Clinical Policy: Pegaptanib (Macugen)

Reference Number: ERX.SPA.204
Effective Date: 01.11.17
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

Revision Log

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

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
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 bevacizumab intravitreal solution, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for bevacizumab intravitreal solution. Requests for IV formulations of Avastin, Mvasi, and Zirabev will not be approved.*
5. Dose does not exceed 0.3 mg (1 syringe) every 6 weeks.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
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) every 6 weeks.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

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
bevacizumab (Avastin®)	**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):
  - Ocular or periocular infections
  - Hypersensitivity
- 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

VII. References

1. Macugen Prescribing Information. Bridgewater, NJ: Bausch + Lomb; July 2016. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021756s018lbl.pdf. Accessed November 9, 2021.

2. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; September 2019. Available at: www.aao.org/ppp. Accessed November 9, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q18 annual review: Converted to new template. Added bevacizumab redirection Added optical coherence tomography and fluorescein angiography as acceptable documentation of positive response to therapy required for continued approval Added specialist requirement Removed criteria checking for contraindications (ocular infections) due to its ophthalmic nature and addition of specialist requirement Added age limit	11.28.17	02.18
1Q 2019 annual review: removed requirement against concurrent use with VEGF medications; references reviewed and updated.	11.20.18	02.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	12.05.19	02.20
Ad Hoc update: clarified redirection from bevacizumab to Avastin as compounding pharmacies often break standard Avastin vials into smaller dosages specifically for ophthalmic use and there is a temporary CPT code not currently available to biosimilars.	10.01.20	
1Q 2021 annual review: no significant changes; references reviewed and updated.	12.01.20	02.21
Ad Hoc update: updated redirection to “bevacizumab intravitreal solution” given availability of generic bevacizumab intravitreal solution and considering goal was to minimize use of IV bevacizumab products, most notably biosimilars; converted redirection language to “must use”	03.04.21	
Ad Hoc update: converted redirection language from “must use” to “Failure of” bevacizumab intravitreal solution.	08.03.21	
1Q 2022 annual review: no significant changes; references reviewed and updated.	11.09.21	02.22

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.