Pegaptanib (Macugen®)

Place of Service

Office Administration Outpatient Facility Administration Infusion Center Administration

HCPCS: J2503 per 0.3 mg

Condition listed in policy (see criteria for details)

- Diabetic macular edema
- Neovascular (WET) age-related macular degeneration (AMD)

AHFS therapeutic class: EENT Drugs, Miscellaneous

Mechanism of action: *VEGF* is a secreted protein that selectively binds and activates its receptors, which are located primarily on the surface of vascular endothelial cells. VEGF induces angiogenesis and increases vascular permeability and inflammation

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please call medical management at the appropriate number for prior auth/review.

(2) Prior Authorization/Medical Review is required for the following condition(s) All requests for Macugen[®] (pegaptanib) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Diabetic macular edema

Covered Doses Up to 0.3 mg intravitreal injection every 6 weeks

Coverage Period

Yearly

ICD-10: (X= 0-9) E08.311, 321X, 331X, 341X, 351X, E09.311, 321X, 331X, 341X, 351X, E10.311, 321X, 331X, 341X, 351X, E11.311, 321X, 331X, 341X, 351X, E13.311, 321X, 331X, 341X, 351X

Neovascular (WET) age-related macular degeneration (AMD)

Covered Doses

Up to 0.3 mg intravitreal injection every 6 weeks

Coverage Period

Yearly

ICD-10: H35.3210-3213, H35.3220-3223,

Commercial

(3) The following condition(s) <u>DO NOT</u> require Prior Authorization/Preservice All requests for Macugen[®] (pegaptanib) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21): -

• Macugen in combination with Verteporfin

<u>Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety</u> <u>Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed</u> <u>indication.</u>

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied: 0.3 mg syringe

Per prescribing information, Macugen intravitreal injection should be carried out under controlled aseptic conditions with adequate anesthesia and a broad-spectrum microbicide provided prior to the injection. Following the injection, patients should be monitored for elevation in intraocular pressure and for endophthalmitis immediately after the injection, within 30 minutes following the injection, and during the week following the injection.

(6) References

- AHFS[®]. Available by subscription at <u>http://www.lexi.com</u>
- American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: www.aao.org/ppp.
- Cunningham ET, Adamis AP, Altaweel M, et al: A phase II randomized double-masked trial of pegaptanib, an anti-vascular endothelial growth factor aptamer, for diabetic macular edema. Ophthalmology 2005; 112(10):1747-1757.
- DrugDex®. Available by subscription at <u>http://www.micromedexsolutions.com</u>
- Gragoudas ES, Adamis AP, Cunningham ET Jr et al. Pegaptanib for neovascular age-related macular degeneration. *N Engl J Med.* 2004; 351:2805-16.
- Macugen® (pegaptanib sodium injection) [Prescribing Information] Bridgewater, NJ: Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC; 7/2016.

(7) Policy Update

Date of last review: 3Q2021 Date of next review: 3Q2022 Changes from previous policy version:

• No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity Reviewed by P&T Committee