Clinical Policy: Pegaptanib (Macugen)

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

FDA Approved Indication(s)
Macugen is indicated for the treatment of neovascular (wet) age-related macular degeneration (AMD).

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

I. Initial Approval Criteria

A. Neovascular Age-Related Macular Degeneration (must meet all)**:**

1. Diagnosis of neovascular (wet) AMD;
2. Prescribed by or in consultation with an ophthalmologist;
3. Age ≥ 18 years;
4. Failure of a trial of bevacizumab unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 0.3 mg (1 syringe) via intravitreal injection every 6 weeks.

Approval duration: 6 months

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

II. Continued Approval

A. Neovascular Age-Related Macular Degeneration (must meet all)**:**

1. Previously received medication via Pennsylvania Health and Wellness benefit or member has previously met all 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, b, c, or d):
   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 0.3 mg (1 syringe) via intravitreal injection every 6 weeks.
4. .

Approval duration: 6 months

B. 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; or
2. Refer to PA.CP.PMN.53

III. 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:
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

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
Added bevacizumab redirection, Added specific documentation of positive response to therapy required for continued approval. Added “not used		

Reviews, Revisions, and Approvals	Date	Approval Date
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.		

References

1. Macugen Prescribing Information. Bridgewater, NJ: Bausch + Lomb; July 2016. Available at: www.macugen.com. Accessed November 13, 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 10, 2017.