Drug Therapy Guidelines

<table>
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<th>Medical Benefit</th>
<th>Applicable</th>
<th>Effective: 6/17</th>
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<tr>
<td>Pharmacy-Formulary 1</td>
<td>x</td>
<td>Next Review: 6/18</td>
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<td>Pharmacy-Formulary 2</td>
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<td>Date of Origin: 3/12</td>
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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 CRVO:
  - 2mg (per eye) every 4 weeks
- DME:
  - 2mg (per eye) every 4 weeks for the first 5 doses; 2mg (per eye) every 8 weeks thereafter
o 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: Eylea 2mg/0.05ml
- 1 billable unit = 1mg aflibercept
- Pertinent indications:
  - diabetic macular edema: E11.311
  - central retinal vein occlusion: H34.819
  - branch retinal vein occlusion: H34.839
  - exudative senile macular degeneration (wet): H35.32
  - retinal edema: 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
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.