RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Lucentis (ranibizumab) is a vascular endothelial growth factor (VEGF) inhibitor used to treat patients with wet (neovascular) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), diabetic retinopathy (DR), myopic choroidal neovascularization (mCNV) 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).

Regulatory Status
FDA-approved indication: Lucentis (ranibizumab) is a VEGF inhibitor indicated for the treatment of patients with: (1-2)

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)
5. Myopic choroidal neovascularization (mCNV)

Lucentis is contraindicated in ocular or periocular infections (1).

Lucentis 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).

Studies have shown that all patients with diabetic macular edema had significant improvement in vision with regular treatment with any of the three anti-VEGF drugs (Eylea, Lucentis, Avastin) (2).

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

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

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

References