

Medical Affairs Policy & Procedure

Title/Service: Intravitreal (Eye) VEGF Inhibitor Injections (Avastin, bevacizumab, Lucentis, ranibizumab)

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| Revised | 09/16/2011 |
| Reviewed | 04/15/11 |
| Developed | 07/27/10 |
| Policy Committee Approval | 09/16/2011 |

Description:

Ranibizumab (Lucentis), a humanized monoclonal antibody fragment, binds to the receptor binding site of active forms of VEGF-A (vascular endothelial growth factor A). VEGF-A, which stimulates the growth of new blood vessels, has been shown to cause neovascularization with blood and fluid leakage in the eye and is thought to contribute to the progression of neovascular AMD (age-related macular degeneration) and macular edema following RVO (retinal vein occlusion). The binding of ranibizumab to VEGF-A prevents the interaction of VEGF-A with its receptors on the surface of endothelial cells, reducing endothelial cell proliferation, vascular leakage, and new blood vessel formation. Bevacizumab (Avastin), the full-sized humanized monoclonal antibody from which ranibizumab was derived, is also used for neovascularization and leakage in the eye.

Indications of Coverage:

- A. Lucentis is considered medically necessary for either of the following diagnoses when a trial of intravitreal Avastin has been ineffective and there is documentation of ongoing visual loss and/or evidence of leakage:
- 1) Neovascular (wet) age-related macular degeneration (AMD)
 - 2) Macular edema following retinal vein occlusion (RVO)
- B. Avastin is considered medically necessary for any of the following diagnoses when there is documentation of ongoing visual loss and/or evidence of leakage:
- 1) Neovascular (wet) age-related macular degeneration (AMD)
 - 2) Diabetic macular edema
 - 3) Macular edema following retinal vein occlusion (RVO)
 - 4) Venous tributary (branch) occlusion (BRVO)

- 5) Central retinal vein occlusion (CRVO)
- 6) Rubeosis iridis
- 7) Glaucoma associated vascular disorders

➤ If criteria are met, the treatment may be approved for one (1) injection per month for up to two (2) months. Subsequent treatment may be approved in four month increments with review of therapeutic response. One “as needed” injection may be approved for future urgent treatment in an individual with a history of one of the above conditions if there is no current leakage.

Limitations of Coverage:

- A. Review contract and endorsements for exclusions and prior authorization or benefit requirements.
- B. If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.
- C. If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.
- D. The use of Avastin or Lucentis for the treatment of diabetic retinopathy is considered experimental or investigative as there is insufficient peer-reviewed scientific literature supporting the use of these medications for this condition.
- E. Simultaneous use of Visudyne PDT in combination with Avastin or Lucentis is considered experimental or investigative as there is insufficient peer-reviewed scientific literature supporting the use of this combination of medications.

Documentation Required:

- Office notes with detailed ophthalmologic history and examination
- Ophthalmologic laboratory data
- Procedure notes

Rationale:

Both Lucentis and Avastin have been shown to improve vision in certain eye disorders. They are very similar drugs, and both have shown efficacy in the treatment of wet macular degeneration (AMD), a condition which causes leakage of blood and fluid into the retina. A recent article from the Comparisons of Age-Related Macular Degeneration Treatments Trials (CATT) reported that Lucentis and Avastin were equally effective in

treating vision loss when given in the same manner. Therefore, documentation of the failure of Avastin is required prior to proceeding with Lucentis injections.

References:

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Approved by the Medical Director