Clinical Policy: Ranibizumab (Lucentis)

Reference Number: PA.CP.PHAR.186
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for ranibizumab (Lucentis®).

FDA Approved Indication(s)
Lucentis is indicated for the treatment of:

- Neovascular (wet) age-related macular degeneration (AMD)
- Macular edema following retinal vein occlusion (RVO)
- Diabetic macular edema (DME)
- Diabetic retinopathy (DR)
- Myopic choroidal neovascularization (mCNV)

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness that Lucentis is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Ophthalmic Disease (must meet all)**:**

1. Diagnosis of one of the following (a, b, c, d, or e):
   a. Neovascular (wet) AMD;
   b. Macular edema following RVO;
   c. DME;
   d. DR;
   e. mCNV;
2. Prescribed by or in consultation with an ophthalmologist;
3. Age ≥ 18 years;
4. Failure of a trial of bevacizuamb unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed:
   a. DME and DR: 0.3 mg via intravitreal injection once a month;
   b. AMD, RVO, and mCNV: 0.5 mg via intravitreal injection once a month.

Approval duration:
***mCNV*: 3 months**
***All other indications*: 6 months**

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

1. **Ophthalmic Disease** (must meet all)**:** Previously received medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy as evidenced by one of the following:
   a. Detained neovascularization;
   b. Improvement in visual acuity;
   c. Maintenance of corrected visual acuity from prior treatment;
   d. Supportive findings from optical coherence tomography or fluorescein angiography;
3. If request is for a dose increase, new dose does not exceed:
   a. DME and DR: 0.3 mg via intravitreal injection once a month;
   b. AMD, RVO, and mCNV: 0.5 mg via intravitreal injection once a month.

Approval duration:
***mCNV*: 3 months**
***All other indications*: 6 months**

A. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
   Approval duration: Duration of request or 6 months (whichever is less); or

III. 2. Refer to PA.CP.PMN.53 **Diagnoses/Indications for which coverage is NOT authorized:**
- **A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53 or evidence of coverage document;
- **B.** Concomitant use with other anti-vascular endothelial growth factor (VEGF) medications.

Background

Description/Mechanism of Action:

Lucentis (ranibizumab) is a recombinant humanized IgG1 kappa isotype monoclonal antibody fragment. Ranibizumab binds to and inhibits the biologic activity of human vascular endothelial growth factor A (VEGF-A). VEGF-A has been shown to cause neovascularization and leakage in models of ocular angiogenesis and vascular occlusion and is thought to contribute to pathophysiology of neovascular AMD, mCNV, diabetic retinopathy, DME, and macular edema following RVO. The binding of ranibizumab to VEGF-A prevents the interaction of VEGF-A with its receptors (VEGFR1 and VEGFR2) on the surface of endothelial cells, reducing endothelial cell proliferation, vascular leakage, and new blood vessel formation.

Formulations:
- Single-use prefilled syringe: 10 mg/mL solution
- Single-use glass vial: 10 mg/mL or 6 mg/mL solution

Appendices

Appendix A: Abbreviation Key

AMD: age-related macular degeneration
DME: diabetic macular edema
mCNV: myopic choroidal neovascularization
NPDR: non proliferative diabetic retinopathy
PDR: proliferative diabetic retinopathy
RVO: retinal vein occlusion
VEGF: vascular endothelial growth factor
DR: diabetic retinopathy

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2778	Injection, ranibizumab, 0.1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
Added bevacizumab redirection, Added specific documentation of positive response to therapy required for continued approval. Added "not used concomitantly with other VEGF therapies" to section III. Diagnoses/indications NOT authorized. Added specialist requirement Removed criteria checking for contraindications (ocular infections) due to its ophthalmic nature and addition of specialist requirement. Added age limit following safety guidance. References reviewed and updated.	02/18	

References

1. Lucentis Prescribing Information. South San Francisco, CA: Genentech, Inc.; April 2017. Available at: www.lucentis.com. Accessed November 14, 2017.
2. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; January 2015. Available at: www.aao.org/ppp. Accessed November 14, 2017.
3. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Retinal Vein Occlusions. San Francisco, CA: American Academy of Ophthalmology; November 2015. Available at: www.aao.org/ppp. Accessed November 14, 2017.
4. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Diabetic Retinopathy. San Francisco, CA: American Academy of Ophthalmology; February 2016. Available at: www.aao.org/ppp. Accessed November 14, 2017.
5. Wolf S, Valciuniene VJ, Laganovska G, et al. RADIANCE: a randomized controlled study of ranibizumab in patients with choroidal neovascularization secondary to pathologic myopia. Ophthalmology March 2014; 121(3):682-92.e2. doi: 10.1016/j.ophtha.2013.10.023. Epub 2013 Dec 8.

6. El Matri L, Chebil A, and Kort F. Current and emerging treatment options for myopic choroidal neovascularization. Clinical Ophthalmology 2015:9 733–744.