Clinical Policy: Pegaptanib (Macugen)

Reference Number: CP.PHAR.185
Effective Date: 03.01.16
Last Review Date: 02.22
Line of Business: Commercial, HIM, Medicaid

Coding Implications
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.

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. 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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit 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 Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage document.

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.

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	P&T Approval Date
1Q18 annual review: Policies combined for Medicaid and commercial; For Medicaid: Added bevacizumab redirection, Added specific documentation of positive response to therapy required for continued	11.28.17	02.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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: reduced commercial approval durations from length of benefit to 6 months; removed section III requirement against concomitant use with other VEGF medications; references reviewed and updated.	11.20.18	02.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	09.26.19	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, added HIM LOB; references to HIM.PHAR.21 revised to HIM.PA.154; 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. 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.