



INLAND EMPIRE HEALTH PLAN

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutics Subcommittee.

Drug: Lucentis (ranibizumab)

Class: Recombinant humanized monoclonal IgG1 kappa-isotype antibody-vascular endothelial growth factor (VEGF) inhibitor

Formulary medication: N/A

Effective Date: November 2006, November 2008, August 2009

Policy/Criteria:

Medi-Cal Formulary: Non-Formulary, both medications may be covered if criteria is satisfied by clinical documentation.

Medicare Formulary: Formulary under Part B, PA required-criteria must be satisfied by clinical documentation.

Use of Avastin:

For the treatment of established neovascular “wet” age related macular degeneration when either of the following selection criteria is met:

1. Patient has failed FDA-approved therapies; or
2. Patient is likely to have a therapeutic response with the use of intravitreal bevacizumab, which is comparable to results from other approved treatments.

J9035 (bevacizumab 10mg) should not be used for Avastin in the treatment of AMD. Misc code: J3490 with explanation of procedure and dosage used should be submitted for billing purposes.

Use of Lucentis:

For the treatment of established neovascular “wet” age related macular degeneration.

Clinical Justification:

1. Avastin (bevacizumab) is a recombinant humanized monoclonal IgG1 antibody that is similar to Lucentis.
2. Protocol for use of intravitreal bevacizumab has been developed and tried in different Institutes.
3. American Academy of Ophthalmology supported the reimbursement for treating age-related macular degeneration (AMD) with intravitreal injections of bevacizumab, to meet the medical needs of many patients who have not responded to therapy with ocular photodynamic therapy (OPT) with verteporfin or intravitreal pegaptanib.
4. More than 6,800 injections in 5,055 patients from 68 centers in 12 countries have been documented with a low rate of ocular or systemic adverse events.
5. The use of Avastin via intravitreal injection is entirely off-label, but the clinical experiences appear that Avastin is working just as well as Lucentis.
6. Avastin is formulated for intravenous infusion, not intravitreal injection. Although Avastin is similar to Lucentis, they are different in several aspects:
 - a. Avastin is about 3 times as large as Lucentis (149kD vs. 48kD) - smaller molecular means better penetration to the layers of the retina;
 - b. Avastin has a longer half-life (20 days compared to 4 hours)- less systemic side-effects if it is significant;
 - c. Lucentis doesn't have Fc portion in this antibody fragment, which may cause less inflammation within the eye.

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