# Clinical Policy: Pegaptanib (Macugen)

Reference Number: PA.CP.PHAR.185
Effective Date: 01/18
Last Review Date: 01/19

Coding Implications
Revision Log

**Description**
Pegaptanib (Macugen®) is a selective vascular endothelial growth factor (VEGF) antagonist.

**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 intravitreal bevacizumab unless contraindicated or clinically significant adverse effects are experienced;

**Prior authorization is required for bevacizumab*

5. Dose does not exceed 0.3 mg (1 syringe) 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) 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;

## 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.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
AMD: age-related macular degeneration
FDA: Food and Drug Administration
VEGF: vascular endothelial growth factor

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| Avastin® (bevacizumab), Mvasi™ (bevacizumab-awwb) | **Neovascular (wet) AMD:** 1.25 to 2.5 mg administered by intravitreal injection every 4 weeks | 2.5 mg/month |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*
- Contraindication(s):
  - In patients with ocular or periocular infections
  - In patients with known hypersensitivity to pegaptanib sodium or any other excipient in this product

- Boxed warning(s): none reported

*Appendix D: General Information*

- In the VEGF Inhibition Study in Ocular Neovascularization (VISION) trial, the proportion of patients who lost fewer than 15 letters at week 54 for patients treated with Macugen 0.3 mg was 70%, compared to 55% for placebo ($p < 0.001$). There was a significant difference in adverse events between patients treated with Macugen compared to placebo for vitreous floaters (33% vs. 8%, $p < 0.001$), vitreous opacities (18% vs. 10%, $p < 0.001$), and anterior chamber inflammation (14% vs. 6%, $p = 0.001$).

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Neovascular (wet) AMD | 0.3 mg (0.09 mL) administered by intravitreal injection every 6 weeks | 0.3 mg every 6 weeks |

## VI. Product Availability

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

## 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 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. | | |
| 1Q 2019 annual review: removed section III requirement against concomitant use with other VEGF medications; references reviewed and updated. | 01//19 | |

## References

1. Macugen Prescribing Information. Bridgewater, NJ: Bausch + Lomb; July 2016. Available at: www.macugen.com. Accessed October 26, 2018.

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 October 26, 2018.