OPHTHALMIC VEGF INHIBITORS
Eylea (aflibercept), Macugen (pegaptanib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Eylea (aflibercept) and Macugen (pegaptanib) are vascular endothelial growth factor (VEGF) inhibitors used to treat patients with wet (neovascular) age-related macular degeneration (AMD). Additional Eylea is used to treat macular edema following retinal vein occlusion (RVO), diabetic retinopathy (DR) and diabetic macular edema (DME). The VEGF inhibitors block the effects of VEGF-A and prevents the interaction of VEGF-A with its receptors (VEGFR1 and VEGFR2) on the surface of endothelial cells, reducing endothelial cell growth, vascular leakage, and new blood vessel formation (1-2).

Regulatory Status
FDA-approved indication:

**Eylea** is a VEGF inhibitors indicated for the treatment of patients with: (1)
1. Neovascular (Wet) Age-Related Macular Degeneration (AMD)
2. Macular Edema Following Retinal Vein Occlusion (RVO)
3. Diabetic Macular Edema (DME)
4. Diabetic Retinopathy (DR) in Patients with DME

**Macugen** is a VEGF inhibitor indicated for the treatment of patients with Neovascular (Wet) Age-Related Macular Degeneration (AMD) (2).

VEGF inhibitors are contraindicated in ocular or periocular infections (1-2). Eylea has an additional contraindication to active intraocular inflammation (1). VEGF inhibitors must only be administered by a qualified physician. Adequate anesthesia and a topical broad–spectrum microbicide should be given prior to the injection. Increases in intraocular pressure have been seen within 60 minutes of an intravitreal injection (1-2).

Safety and effectiveness in pediatric patients have not been established (1-2).

Summary

VEGF inhibitors prevent the binding and activation of VEGF receptors leading to a decrease in the neovascularization and vascular permeability associated with neovascular AMD and macular...
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edema following RVO, DR and DME. Patients taking VEGF inhibitors must be monitored and managed for intravitreal injection procedure associated effects, elevated intraocular pressure and appropriate perfusion of the optic nerve head. VEGF inhibitors must only be administered by a retina trained ophthalmologist. Safety and effectiveness in pediatric patients have not been established (1-2).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Eylea and Macugen while maintaining optimal therapeutic outcomes.

References