

LUCENTIS (ranibizumab), **BYOOVIZ** (ranibizumab-nuna),  
**CIMERLI** (ranibizumab-eqrn)

Preferred products: Byooviz, Cimerli

## **RATIONALE FOR INCLUSION IN PA PROGRAM**

### **Background**

Lucentis (ranibizumab) and its biosimilars are vascular endothelial growth factor (VEGF) inhibitors 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 (VEGFR<sub>1</sub> and VEGFR<sub>2</sub>) on the surface of endothelial cells, reducing endothelial cell growth, vascular leakage, and new blood vessel formation (1-3).

### **Regulatory Status**

FDA-approved indications: Lucentis (ranibizumab) and its biosimilars are vascular endothelial growth factor (VEGF) inhibitors indicated for the treatment of patients with: (1-3)

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 and its biosimilars are contraindicated in ocular or periocular infections (1-3).

Lucentis and its biosimilars 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 noted both pre-injection and post-injection (within 60 minutes) while being treated with Lucentis or its biosimilars (1-3).

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) (4).

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Safety and effectiveness in pediatric patients have not been established (1-3).

### Summary

Lucentis (ranibizumab) and its biosimilars prevent 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 ranibizumab 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 and its biosimilars while maintaining optimal therapeutic outcomes.

### References

1. Lucentis [package insert]. South San Francisco, CA: Genentech, Inc.; February 2024.
2. Byooviz [package insert]. Cambridge, MA: Biogen Inc.; October 2023.
3. Cimerli [package insert]. Princeton, NJ: Sandoz Inc.; June 2024.
4. Grudgel, Dan. Study Compares Eylea, Lucentis and Avastin for Diabetic Macular Edema. American Academy of Ophthalmology. June 2015.