I. Medication Description

Macugen® is an aptamer, a pegylated modified oligonucleotide, which is a selective vascular endothelial growth factor (VEGF) antagonist. It is a type of signal-transduction inhibitor (STI) and angiogenesis inhibitor indicated for the treatment of neovascular (wet) age-related macular degeneration (AMD), a leading form of blindness. Intravitreal injection targets VEGF-165, a very specific VEGF isoform involved in the disease process of AMD. The role of agents like pegaptanib is to maintain current vision status or to slow the progression of vision loss. It should be noted that antiangiogenic drugs, like pegaptanib, do not restore vision in cases where the photoreceptors are already damaged and degenerated.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage for Macugen® is provided in accordance with the following:

- Member is being treated for one of the following diagnoses:
  - Neovascular (wet) Age-related macular degeneration OR
  - Diabetic macular edema (DME) OR
  - Proliferative diabetic retinopathy AND
- Diagnosis and administration is performed by a retinal specialist AND
- Documentation is provided of baseline visual status

IV. Quantity Limitations

1 billable unit (1 syringe) every 6 weeks (42 days) per eye

V. Coverage Duration

Coverage is provided for 12 months and may be renewed.
VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Documentation of benefit from therapy: baseline and updated vision status should be provided with evidence of:
  - Improvement or stabilization compared to baseline OR
  - Decrease in rate of vision loss compared to baseline
- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

- JCode: J2503 (0.3 mg per 1 billable unit)
- Available as 0.3 mg in 0.09 ml pre-filled syringe
- Pertinent Indications:
  - Exudative senile macular degeneration (wet): H35.32
  - Diabetic retinopathy: E11.319, E11.359

VIII. Summary of Policy Changes

- 3/1/11:
  - Single agent policy instead of part of a combined VEGF Inhibitor policy
  - Autopay ICD-9 code logic removed for Macugen
  - Addition of Warnings/Precautions section
  - Addition of Billing/Coding Information
- 6/15/12:
  - Removed specific diagnostic procedure criteria
  - Extended authorization duration
  - Added coverage for BRVO, CRVO
- 6/15/13: Addition of diabetic macular edema to covered diagnoses; Included statement regarding investigational administration
- 6/15/14: no policy changes
- 7/1/15: formulary distinctions made
- 7/19/16: no policy changes
- 6/21/17: added coverage for diabetic retinopathy; removed coverage for BRVO, CRVO

IX. References

1. UpToDate Online, retrieved November 2010
3. Facts and Comparisons Online, retrieved November 2010
5. Chakravarthy U; Adamis AP; Cunningham ET Jr; Goldbaum M; Guyer DR; Katz B; Patel M. Year 2 efficacy results of 2 randomized controlled clinical trials of pegaptanib for neovascular age-related macular degeneration. Ophthalmology. 2006 Sep;113(9):1508.e1-25.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.