



<b>Policy Title:</b>	Ranibizumab: Lucentis, Byooviz		
		<b>Department:</b>	PHA
<b>Effective Date:</b>	01/01/2020		
<b>Review Date:</b>	04/10/2019, 9/18/2019, 12/20/2019, 1/29/2020, 4/15/2020, 5/20/2021, 06/16/2022		
<b>Revision Date:</b>	04/10/2019, 9/18/2019, 12/20/2019, 1/29/2020, 4/15/2020, 5/20/2021, 06/16/2022		

**Purpose:** To support safe, effective and appropriate use of ranibizumab in patients with neovascular (wet) age related macular degeneration (AMD), macular edema due to retinal vein occlusion (RVO), diabetic macular edema (DME) or diabetic retinopathy or Myopic Choroidal Neovascularization (mCNV).

**Scope:** Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

**Policy Statement:**

Lucentis (ranibizumab) and Byooviz (ranibizumab) are covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

**Procedure:**

Coverage of Lucentis (ranibizumab) and Byooviz (ranibizumab) will be reviewed prospectively via the prior authorization process based on criteria below.

**Initial Criteria:**

- Patient is at least 18 years of age or older; AND
- Prescribed by or in consultation with an Retina Specialist; AND
- Must have a diagnosis of one of the following:
  - Neovascular (wet) age related macular degeneration (AMD)
  - Macular edema due to retinal vein occlusion (RVO)
  - Diabetic macular edema (DME)
  - Diabetic retinopathy
  - Myopic Choroidal Neovascularization (mCNV);AND
- If the requested drug is Lucentis or Byooviz, the patient must have an inadequate treatment response, documented intolerance or contraindication to treatment with bevacizumab; AND

- If the requested drug is Lucentis for AMD, RVO or mCNV, the patient must also have an inadequate treatment response, intolerance or contraindication to treatment with Byooviz; AND
- Patient is free of ocular and/or peri-ocular infections; AND
- Therapy will not be used with other ophthalmic VEGF inhibitors (i.e., aflibercept, pegaptanib, brolucizumab, bevacizumab, ranibizumab via ocular implant\*, etc.)
- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; AND
- Dose does not exceed:
  - Macular edema due to RVO/AMD: 0.5mg administered via intravitreal injection every 4 weeks
  - DME and DR: 0.3mg administered via intravitreal injection every 4 weeks
  - mCNV: 0.5mg administered via intravitreal injection every 4 weeks for up to 3 months;
- Patients that are currently on treatment with Lucentis (ranibizumab) or Byooviz (ranibizumab) can remain on treatment OR MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

*\*Note: Excludes use as 'supplemental-treatment' in conjunction with Susvimo for Neovascular (Wet) Age-Related Macular Degeneration (AMD), if clinically necessary*

#### Renewal coverage:

- Patient meets all initial criteria; AND
- Patient is tolerating treatment; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: endophthalmitis and retinal detachments, increase in intraocular pressure, arterial thromboembolic events, etc.;
- Patient is responding to therapy with stabilization or improvement of visual acuity OR for Myopic choroidal neovascularization ONLY:
  - Continued administration is necessary due to disease activity (i.e., drop in vision, visual symptoms (e.g., metamorphopsia), or the presence of intra-/sub- retinal fluid or active leakage)

#### Coverage durations:

- **Initial coverage:** 12 months for AMD, RVO, DME, & DR  
3 months for mCNV
- **Renewal coverage:** 12 months for AMD, RVO, DME, & DR  
3 months for mCNV

\*\*\* Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. \*\*\*



**Dosage/Administration:**

Drug	Diagnosis	Maximum units (1 billable unit = 0.1 mg)
Lucentis & Byooviz	AMD/RVO/mCNV	10 units every 28 days*
Lucentis	DME/DR	6 units every 28 days *

\*based on administration to both eyes

**Investigational Use:** All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug Information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

**Applicable Codes:**

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
Q5124	Injection, ranibizumab-nuna, biosimilar (byooviz), 0.1mg
J2778	Injection, ranibizumab, 0.1mg

**References:**

1. Lucentis prescribing information. South San Francisco, CA; Genetech, Inc; 2020 October 2020. Accessed June 2022.
2. Wells JA, Glassman AR, Ayala AR, et al. Aflibercept, bevacizumab, or ranibizumab for diabetic macular edema. N Engl J Med. 2015 Mar 26;372(13):1193-203. doi: 10.1056/NEJMoa1414264
3. CATT Research Group, Martin DF, Maguire MG, et al. Ranibizumab and bevacizumab for neovascular age-related macular degeneration. N Engl J Med. 2011May 19 364(20):1897-908. doi: 10.1056/NEJMoa1102673