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| **Policy Title:** | Eylea (aflibercept) | | |
| | | **Department:** | PHA |
| **Effective Date:** | 01/01/2020 | | |
| **Review Date:** | 04/10/2019, 9/18/2019, 12/18/2019, 1/29/2020, 5/20/2021, 10/21/2021, 6/16/2022, 7/27/2023, 12/07/2023, 01/04/2024 | | |

**Purpose:** To support safe, effective, and appropriate use of Eylea (aflibercept) 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 patents with DME.

**Scope:** Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

**Policy Statement:**

Eylea (aflibercept) 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 (aflibercept) 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)
  - Retinopathy of Prematurity (ROP); AND
- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; AND
- The patient meets one of the following:
  - For patients with DR or ROP, the patient must have an inadequate treatment response, intolerance or contraindication to treatment with bevacizumab;
  - For patients with AMD, or RVO, they must have an inadequate treatment response, intolerance or contraindication to treatment with bevacizumab or Byooviz;

- For patients with DME and baseline visual acuity of 20/50 or worse, they must have an inadequate treatment response, intolerance or contraindication to treatment with bevacizumab or ranibizumab (Lucentis);
- For patients with DME and baseline visual acuity better than 20/50, the patient must have an inadequate treatment response, intolerance, or contraindication to treatment with bevacizumab; AND

- Patient is free of ocular and periocular infections; AND
- Patient does not have active intraocular inflammation; AND
- Therapy will not be used with other ophthalmic VEGF inhibitors (i.e., pegaptanib, brolucizumab, bevacizumab, ranibizumab or ranibizumab via ocular implant, etc.)
- 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

  *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**:

- Meets all initial criteria; AND
- Patient is tolerating treatment with absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: endophthalmitis and retinal detachments; increase in intraocular pressure; arterial thromboembolic events; AND
- Patient has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity (BCVA), etc.) and continued administration is necessary for the maintenance treatment of the condition

**Coverage Durations:**

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

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

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 |
| Retinopathy of Prematurity (ROP) | 0.8 units every 10 days | 0.8 units* every 10 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 |
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| J0178 | Injection, aflibercept, 1mg |

References:


1. Eylea prescribing information. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; October 2023. Accessed November 2023.
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. 2011May 19 364(20):1897-908. doi: 10.1056/NEJMoa1102673