Eylea® (aflibercept)

Humana

Pharmacy Coverage Policy

Effective Date: January 01, 2023
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Review Date: September 22, 2022
Line of Business: Medicaid - Louisiana
Policy Type: Prior Authorization

Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at http://www.cms.hhs.gov/. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically.

Description

Eylea (aflibercept injection) is a vascular endothelial growth factor (VEGF) inhibitor administered as an intravitreal injection.

Aflibercept is a fully human recombinant fusion protein that binds all isoforms of VEGF-
A, and prevents their binding to VEGFR-1 and VEGFR-2. Aflibercept also binds to Placental Growth Factor (PlGF) inhibiting it's binding to VEGFR-1. Inhibiting the binding to these receptors decreases inflammation and vascular permeability, prevents the progression of neovascular AMD, and prevents further loss of vision.

Eylea (aflibercept injection) is indicated for the treatment of neovascular (wet) agerelated macular degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO),Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR).

Aflibercept is available as Eylea as a 40mg/ml solution in a single-use (3ml) vial and prefilled syringe, designed to provide 0.05 ml for a 2mg dose.

Coverage

Please note the following regarding medically accepted indications:

Determination

All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Health Analytics Micromedex DrugDEX
- Elsevier/Gold Standard Clinical Pharmacology

Wolters Kluwer Lexi-Drugs

Eylea (aflibercept injection) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

Diabetic Retinopathy (DR)

- **Has a diagnosis of Diabetic Retinopathy AND**
- **Has a contraindication, or intolerance to bevacizumab** OR
- **Has had prior therapy to bevacizumab and provider attests that the member has NOT demonstrated a positive clinical response to bevacizumab (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss).**
  - ***Step therapy requirement does not apply for members with 20/50 or worse vision**

Age-Related Macular Degeneration

- **Has a diagnosis of neovascular (wet) age-related macular degeneration AND**
- **Has a contraindication, or intolerance to bevacizumab OR**
- **Has had prior therapy to bevacizumab and provider attests that the member has NOT demonstrated a positive clinical response to bevacizumab (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss).**

Macular Edema following Retinal Vein Occlusion (RVO)

- **Has a diagnosis of Macular Edema following Retinal Vein Occlusion (RVO) AND**
- **Has a contraindication, or intolerance to bevacizumab OR**
- **Has had prior therapy to bevacizumab and provider attests that the member has NOT demonstrated a positive clinical response to bevacizumab (e.g., improvement**

or maintenance in best corrected visual acuity [BCVA] or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss).

Diabetic Macular Edema (DME)

- **Has a diagnosis of Diabetic Macular Edema AND**
- **Has a contraindication or intolerance to bevacizumab OR**
- **Has had prior therapy with bevacizumab and provider attests that the member has NOT demonstrated a positive clinical response to bevacizumab (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss).**
  - ***Step therapy requirement does not apply for members with 20/50 or worse vision**

Eylea (aflibercept injection) will be approved in plan year durations or as determined through clinical review.

Coverage Limitations

Eylea (aflibercept injection) therapy is not considered medically necessary for members with the following concomitant conditions:

- **Member has an active ocular or periocular infection**
- **Member 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**

- **Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.** **Background** **This is a prior authorization policy about Eylea (aflibercept injection).**

VEGF is a naturally occurring substance in the body responsible for the growth of new blood vessels (neovascularization). In the retina however, VEGF may stimulate

growth of abnormally fragile vessels prone to leakage. This leakage causes scarring in the macula and eventually leads to loss of central vision.

Although maintenance dosing can be as frequent as 2mg every month, additional efficacy was not demonstrated with this dosing compared to every 2 months.

Neovascular/exudative/wet AMD is associated with the development of new blood vessels in the subretinal space which gradually lead to vision loss. Exudation and bleeding from these vessels can cause scarring and permanent vision loss. Treatment options for AMD include laser phototherapy and VEGF inhibitors.

Retinal vein occlusion is a common retinal vascular disorder. The exact etiology is un known, however may be caused by arteriosclerotic changes in the central retinal artery or from a thrombotic occlusion of the central retinal vein. Occlusion of the central retinal vein leads to backup of the blood in the retinal venous system and increases resistance to the venous blood flow. This increased resistance causes stagnation of the blood and ischemia to the retina. Ischemic damage to the retina stimulates increase production of vascular endothelial growth factor (VEGF), and increased levels of VEGF stimulate neovascularization of the posterior and anterior segment of the eye.
Treatment of RVO includes aspirin, anti-inflammatory agents, isovolemic hemodilution, plasmapheresis, systemic anticoagulation, fibrinolytic agents, systemic corticosteroids, local anticoagulation with intravitreal injections of alteplase, intravitreal injections of triamcinolone, and intravitreal injections of bevacizumab. Retinal Vein Occlusion can lead to Macular Edema or growth of fragile new blood vessels.

Eylea has not been studied in pediatric populations. Eylea is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, and a known hypersensitivity to aflibercept or any of the excipients in Eylea.

Provider Claims Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Eylea, Aflibercept, Age Related Macular Degeneration; AMD; Intravitreal; Macular Edema,; Diabetic Retinopathy;Retinal Vein Occlusion; RVO; pharmacy

References

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