranibizumab-eqrn), 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. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. 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 (Lucentis, Cimerli Only), Diabetic retinopathy (Lucentis, Cimerli Only), or Myopic choroidal neovascularization
   AND
2. Documentation of baseline visual status with notation of eye(s) being treated [DOCUMENTATION REQUIRED]
   AND
3. Prescriber attests or clinical reviewer has found that requested medication will not be used with other ophthalmic VEGF inhibitors (i.e., aflibercept, bevacizumab, brolucizumab, faricimab, etc.)
   AND
4. Documentation of an inadequate response (defined as 1-2 injections with minimal to no improvement), clinically significant adverse effects, or contraindication to bevacizumab OR bevacizumab is indicated by the provider as unavailable
   AND
5. 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 for review [Contraindications to Ranibizumab include: ocular or periocular infections, known hypersensitivity to ranibizumab or any of the product excipients.]
   AND
6. (a) IF THIS IS A PHARMACY BENEFIT REQUEST FOR A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary alternatives for the given diagnosis. Documentation of medication(s) tried, dates of trial(s) and reason for treatment failure(s) is required.
   AND
   (b) If request is for reference product with a biosimilar available for initial or continuation of therapy requests: Documentation of a trial and failure, serious side effects or contraindication to a majority (not more than 3) biosimilar product(s) is required (unless otherwise specified per applicable state regulations and/or there is data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs).
   [DOCUMENTATION REQUIRED: Document when the preferred biologic product or biosimilar was tried and the length of the trial period. Provide specific clinical documentation of therapeutic failure on the preferred biologic product or biosimilar whenever possible. Describe the medical problem caused by the preferred referenced biologic. Vague and non-descriptive symptoms are not adequate rationale (e.g., stomachache).]
   OR
7. FOR INITIAL OR CONTINUATION OF THERAPY REQUESTS OF A PHYSICIAN ADMINISTERED MEDICATION: BIOSIMILAR DRUGS are preferred when requested as a physician administered drug per applicable state regulations and/or there is a lack of data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs. A reference medication is approved under the following conditions:
   a. Treatment with at least two associated biosimilar drug(s) has been ineffective, resulted in serious side effects, or is contraindicated (i.e. an allergic reaction to a specific inactive ingredient in the preferred biologic product or biosimilar OR an adverse reaction to a specific inactive ingredient in the preferred biologic product or biosimilar OR therapeutic success while taking a non-preferred biologic product or biosimilar and therapeutic failure while taking the preferred biologic product or biosimilar documented by patient diary or medical charted notes)

   [DOCUMENTATION REQUIRED: Document when the preferred biologic product or biosimilar was tried and the length of the trial period. Provide specific clinical documentation of therapeutic failure on the preferred biologic product or biosimilar whenever possible. Describe the medical

problem caused by the preferred referenced biologic. Vague and non-descriptive symptoms are not adequate rationale (e.g., stomachache).]

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:

1. Reauthorization request is for the same eye(s) as initial authorization
   NOTE: The continuation of therapy criteria is only for the same previously treated eye(s). If member has developed condition in an untreated eye, Prescriber must submit new request with Initial Coverage criteria.
   AND
2. Documentation of improvement or stabilization of disease state (e.g., reduction in rate of progression and frequency of retinopathy, hemorrhage, macular edema, etc.) and visual status [DOCUMENTATION REQUIRED]
   AND
3. Documentation of administration records showing dates and eye(s) administered, along with documentation of member compliance with treatment plan
   AND
4. Prescriber attests to or clinical reviewer has found no evidence of unacceptable toxicity from the drug (i.e., endophthalmitis and retinal detachments, increase in intraocular pressure or arterial thromboembolic events)
   AND
5. Prescriber attests or clinical reviewer has found that requested medication will not be used with other ophthalmic VEGF inhibitors (i.e., aflibercept, bevacizumab, brolucizumab, faricimab, etc.)

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 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 with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

Age-related macular degeneration (AMD), neovascular (wet):
0.5mg (0.05 mL) once a month (approximately 28 days)

Diabetic macular edema (DME), Diabetic retinopathy (DR) [Lucentis, Cimerli Only]:
0.3 mg (0.05 mL) once a month (approximately 28 days)

Myopic choroidal neovascularization:
0.5mg (0.05 mL) once a month (approximately 28 days) for up to 3 months; may be retreated if needed

Macular edema following retinal vein occlusion:
0.5mg (0.05 mL) once a month (approximately 28 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 (ranibizumab injection), Cimerli (ranibizumab-eqrn) are indicated for the treatment of patients with: Neovascular (Wet) age-related macular degeneration, Macular edema following retinal vein occlusion, Diabetic macular edema, Diabetic retinopathy and Myopic choroidal neovascularization

Byooviz (ranibizumab-nuna) is indicated for the treatment of patients with:
Neovascular (Wet) Age-Related Macular Degeneration, Macular Edema Following Retinal Vein Occlusion, Myopic Choroidal Neovascularization

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
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/ Q5124 – 5 units/eye (0.5 mg) every 30 days
Diabetic macular edema (DME) [Lucentis, Cimerli Only]: Intravitreal: 0.3 mg once a month (approximately every 28 days); J2778 – 3 units/eye (0.3 mg) every 30 days
Diabetic retinopathy [Lucentis, Cimerli Only]: 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/ Q5124 – 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 year J2778 – 5 units/eye (0.5mg) every 30 days

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of ranibizumab are considered experimental/investigational and therefore, will follow Molina's Off-Label policy.
Contraindications to ranibizumab include: ocular or periocular infection, hypersensitivity to ranibizumab or any of the product excipients.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J2778	Injection, ranibizumab, 0.1 mg
Q5124	Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg
Q5128	Injection, ranibizumab-eqrn, biosimilar, (cimerli), 0.1 mg

AVAILABLE DOSAGE FORMS:

Byooviz SOLN 0.5MG/0.05ML single-dose vial
Cimerli SOLN 0.3MG/0.05ML single-dose vial
Cimerli SOLN 0.5MG/0.05ML single-dose vial
Lucentis SOLN 0.3MG/0.05ML
Lucentis SOLN 0.5MG/0.05ML
Lucentis SOSY 0.3MG/0.05ML prefilled syringe
Lucentis SOSY 0.5MG/0.05ML prefilled syringe

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information	Q1 2025
REVISION- Notable revisions: Coding/Billing Information Template Update References	Q4 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity Appendix Contraindications/Exclusions/Discontinuation Coding/Billing Information Available Dosage Forms References	Q4 2023
REVISION- Notable revisions: Title Required Medical Information Continuation of Therapy Quantity Other Special Considerations Available Dosage Forms References	Q4 2022
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity FDA Approved Uses Coding/Billing Information Available Dosage Forms References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file