

## SPECIALTY GUIDELINE MANAGEMENT MACUGEN (pegaptanib)

### POLICY

#### A. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indications

Macugen is indicated for the treatment of patients with neovascular (wet) age-related macular degeneration.

##### Compendial Use

Treatment of diabetic macular edema

All other indications are considered experimental/investigational and are not covered benefits.

#### B. PRESCRIBER RESTRICTION

Macugen must be prescribed by, or in conjunction with, an ophthalmologist.

#### C. REQUIRED DOCUMENTATION

The following information is necessary to initiate a prior authorization review:

- Optical coherence tomography report, fluorescein angiography report, or an office note detailing the findings of the examination of the macula and fundus

#### D. CRITERIA FOR APPROVAL

##### 1. Neovascular (Wet) Age-Related Macular Degeneration

- a. Authorization for 12 months may be granted for members prescribed Macugen for the treatment of neovascular (wet) age-related macular degeneration which is supported by examination of the macula and fundus, optical coherence tomography, or fluorescein angiography

##### 2. Diabetic Macular Edema

- a. Authorization for 12 months may be granted for members prescribed Macugen, in combination with a comprehensive glucose management strategy, for the treatment of diabetic macular edema which is supported by examination of the macula and fundus, optical coherence tomography, or fluorescein angiography

#### E. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

#### F. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

The following dosing limits apply:

0.3 mg every 6 weeks

#### REFERENCES

1. Macugen [package insert]. Palm Beach Gardens, FL: Eyetech Inc; October 2011.

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2. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; 2014. Available at: [www.aao.org/ppp](http://www.aao.org/ppp).
3. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado. Available at <http://www.micromedexsolutions.com>. Accessed February 28, 2014.
4. Loftus JV, Sultan MB, Pleil AM. Macugen Study Group: Changes in vision – and health-related quality of life in patients with diabetic macular edema treated with pegaptanib sodium or sham. *Invest Ophthalmol Vis Sci*. 2011;52(10):7498-7505.
5. Sultan MB, Zhou D, Loftus J, et al. Macugen 1013 Study Group: A phase 2/3, multicenter, randomized, double-masked, 2-year trial of pegaptanib sodium for the treatment of diabetic macular edema. *Ophthalmology*. 2011;118(6):1107-1118.