

Complete Patient and Physician information (PLEASE PRINT)

STEP
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI #:

If Applicable: Pharmacy Name: _____
Pharmacy Phone: _____

Complete the Clinical Assessment:

Please attach all relevant medical records and test results.

STEP
2

Diagnosis	<input type="checkbox"/> Neovascular (wet) Age Related Macular Degeneration <input type="checkbox"/> Macular Retinal edema following retinal vein occlusion (central or branch RVO)	<input type="checkbox"/> Other Diagnosis (please state): _____ _____
Clinical Consideration	<input type="checkbox"/> Intravitreal injection(s) of Lucentis will be administered by an Ophthalmologist. <input type="checkbox"/> Other practitioner (please state): _____ <input type="checkbox"/> Patient is refractory to other therapies: Avastin, Macugen, Eylea, or Visudyne _____ <input type="checkbox"/> This patient has been informed of the potentially dramatic cost savings with the use of compounded Avastin (bevacizumab) and you have weighed the risks/benefits of using compounded Avastin for the treatment of AMD in place of Lucentis.	
Physician Specialty	<input type="checkbox"/> Ophthalmologist <input type="checkbox"/> Other (please state): _____	
Supporting Documentation	Diagnosis: ICD-9 Code #/ Description / J Code (required):	
	Please attach a copy of the prescription or provide ALL of the information below: Lucentis® (ranibizumab)	
	Strength _____ Sig _____ Qty _____ Refills _____	
<p>We will not process incomplete forms. If we do not receive the completed form & all relevant medical records & test results within 10 calendar days of this request, it will be denied.</p>		

STEP
3

I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date)

Prescriber Signature

Date

STEP
4

**Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk:
970-248-5034**

Name of Person filling out form: _____

Pharmacy Technician initials _____ Date Initiated _____

Confidentiality Notice:

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 04/05/12

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Lucentis (ranibizumab)

CLASSIFICATION

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

DESCRIPTION

- Ranibizumab (Lucentis®) is a recombinant humanized IgG1 kappa isotype monoclonal antibody fragment designed for intraocular use. Ranibizumab binds to and inhibits the biologic activity of human vascular endothelial growth factor A (VEGF-A). Ranibizumab has a molecular weight of approximately 48 kilodaltons and is produced by an *E. coli* expression system in a nutrient medium containing the antibiotic tetracycline. Tetracycline is not detectable in the final product. Ranibizumab binds to the receptor binding site of active forms of VEGF-A, including the biologically active, cleaved form of this molecule, VEGF. VEGF-A has been shown to cause neovascularization and leakage in models of ocular angiogenesis and is thought to contribute to the progression of the neovascular form of age-related macular degeneration (AMD). The binding of ranibizumab to VEGF-A prevents the interaction of VEGF-A with its receptors (VEGFR1 and VEGFR2) on the surface of endothelial cells, reducing endothelial cell proliferation, vascular leakage, and new blood vessel formation.
- Ranibizumab is a selective vascular endothelial growth factor (VEGF) antagonist that is indicated for the treatment of neovascular (wet) age-related macular degeneration in adults. In clinical studies, ranibizumab was apparently more effective than verteporfin photodynamic therapy.
- Bevacizumab (Avastin) is closely related to ranibizumab and appears to be a safe and effective treatment in the short term for AMD (Ziemssen et al.). It has been used off-label for many years for these patients. At about 1%-5% of the cost of ranibizumab, many clinicians believe that patients should be informed about this alternative, especially the significant price difference (Ziemssen et al.). The Comparison of the Age-related Macular Degeneration Treatment Trials (sponsored by the US National Eye Institute) is currently in progress. Some authors who have undergone smaller trials and systematic reviews believe that these two modalities will be shown to be equivalent in effect (Schouten et al.).
- Bevacizumab is formulated for intravenous infusion, not intravitreal injection. Thus, although Avastin is similar to Lucentis, they differ in some respects:
 - The Avastin molecule is larger than Lucentis (149kD vs. 48kD). This may impact penetration into the layers of the retina, but the clinical implications are unknown
 - Avastin has a longer half-life than Lucentis (20 days compared to 4 hours), which may allow less frequent administration
 - Lucentis doesn't have Fc portion in this antibody fragment, which may cause less inflammation within the eye.

FORMULARY COVERAGE

Prior authorization: Required

Good Health Formulary: Medical Benefit

Commercial Formulary: Medical Benefit

Medicare Part D coverage: Part B (incident to physician's service), Part D/T4 (at a pharmacy)

COVERAGE CRITERIA

Lucentis® (ranibizumab) meets the definition of **medical necessity** for the following:

- Exudative age-related macular degeneration
- Macular retinal edema following central or branch retinal vein occlusion (CRVO or BRVO)
- Providers are encouraged to consider therapy with Avastin (bevacizumab) as an equally efficacious alternative to Lucentis at a vastly lower cost, as well as inform their patients of this alternative
- Providers are encouraged to consider therapy with Eylea (aflibercept) as trials VIEW-1 and VIEW-2 found Eylea to be non-inferior to Lucentis. Eylea has the advantage of fewer injections and is more cost effective than Lucentis.

Lucentis® (ranibizumab) is considered **experimental** for the following:

- Any condition or diagnosis not FDA approved or Compendia supported
- Diabetic Macular Edema

Required Provider Specialty:

- Approval is limited to Ophthalmology

DOSAGE/ADMINISTRATION:

For ophthalmic intravitreal injection only:

- Exudative age-related macular degeneration and Macular retinal edema:
 - 0.5 mg (0.05 mL) by INTRAVITREAL injection once a month (approximately 28 days)
 - May reduce to 0.5 mg (0.05 mL) by INTRAVITREAL injection every 3 months after the first 4 injections if monthly injections are not feasible; dose will be less effective, leading to an approximate 5-letter (1-line) average loss of visual acuity over the following 9 months. Patients should be evaluated regularly.

Preparation for Administration:

- Using aseptic technique, all (0.2 mL) of the Lucentis® vial contents are withdrawn through a 5-micron, 19-gauge filter needle attached to a 1-cc tuberculin syringe. The filter needle should be discarded after withdrawal of the vial contents and should not be used for intravitreal injection. The filter needle should be replaced with a sterile 30-gauge x 1/2-inch needle for the intravitreal injection. The contents should be expelled until the plunger tip is aligned with the line that marks 0.05 mL on the syringe.

Administration:

- The intravitreal injection procedure should be carried out under controlled aseptic conditions. Adequate anesthesia and a broad-spectrum microbicide should be given prior to the injection.
- Following the intravitreal injection, patients should be monitored for elevation in intraocular pressure and for endophthalmitis. Monitoring may consist of a check for perfusion of the optic nerve head immediately after the injection, tonometry within 30 minutes following the injection, and biomicroscopy between two and seven days following the injection. Patients should be instructed to report any symptoms suggestive of endophthalmitis without delay.
- Each vial should only be used for the treatment of a single eye. If the contralateral eye requires treatment, a new vial should be used and the sterile field, syringe, gloves, drapes, eyelid speculum, filter, and injection needles should be changed before Lucentis® is administered to the other eye.

PRECAUTIONS:

- Contraindicated in patients with ocular or periocular infections
- Arterial thromboembolic events have occurred
- Endophthalmitis has been reported; aseptic technique is necessary to mitigate risk. Monitor patients during the week following the injection for infection
- Intraocular pressure increase has been observed within 60 minutes of injection; monitoring recommended
- Retinal detachment has occurred

Billing/Coding information

HCPCS Code:

J2778	Injection, ranibizumab, 0.1 mg
-------	--------------------------------

Associated CPT Coding:

67028	Intravitreal injection of a pharmacologic agent (separate procedure)
-------	--

Associated ICD-9 Coding:

362.52	Exudative senile macular degeneration
--------	---------------------------------------

COST

- AWP (April 2010):
 - Lucentis 0.5mg/0.05ml injection: \$2,437.50 per treated eye per month
 - Avastin: Preparation for intravitreal injection (non-licensed): <\$100 per treated eye per month

COMMITTEE APPROVAL:

- January 2007

GUIDELINE UPDATE INFORMATION:

April 2010	New Medical Coverage Guideline.

REFERENCES:

- DRUGDEX®, accessed 03/29/2010, 3/20/2012
- Product Information: LUCENTIS(R) intravitreal injection, ranibizumab intravitreal injection. Genentech, Inc, South San Francisco, CA, 2008.
- Schouten et al. A systematic review on the effect of bevacizumab in exudative age-related macular degeneration. Graefes Arch Clin Exp Ophthalmol. 2009; 247: 1-11.
- Ziemssen et al. Off-Label Use of Bevacizumab for the Treatment of Age-Related Macular Degeneration- What is the Evidence? Drugs Aging. 2009; 26(4): 295-314.