Policy Title:	Lucentis (ranibizumab)		
Policy Number:	000669	**Department:**	PHA
Effective Date:	07/01/2019		
Review Date:	04/10/2019		
Revision Date:	04/10/2019		

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, Integrity

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 Coverage for Medicaid and Exchange ONLY:

- 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 a current infection, ocular or periocular infection
- 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

- For patients that are currently on treatment with Lucentis (ranibizumab) they can remain on treatment as long as the medication was not obtained as samples or via manufacturer's patient assistance programs; AND
- Dose does not exceed:
  - Macular edema due to RVO/AMD: 0.5mg 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

Initial Criteria Coverage for Integrity ONLY:

- 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
- Lucentis (ranibizumab) is not considered medically necessary with any of the following concomitant conditions:
  - Patient has a current infection, ocular or periocular infection
  - 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
- For patients that are currently on treatment with Lucentis (ranibizumab) they can remain on treatment as long as the medication was not obtained as samples or via manufacturer's patient assistance programs; AND
- Dose does not exceed:
  - Macular edema due to RVO/AMD: 0.5mg 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

Renewal coverage (Medicaid, Exchange, Integrity):

- 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

Maximum units(1 billable unit = 0.1 mg)

Diagnosis	Maximum units
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
67028	Injection eye drug
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