Eylea® (aflibercept injection)

Humana

Pharmacy Coverage Policy

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Line of Business: Commercial, Medicare, Puerto Rico
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Medical Prior Authorization (Commercial)

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Disclaimer

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) age-related macular degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), and Diabetic Macular Edema (DME).

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

Coverage Determination

Please note the following regarding medically accepted indications:

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 (AHFS) Compendium
- Thomson Micromedex/DrugDex (not Drug Points) Compendium
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium™
- Elsevier Gold Standard's Clinical Pharmacology Compendium

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

Age-Related Macular Degeneration

- Member has a diagnosis of neovascular (wet) age-related macular degeneration
- Member has had prior therapy, contraindication, or intolerance to bevacizumab (for Commercial requests only)

Macular Edema following Retinal Vein Occlusion (RVO)

- Member has a diagnosis of Macular Edema following Retinal Vein Occlusion (RVO)

- Member has had prior therapy, contraindication, or intolerance to bevacizumab (for Commercial requests only)

Diabetic Macular Edema (DME)

- Member has a diagnosis of Diabetic Macular Edema
- Member has had prior therapy, contraindication, or intolerance to bevacizumab (for Commercial requests only)

For Age-Related Macular Degeneration: Initial dosing of 2mg (0.05mL) administered monthly via intravitreal injection for 3 months, followed by maintenance dose of 2mg every 2 months.

For Macular Edema following Retinal Vein Occlusion (RVO): Dosing of 2mg (0.05mL) administered every 4 weeks (monthly) via intravitreal injection.

For Diabetic Macular Edema (DME): Dosing is 2mg (0.05 mL) administered every 4 weeks (monthly) for the first 5 injections following by 2mg (0.05 mL) administered once every 8 weeks (2 months).

- Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated when EYLEA was dosed every 4 weeks compared to every 8 weeks.

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

The quantity limit for all strengths of Eylea/aflibercept is one 3 ml vial per affected eye per month.

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).

Table: Comparison of VEGF inhibitors (Ophthalmic use)

Humana Coverage Policies for Ophthalmic VEGF Inhibitors				
	Lucentis	**Eylea**	**Macugen**	**Avastin**
Indications	ranibizumab	afilbercept	pegatanib	bevacizumab
Age-Related Macular Degeneration (Wet/Exudative)	FDA*	FDA*	FDA*	Compendia*
Macular Retinal Edema post Retinal Vein Occlusion	FDA*	FDA*		Compendia*
Diabetic Macular Edema	FDA*	FDA*	Compendia	Compendia*
Retinopathy of Prematurity				Compendia
Posterior uveitis, non-infectious				
Histoplasmosis				
Pathologic Myopia				
Diabetic Retinopathy	Compendia		Compendia	Compendia
Ocular Inflammation				
Vitrectomy (visualization during surgery)				
Choroidal Retinal Neovascularization	Compendia			Compendia
Neovascular Glaucoma				Compendia

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 or geriatric 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

All provider claims codes surrounding this topic may not be included in the following table:

CPT© Codes	Description	Comments
67028-LT	Intravitreal injection of a pharmacologic agent (separate procedure)	
67028-RT	Intravitreal injection of a pharmacologic agent (separate procedure)	
HCPC© Codes	**Description**	**Comments**

J0178	Injection, aflibercept, 1 mg	
ICD.9© Procedure Codes	**Description**	**Comments**
14.75	Injection of vitreous substitute	

Medical Terms

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

References

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Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2014. URL: http://www.clinicalpharmacology.com. Updated July 2014.

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