ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Initial Request** ☐ **Renewal** ☐ **Appeal/Redetermination**[1]

☐ **Urgent**[2] ☐ **Non-Urgent**

Requested Drug Name: Lucentis® (ranibizumab) – Medicare Part B

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit:

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Lucentis® (ranibizumab)

Diagnosis (documentation supportive of diagnosis is required for approval)

☐ Neovascular Age Related Macular Degeneration
☐ Macular Retinal edema following retinal vein occlusion (central or branch RVO)
☐ Diabetic Macular Edema
☐ Other (please state): _____

Clinical Consideration (for approval, please indicate and provide documentation of the following):

☐ Intravitreal injection(s) of Lucentis will be administered by an Ophthalmologist
☐ Other practitioner (please state): _____

☐ Patient is refractory to other therapies *(please indicate which therapy)*:

- ☐ Avastin
- ☐ Eylea
- ☐ Macugen
- ☐ Visudyne

☐ **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

☐ Ophthalmologist

☐ Other (please state):_____

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	
Product will be delivered to: ☐ Patient's Home ☐ Physician Office		Other:
Prescriber or Authorized Signature:		Date:
Dispensing Pharmacy Name and Phone Number:		

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. Appeal/redetermination requests can be made for this medication within 60 calendar days from the date on the faxed/written denial notice you received at the time of the original request.

2. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request.

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: Tier 6, Medical Benefit
Commercial Formulary: Tier 6, Medical Benefit
Medicare Part D coverage: Part B (incident to physician’s service)

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)
- Diabetic macular edema.

**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) for the diagnosis of exudative age-related macular degeneration, 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

Required Provider Specialty:

- Approval is limited to Ophthalmology

DOSAGE/ADMINISTRATION:

For ophthalmic intravitreal injection only (safety and efficacy of ranibizumab have not been established in pediatric patients):

- Exudative age-related macular degeneration:
  - 0.5 mg (0.05 mL of 10 mg/mL ranibizumab solution) injected intravitreally into the affected eye once monthly (approximately 28 days).
  - Alternative dosing: The ranibizumab dose may be reduced to 0.5 mg by intravitreal injection every 3 months after the first 4 monthly injections if monthly injections are not feasible. This dosing schedule will be less effective, leading to an approximate 5-letter (1-line) average loss of visual acuity over the following 9 months. In another alternative schedule, the ranibizumab dose may be reduced to 0.5 mg by intravitreal injection monthly for 3 months followed by less frequent injections (average 4 to 5 injections over 9 months) if monthly injections are not feasible. This dose will be less effective, leading to a maintenance of visual acuity compared with a 1- to 2-letter gain with monthly injections.
  - Alternative effective dose of ranibizumab for the treatment of neovascular macular degeneration was 0.3 mg intravitreally once monthly. Effectiveness at this dose beyond 2 years has not been established.
- Macular edema following retinal vein occlusion (RVO):
  - 0.5 mg (0.05 mL of 10 mg/mL ranibizumab solution) injected intravitreally into the affected eye once a month (approximately 28 days). Monthly treatment is recommended. In clinical studies, a loss of visual acuity at month 7 was reported among patients who did not receive a month 6 injection but not among patients who did receive a month 6 injection.
- Diabetic macular edema:
  - 0.3 mg (0.05 mL of 6 mg/mL ranibizumab solution) injected intravitreally once monthly (approximately 28 days).

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.
- Contraindicated if hypersensitivity to ranibizumab or any component of the product; reactions may manifest as severe intraocular inflammation.
- Arterial thromboembolic events have occurred (e.g. nonfatal stroke, nonfatal myocardial infarction, or vascular death).
- 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)

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
- AWP (September 2012 to current):
  - Lucentis 0.5mg/0.05ml injection: $2,340 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.
April 2013	Coverage policy updated

REFERENCES:

- DRUGDEX®, accessed 03/29/2010, 3/20/2012, 4/3/13, 7/10/14
- 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.