

Criteria for Non-Formulary Use of Pegaptanib (Macugen®)
VHA Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel

The following recommendations are based on current medical evidence and expert opinion from clinicians. The content of the document is dynamic and will be revised as new clinical data becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of the individual patient situation.

Inclusion Criteria

- Diagnosis of subfoveal choroidal neovascularization (CNV) secondary to Age Related Macular Degeneration (AMD)
- Lesion subtype of predominately classic, minimally classic or occult
- Total lesion size up to 12 disc areas including blood, scar, atrophy, or neovascularization
- Best corrected Visual acuity (VA) 20/40 to ability to count fingers
- Subretinal hemorrhage constituting $\leq 50\%$ of total lesion size
- Age ≥ 50 years

Exclusion Criteria

- CNV due to conditions other than AMD
- Scarring or atrophy constituting $>25\%$ of total lesion size
- Previous subfoveal thermal laser photocoagulation
- Hypersensitivity to pegaptanib
- Current evidence of endophthalmitis or elevated intraocular pressure (IOP)

Dose

Pegaptanib is administered every six weeks by intravitreal injection. The dose used is 0.3 mg. Aseptic technique should be used during the injection process. This includes the use of sterile gloves, sterile drape and sterile eyelid speculum. Anesthesia and a broad spectrum antibiotic should be administered to the eye which will be treated. Following injection, patients should be evaluated for evidence of IOP. Patients should be educated on the signs/symptoms of endophthalmitis. Currently available evidence supports the use of pegaptanib over a nine injection time frame (54 weeks). Therapy past this time should be evaluated on a case by case basis.

For further information please refer to the pegaptanib monograph at www.pbm.va.gov or vaww.pbm.va.gov

June 2005

Updates may be found @ www.pbm.va.gov or <http://vaww.pbm.va.gov>