Clinical Policy: Ranibizumab (Lucentis)

Reference Number: CP.PHAR.186
Effective Date: 03/16
Last Review Date: 03/17

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® that Lucentis is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Macular Degeneration and Edema (must meet all):

1. Member has one of the following diagnoses (a, b, c, d, or e):
   a. Neovascular (wet) age-related macular degeneration (AMD);
   b. Macular edema following retinal vein occlusion (RVO);
   c. Diabetic macular edema (DME);
   d. Diabetic retinopathy (DR) (non-proliferative or proliferative) in the presence of DME;
   e. Myopic choroidal neovascularization (mCNV);
2. Prescribed dose of Lucentis does not exceed:
   a. DME and DR in the presence of DME: 0.3 mg every 28 days;
   b. AMD, RVO, and mCNV: 0.5 mg every 28 days;
3. Lucentis will not be used concomitantly with other anti-VEGF medications;
4. At the time of request, member has no ocular or periocular infection.

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

B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

A. Macular Degeneration and Edema (must meet all)**:**

1. Previously received medication via Centene benefit or member has previously met all initial approval criteria;
2. Documentation of positive response to therapy (e.g., detained neovascularization, improvement/stabilization of visual acuity, supportive findings on optical coherence tomography or fluorescein angiography);
3. Lucentis is not being used concomitantly with other anti-vascular endothelial growth factor (VEGF) medications;
4. Prescribed dose does not exceed:

a. DME and DR in the presence of DME: 0.3 mg every 28 days;
b. AMD, RVO, and mCNV: 0.5 mg every 28 days.

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

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy;
2. Refer to CP.PHAR.57 - Global Biopharm Policy**.**

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

FDA Approved Indications:
Lucentis (ranibizumab) is a VEGF inhibitor/solution for intravitreal injection indicated for the treatment of:
- Neovascular (wet) age-related macular degeneration
- Macular edema following retinal vein occlusion
- Diabetic macular edema
- Diabetic retinopathy (non-proliferative diabetic retinopathy, proliferative diabetic retinopathy) in patients with DME
- Myopic choroidal neovascularization

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
Policy converted to new template and split from CP.PHAR.39 AMD Retinal Disorder Treatments. Criteria: added age and max dose; monotherapy defined as "other anti-VEGF drugs" since Visudyne is sometimes used with anti-VEGF drugs in nonresponsive cases; removed requests for documentation.	03/16	03/16
Removed age restriction. Added new FDA-approved indication, mCNV; approval periods are set at 3 months. Removed hypersensitivity safety criteria. Modified "once a month" to "every 28 days." For re-auth: modified "Currently receiving…" to "Previously received…"; modified documentation of positive response criterion to be open-ended; added criterion to verify that Lucentis is not being used with other anti-VEGF therapies.	03/17	03/17

References

1. Lucentis Prescribing Information. South San Francisco, CA: Genentech, Inc.; January 2017. Available at: www.lucentis.com. Accessed February 27, 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 February 24, 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 February 27, 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 February 27, 2017.
5. Matri LE, Chebil A, Kort F. Current and emerging treatment options for myopic choroidal neovascularization. Clin Ophthalmol. 2015; 9: 733-744.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status;

evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.