I. Medication Description

Eylea (aflibercept) is a recombinant fusion protein consisting of portions of human VEGF receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1. Aflibercept acts as a soluble decoy receptor that binds VEGF-A (vascular endothelial growth factor-A) and PIGF (placental growth factor) thereby inhibiting the binding and activation of these receptors. VEGF-A and PIGF are members of the VEGF family of angiogenic factors that can act as mitogenic, chemotactic and vascular permeability factors for endothelial cells. Eylea is also known as VEGF Trap-Eye.

II. Position Statement

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

III. Policy

Initial coverage for Eylea is provided when the following criteria are met:

- Eylea is being used to treat one of the following diagnoses:
  - Neovascular (wet) Age-related Macular Degeneration (AMD) OR
  - Macular Edema following Retinal Vein Occlusion (RVO) OR
  - Diabetic Macular Edema (DME) OR
  - Diabetic Retinopathy in members with DME AND
- Diagnosis is made and drug is administered by a retinal specialist AND
- Documentation is provided of baseline visual status

IV. Quantity Limitations

- AMD:
  - 2mg (per eye) every 4 weeks for first 3 doses; 2mg (per eye) every 8 weeks thereafter
  - 2mg (per eye) every 4 weeks chronically may be considered on a case-by-case basis depending on member’s initial response to every 8 week maintenance dosing
- Macular Edema following RVO:
  - 2mg (per eye) every 4 weeks
- DME / Diabetic Retinopathy in DME:
  - 2mg (per eye) every 4 weeks for the first 5 doses; 2mg (per eye) every 8 weeks thereafter
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- 2mg (per eye) every 4 weeks chronically may be considered on a case-by-case basis depending on member’s initial response to every 8 week maintenance dosing

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
- Also: Renewal of every 4 week maintenance dosing can be granted if there is a clear benefit shown compared with every 8 weeks usage for the treatment of AMD, DME, or diabetic retinopathy in DME

VII. Billing/Coding Information

- J0178: 1 billable unit = 1mg aflibercept
- Available as:
  - Eylea 2mg/0.05ml solution in a single-dose vial
  - Eylea 2mg/0.5ml solution in a single-dose prefilled syringe
- Pertinent indications:
  - Exudative senile macular degeneration (wet): H35.32
  - Macular edema following retinal vein occlusion: H34.813, H34.819, H34.839, H34.9, H35.81

VIII. Summary of Policy Changes

- 6/15/12: new policy
- 11/2012: new FDA approved indication of retinal edema after CRVO and corresponding information
- 6/15/13: dosing information updated, new Jcode updated, renewal criteria updated
- 6/2013: Included statement regarding investigational administration
- 6/15/14: quantity limits clarified
- 8/1/14: criteria for new FDA-approved indication of DME added
- 7/1/15: formulary distinctions made
- 9/15/15: criteria for diabetic retinopathy in DME added
- 7/19/16: no policy changes
- 6/21/17: clarified renewal criteria
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- 6/15/18: updated billing/coding information, added indication for diabetic retinopathy in DME under quantity limitations
- 8/15/19: updated billing/coding information
- 11/15/19: updated billing/coding information to include new dosage form: prefilled syringe

IX. References


*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.

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.