Clinical Policy: Pegaptanib (Macugen)

Reference Number: CP.PHAR.185
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 pegaptanib (Macugen®).

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

I. Initial Approval Criteria

A. Macular Degeneration (must meet all):

1. Diagnosis of neovascular (wet) age-related macular degeneration (AMD);
2. Prescribed dose of Macugen does not exceed 0.3 mg (1 syringe) every six weeks;
3. Macugen will not be used concomitantly with other anti-vascular endothelial growth factor (VEGF) medications;
4. At the time of request, member has no ocular or periocular infections.

Approval duration: 6 months

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

II. Continued Approval

A. Macular Degeneration (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. Prescribed dose does not exceed 0.3 mg (1 syringe) every six weeks;
4. Macugen is not being used concomitantly with other anti-VEGF medications.

Approval duration: 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; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy**.**

Background
Description/Mechanism of Action:

Pegaptanib is a selective vascular endothelial growth factor (VEGF) antagonist. VEGF is a secreted protein that selectively binds and activates its receptors located primarily on the surface of vascular endothelial cells. VEGF induces angiogenesis and increases vascular permeability and inflammation, all of which are thought to contribute to the progression of the neovascular (wet) form of age-related macular degeneration (AMD), a leading cause of blindness. VEGF has been implicated in blood retinal barrier breakdown and pathological ocular neovascularization.

Formulations:
Single-use syringe for intravitreal injection: 0.3 mg/90 µL solution

FDA Approved Indication:
Macugen (pegaptanib) is a selective VEGF antagonist/solution for intravitreal injection indicated for the treatment of:

- Neovascular (wet) age-related macular degeneration (AMD).

Appendices
Appendix A: Abbreviation Key
AMD: age-related macular degeneration
VEGF: vascular endothelial growth factor

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
J2503	Injection, pegaptanib sodium, 0.3 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. Removed hypersensitivity safety criteria. For re-auth: modified "Currently receiving…" to "Previously received…"; modified documentation of positive response criterion to be open-ended; added criterion to verify that Macugen is not being used with other anti-VEGF therapies.	03/17	03/17

References

1. Macugen Prescribing Information. Palm Beach Gardens, FL: Eyetech, Inc.; July 2016. Available at: www.macugen.com. Accessed February 24, 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.

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.