Lucentis

Description

Lucentis (ranibizumab)

Background
Lucentis (ranibizumab) is a vascular endothelial growth factor (VEGF) inhibitor used to treat patients with wet (neovascular) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), diabetic retinopathy (DR), myopic choroidal neovascularization (mCNV) and diabetic macular edema (DME). The VEGF inhibitors block the effects of VEGF-A and prevents the interaction of VEGF-A with its receptors (VEGFR1 and VEGFR2) on the surface of endothelial cells, reducing endothelial cell growth, vascular leakage, and new blood vessel formation (1).

Regulatory Status
FDA-approved indication: Lucentis (ranibizumab) is a VEGF inhibitor indicated for the treatment of patients with: (1-2)
1. Neovascular (Wet) Age-Related Macular Degeneration (AMD)
2. Macular Edema following Retinal Vein Occlusion (RVO)
3. Diabetic Macular Edema (DME)
4. Diabetic Retinopathy (DR)
5. Myopic choroidal neovascularization (mCNV)

Lucentis is contraindicated in ocular or periocular infections (1).
Lucentis must only be administered by a qualified physician. Adequate anesthesia and a topical broad–spectrum microbicide should be given prior to the injection. Increases in intraocular pressure have been seen within 60 minutes of an intravitreal injection (1).

Studies have shown that all patients with diabetic macular edema had significant improvement in vision with regular treatment with any of the three anti-VEGF drugs (Eylea, Lucentis, Avastin) (2).

Safety and effectiveness in pediatric patients have not been established (1).

Related policies
Avastin, VEGF Inhibitors

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Lucentis may be considered medically necessary in patients who are 18 years of age and older with neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), diabetic macular edema (DME), diabetic retinopathy (DR), or in myopic choroidal neovascularization (mCNV) and if the conditions indicated below are met.

Lucentis is considered investigational for patients less than 18 years of age and for all other indications.

Prior-Approval Requirements
Age
18 years of age or older

Diagnoses
Patient must have ONE of the following:

1. Neovascular (wet) age-related macular degeneration (AMD)
2. Macular edema following retinal vein occlusion (RVO)
3. Diabetic macular edema (DME)
4. Diabetic retinopathy (DR)
5. Myopic choroidal neovascularization (mCNV)
AND ALL of the following:
   a. Inadequate treatment response, intolerance, contraindication, or limited access to Avastin (bevacizumab)*
   b. Documented baseline visual acuity test with letter count
   c. NO ocular or periocular infection
   d. NOT to be used in combination therapy with other vascular endothelial growth factor (VEGF) inhibitors

* This requirement only applies to patients just starting on Lucentis or initiating a prior authorization

Prior – Approval Renewal Requirements

Age 18 years of age or older

Diagnoses

Patient must have ONE of the following:

1. Neovascular (wet) age-related macular degeneration (AMD)
2. Macular edema following retinal vein occlusion (RVO)
3. Diabetic macular edema (DME)
4. Diabetic retinopathy (DR)
5. Myopic choroidal neovascularization (mCNV)

AND NONE of the following:

a. Ocular or periocular infection
b. Loss of greater than 15 letters of visual acuity
c. Combination therapy with other vascular endothelial growth factor (VEGF) inhibitors

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months
Prior – Approval *Renewal* Limits

**Duration**  
12 months

**Rationale**

**Summary**  
Lucentis prevents the binding and activation of VEGF receptors leading to a decrease in the neovascularization and vascular permeability associated with neovascular AMD and macular edema following RVO, DR, mCNV and DME. Patients taking Lucentis must be monitored and managed for intravitreal injection procedure associated effects, elevated intraocular pressure and appropriate perfusion of the optic nerve head. Lucentis must only be administered by a retina trained ophthalmologist. Safety and effectiveness in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Lucentis while maintaining optimal therapeutic outcomes.

**References**  

**Policy History**

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| June 2017     | Annual review  
Removed the Lucentis from 5.90.26 VEGF Inhibitors criteria to stand alone criteria  
Addition of the requirement: not be used in combination therapy with other vascular endothelial growth factor (VEGF) inhibitors  
Addition of Myopic choroidal neovascularization (mCNV) |
<p>| September 2017| Annual review                                                                                     |
| January 2018  | Addition of the statement in initial PA requirements of “this requirement only applies to patients just starting on Lucentis or initiating a prior authorization” |
| March 2018    | Annual review                                                                                     |</p>
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September 2019   Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.