

## **Specialty Pharmacy Program**

### **Lucentis™ (ranibizumab) and Macugen® (pegaptanib)**

#### **CLINICAL BACKGROUND**

Age-related macular degeneration (AMD) occurs when there is a deterioration of the central portion of the retina. It is characterized by any of the following fundus changes: pigmentary atrophy and degeneration, drusen and lipofuscin deposits, and exudative elevation of the outer retinal complex in the macular area. The most common symptoms of AMD are blurring of central vision, metamorphopsia and reduced vision. The exact etiology of AMD is unknown; however, several risk factors have been recognized such as advancing age and hypertension.

“Dry” AMD accounts for 90 percent of all patients with AMD in the United States and results from a gradual breakdown of the retinal pigment epithelium (RPE), the accumulation of drusen deposits, and loss of function of the overlying photoreceptors. Most patients with dry AMD experience gradual, progressive loss of central visual function. Unfortunately there is no medical or surgical treatment currently available for dry AMD.

“Wet” AMD accounts for only 10 percent of patients with AMD, however, 90 percent of these patients have significant vision loss. Wet AMD occurs when neovascularization develops in the choroid and/or retina, leading to serous or hemorrhagic leakage and subsequent elevation of the RPE or neurosensory retina. There is a more profound and rapid decrease in central visual function. Serous or hemorrhagic leakage from the new choroidal vessels causes dysmophopsia, scotoma, and blurred vision. Unlike, “dry” AMD, there are several medical options available to treat “wet” AMD.

Vascular endothelial growth factor (VEGF) plays a significant role in the development and maintenance of choroidal neovascularization (CNV). Lucentis and Macugen are anti-VEGF agents used to treat the wide range of subfoveal CNV lesions that occur with wet AMD.

Lucentis and Macugen should not be administered to patients with ocular or periocular infections.

#### **APPROVAL DURATION**

Initial authorization: 3 months

Re-authorization: Up to 24 months total

#### **APPROVAL CRITERIA**

##### **FDA-Approved Indication(s)**

1. Treatment of patients with neovascular (wet) age-related macular degeneration.