

<b>Policy Title:</b>	Lucentis (ranibizumab)		
		<b>Department:</b>	PHA
<b>Effective Date:</b>	01/01/2020		
<b>Review Date:</b>	04/10/2019, 9/18/2019, 12/20/2019, 1/29/20		
<b>Revision Date:</b>	04/10/2019, 9/18/2019, 12/20/2019, 1/29/20		

**Purpose:** To support safe, effective and appropriate use of Lucentis (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 (mCMV).

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

**Policy Statement:**

Lucentis (ranibizumab) is 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) 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 (mCMV); AND
- Patient must have an adequate trial, documented intolerance or contraindication to treatment with bevacizumab; AND
- Lucentis (ranibizumab) is not considered medically necessary with any of the following concomitant conditions:



- Patient has an ocular and/or peri-ocular infections;
- Concurrent use with other VEGF inhibitors for intraocular use in the absence of documentation indicating that individual products are to be used in different eyes; 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) 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

#### Renewal coverage:

- Patient is tolerating treatment; AND
- 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:** 6 months for AMD, RVO, DME, & DR  
3 months for mCMV
- **Renewal coverage:** 12 months for AMD, RVO, DME, & DR  
3 months for mCMV

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

#### Dosage/Administration:

Diagnosis	Maximum units (1 billable unit = 0.1 mg)
AMD/RVO/mCMV	10 units every 28 days*
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
J2778	Injection, ranibizumab, 0.1mg

#### **References:**

1. Lucentis prescribing information. South San Francisco, CA; Genetech, Inc; 2018 November.
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