Policy Title:	Ranibizumab: Lucentis, Byooviz, Cimerli		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	04/10/2019, 9/18/2019, 12/20/2019, 1/29/2020, 4/15/2020, 5/20/2021, 06/16/2022, 7/27/2023, 12/07/2023, 01/04/2024, 12/04/2024		

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), Cimerli (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), Cimerli (ranibizumab) and Byooviz (ranibizumab) will be reviewed prospectively via the prior authorization process based on criteria below.

Summary of Evidence:

Clinical trials evaluating the efficacy and safety of ranibizumab have demonstrated its effectiveness in improving visual acuity and reducing retinal thickness in patients with wet AMD, DME, and macular edema following RVO. Ranibizumab works by inhibiting vascular endothelial growth factor (VEGF), thereby reducing abnormal blood vessel growth and leakage in the retina. Studies have shown that intravitreal injections of ranibizumab lead to significant improvements in visual function and quality of life for patients with these retinal conditions.

Initial Criteria:

- Patient is at least 18 years of age or older; AND
- Prescribed by or in consultation with a Retina Specialist; AND
- Must have a documented 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) (Lucentis and Cimerli only)
  - Diabetic retinopathy (DR) (Lucentis and Cimerli only)
  - Myopic Choroidal Neovascularization (mCNV); AND
- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment**;** AND
- If the requested drug is Lucentis, Cimerli or Byooviz, the patient must have an inadequate treatment response, documented intolerance or contraindication to treatment with bevacizumab; AND
- If the requested drug is Cimerli for AMD, RVO or mCNV, the patient must also have an inadequate treatment response, intolerance or contraindication to treatment with Lucentis or 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.); AND
- Patients that are currently on treatment with Lucentis (ranibizumab), Cimerli (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 with the 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.; AND
  - Patient has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity (BCVA), etc.) and continued administration is necessary for the maintenance treatment of the condition; **OR**
  - 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

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale:
Lucentis, Byooviz, and Cimerli were reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Lucentis, Byooviz, and Cimerli according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using these drugs for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

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
Q5128	Injection, ranibizumab-eqrn(cimerli), biosimilar, 0.1mg
J2778	Injection, ranibizumab, 0.1mg

References:

1. Lucentis prescribing information. South San Francisco, CA; Genetech, Inc; 2020 August 2023. Accessed November 2023.
2. Byooviz [package insert]. Cambridge, MA; Biogen, Inc; October 2023. Accessed November 2023.
3. Cimerli [package insert]. Redwood City, CA; Coherus Biosciences, Inc; November 2022. Accessed November 2023.
4. 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
5. 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