I. Medication Description

Lucentis is a recombinant humanized monoclonal antibody fragment designed to bind to all active isoforms of vascular endothelial growth factor (VEGF). While Macugen specifically binds to the VEGF 165 isoform, the major pathologic isoform for neovascular AMD, ranibizumab has specificity for all active isoforms of VEGF. Ranibizumab is derived from bevacizumab (Avastin), a full-length anti-VEGF antibody.

II. Position Statement

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

III. Policy

Coverage for Lucentis is provided for any of the following diagnoses:

- Neovascular (wet) Age-related macular degeneration (AMD)
- Macular edema following retinal vein occlusion, (RVO) central or branch
- Diabetic macular edema (DME)
- Diabetic retinopathy in members with DME

When the following criteria are met:

- Diagnosis and administration by a retinal specialist AND
- Documentation is provided of baseline visual status

IV. Quantity Limitations

- J2778: 1 billable unit = 0.1mg
- AMD/RVO: 5 billable units once monthly (every 28 days) per eye
- DME/diabetic retinopathy in DME: 3 billable units once monthly (every 28 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

- Available as
  - 0.5mg in 0.05 mL (10 mg/ml) single eye use only vial
  - 0.3mg in 0.05ml (6mg/ml) single eye use only vial
- J2778 – 1 billable unit is 0.1mg

VIII. Summary of Policy Changes

- 3/1/11:
  - Addition of new FDA approved indication for treatment of macular edema following Retinal Vein occlusion (RVO)
  - Single agent policy instead of part of a combined VEGF Inhibitor policy
  - Autopay ICD-9 code logic removed for Lucentis
  - Addition of Warnings/Precautions section
  - Addition of Billing/Coding Information
- 6/15/12: Removed specific diagnostic procedure criteria, extended authorization duration
- 6/15/13: Addition of new FDA-approved indication for treatment of diabetic macular edema; Included statement regarding investigational administration
- 6/15/14: no policy changes
- 7/1/15: formulary distinctions made
- 9/15/15: no policy changes
- 7/19/16: no policy changes
- 6/21/17: no policy changes

IX. References

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.