

Policy Title:	Eylea (afibercept)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	04/10/2019, 9/18/2019, 12/18/19, 1/29/20		
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Purpose: To support safe, effective and appropriate use of Eylea (afibercept) in patients with neovascular (wet) age related macular degeneration (AMD), macular edema due to retinal vein occlusion (RVO), diabetic macular edema (DME) or diabetic retinopathy in patients with DME.

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement:

Eylea (afibercept) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Eylea (afibercept) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

- Patient is at least 18 years of age or older; AND
- Prescribed by or in consultation with Retina Specialist; AND
- Must have a diagnosis of one of the following:
 - Neovascular (wet) age related macular degeneration (AMD)
 - Macular edema due to retinal vein occlusion (RVO)
 - Diabetic macular edema (DME)
 - Diabetic retinopathy (DR); AND
- For all indications except DME, the patient must have an adequate trial, intolerance or contraindication to treatment with bevacizumab; AND
- For patients with DME and baseline visual acuity of 20/50 or worse, they must have an adequate trial, intolerance or contraindication to treatment with bevacizumab or ranibizumab (Lucentis); AND
- For patients with DME and baseline visual acuity better than 20/50, the patient must have an adequate trial, intolerance or contraindication to treatment with bevacizumab;
- Eylea (afibercept) is not considered medically necessary with any of the following concomitant conditions:
 - Patient has an active ocular or periocular infection

- Patient has active intraocular inflammation
- Concurrent use with other VEGF inhibitors for intraocular use in the absence of documentation indicating that individual products are to be used in different eyes; AND
- For patients that are currently on treatment with Eylea (afibercept) they can remain on treatment OR MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements; AND
- Dose does not exceed:
 - AMD: 2mg (1vial) via intravitreal injection every 4 weeks for the first 3 months, then every 8 weeks thereafter*
 - DME and DR: 2mg (1vial) via intravitreal injection every 4 weeks for the first 5 injections, then every 8 weeks thereafter*;
 - RVO: 2mg (1vial) via intravitreal injection every 4 weeks

*Patients with an insufficient response during initial therapy for AMD, DME & DR administered every 4 weeks may continue with dosing every 4 weeks. Patients with an inadequate response to maintenance therapy administered every 8 weeks may increase the dosing frequency up to every 4 weeks.

Continuation of Therapy coverage:

- Patient is tolerating treatment; AND
- Patient is responding to therapy as evidenced by one of the following:
 - Detained neovascularization;
 - Improvement or stabilization in visual acuity;
 - Maintenance of corrected visual acuity from prior treatment;
 - Supportive findings from optical coherence tomography or fluorescein angiography;

Coverage durations:

- Initial coverage: 6 months
- Renewal coverage: 12 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Maximum units* (1 billable unit = 1 mg)

Diagnosis	Maximum units for initial dosing	Maximum units for Maintenance dosing
Neovascular age-related macular degeneration (AMD)	4 units every 28 days x 3 doses	4 units every 28-56 days

Macular edema following retinal vein occlusion (RVO)	4 units every 28 days	4 units every 28 days
Diabetic Macular Edema (DME)/ Diabetic retinopathy (DR) in DME	4 units every 28 days x 5 doses	4 units every 28-56 days

*based on administration to both eyes

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J0178	Injection, aflibercept, 1mg

References:

1. Eylea prescribing information. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; 2018 December.
2. Wells JA, Glassman AR, Ayala AR, et al. Aflibercept, bevacizumab, or ranibizumab for diabetic macular edema. N Engl J Med. 2015 Mar 26;372(13):1193-203. doi: 10.1056/NEJMoa1414264
3. CATT Research Group, Martin DF, Maguire MG, et al. Ranibizumab and bevacizumab for neovascular age-related macular degeneration. N Engl J Med. 2011 May 19 364(20):1897-908. doi: 10.1056/NEJMoa1102673