Lucentis® (ranibizumab)

Humana

Pharmacy Coverage Policy

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Line of Business: Medicare, Commercial, Medicaid - South Carolina, Medicaid - Ohio
Policy Type: Prior Authorization

Disclaimer

Description

Lucentis (ranibizumab) is a recombinant monoclonal antibody, ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitor.

Lucentis (ranibizumab) binds to and inhibits vascular endothelial growth factor (VEGF-A) from promoting growth of new blood vessels beneath the retina, by intravitreal injection.

Ranibizumab is indicated for the treatment of Exudative (wet) Age-related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), Diabetic Retinopathy, and Myopic Choroidal Neovascularization (mCNV).

Ranibizumab is available as Lucentis:

- Single-use prefilled syringe designed to provide 0.05 mL for intravitreal injection
  - 10 mg/mL solution (Lucentis 0.5 mg)
  - 0.3 mg/0.05mL solution (Lucentis 0.3mg)
- Single-use glass vial designed to provide 0.05 mL for intravitreal injections
  - 10 mg/mL solution (Lucentis 0.5 mg)

- 6 mg/mL solution (Lucentis 0.3 mg)

Coverage Determination

Please note the following regarding medically accepted indications:

All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Health Analytics Micromedex DrugDEX
- Elsevier/Gold Standard Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

Lucentis (ranibizumab) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

Neovascular (Wet) Age-Related Exudative Macular Degeneration (AMD)

- Diagnosed with neovascular (wet) age-related macular degeneration **AND**
- Has a contraindication, or intolerance to bevacizumab.* **OR**
- Has had prior therapy with bevacizumab* and provider attests that the member has NOT demonstrated a positive clinical response to bevacizumab (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss)
  - *For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days

Diabetic Macular Edema (DME)

- Diagnosed with Diabetic Macular Edema **AND**
- Has a contraindication, or intolerance to bevacizumab.* **OR**
- Has had prior therapy with bevacizumab* and provider attests that the member has NOT demonstrated a positive clinical response to bevacizumab (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss).
  - *For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.

Diabetic Retinopathy

- Diagnosed with Diabetic Retinopathy **AND**
- Has a contraindication, or intolerance to bevacizumab.* **OR**
- Has had prior therapy with bevacizumab* and provider attests that the member has NOT demonstrated a positive clinical response to bevacizumab (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss).
  - *For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.

Macular Edema Following Retinal Vein Occlusion (RVO)

- Diagnosed with macular edema following Retinal Vein Occlusion **AND**
- Has a contraindication, or intolerance to bevacizumab.* **OR**
- Has had previous treatment with bevacizumab* and provider attests that the member has NOT demonstrated a positive clinical response to bevacizumab (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss).
  - *For Medicare Part B requests, the step therapy requirement does not apply if

the request is a continuation of prior therapy within the past 365 days.

Myopic Choroidal Neovascularization (mCNV)

- Diagnosed with Myopic Choroidal Neovascularization (mCNV) **AND**
- Has a contraindication, or intolerance to bevacizumab.* **OR**
- Has had previous treatment with bevacizumab* and provider attests that the member has NOT demonstrated a positive clinical response to bevacizumab (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss).
  - *For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.

Lucentis will be approved in plan year durations or as determined through clinical review.

Coverage Limitations

Lucentis (ranibizumab) therapy is not considered medically necessary for members with the following concomitant conditions:

- Current infection, ocular or periocular.
- Lucentis should not be used concurrently with other VEGF inhibitors for intraocular use in the absence of documentation indicating that individual products are to be used in different eyes.

- Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

Background

This is a prior authorization policy about Lucentis (ranibizumab).

VEGF is a naturally occurring substance in the body responsible for the growth of new blood vessels (neovascularization). In the retina however, VEGF may stimulate growth of abnormally fragile vessels prone to leakage. This leakage causes scarring in the macula

and eventually leads to loss of central vision.

Age-related macular degeneration (AMD) is a major cause of painless central vision loss and is a leading cause of blindness in people over 60.

AMD occurs in two forms: dry and wet.

- Dry AMD is associated with atrophic cell death of the central retina or macula, which is required for fine vision used for activities such as reading, driving or recognizing faces. Approximately 10-20% of patients with dry AMD eventually progress to wet AMD.
- Wet AMD is associated with growth of abnormal blood vessels under the macula. These new blood vessels tend to be very fragile and often leak blood and fluid and cause scar tissue that destroys the central retina. The blood and fluid raise the macula from its normal place at the back of the eye.Damage to the macula occurs rapidly and results in a deterioration of sight over a period of months to years. Between 80% to 90% of AMD is dry, yet more than 80% of the visual loss attributable to AMD is caused by the wet form.
  The natural history of AMD is variable, with clinical manifestations dependent on disease type, extent, and whether one or both eyes are affected. Principle risk factors include age, smoking, family history, Caucasian ethnicity, contralateral eye disease, diabetes, and cataract surgery. Genetics play a particularly strong role, with a single polymorphism estimated responsible for as much as 43% of disease occurrence.
  Central retinal vein occlusion (CRVO) is a common retinal vascular disorder. The exact etiology is un known, however may be caused by arteriosclerotic changes in the central retinal artery or from a thrombotic occlusion of the central retinal vein. Occlusion of the central retinal vein leads to backup of the blood in the retinal venous system and increases resistance to the venous blood flow. This increased resistance causes stagnation of the blood and ischemia to the retina. Ischemic damage to the retina stimulates increase production of vascular endothelial growth factor (VEGF), and increased levels of VEGF stimulate neovascularization of the posterior and anterior segment of the eye. Treatment of CRVO includes aspirin, anti-inflammatory agents, isovolemic hemodilution, plasmapheresis, systemic

anticoagulation, fibrinolytic agents, systemic corticosteroids, local anticoagulation with intravitreal injections of alteplase, intravitreal injections of triamcinolone, intravitreal injections of bevacizumab.
There are two types of CRVO; ischemic and nonischemic.

- Nonischemic CRVO is the milder form of the disease and presents with good vision, few retinal hemorrhages and cotton-wool spots, and good perfusion to the retina. This type may resolve fully with good visual outcome or may progress to the ischemic type.
- Ischemic CRVO is the more severe form and presents with severe visual loss, extensive retinal hemorrhages, and cotton-wool spots. Poor perfusion of the retinal and patients may end up with neovascular glaucoma and painful blind eye.

In Branched retinal vein occlusion (BRVO) the blockage occurs in a smaller branch of the vessels that connect to the central retinal vein.

Both types of Retinal Vein Occlusion can lead to Macular Edema or growth of fragile new blood vessels.

Diabetic Macular Edema (DME) is the consequence of retinal microvascular changes from poorly controlled diabetes and diabetic retinopathy. DME is associated with thickening of the basement membrane and reduction of pericytes which are believed to increase permeability of the retinal vasculature. This compromises the blood-retinal barrier causing a leakage of plasma constituents and subsequent retinal edema and hypoxia, all of which stimulates the production of vascular endothelial growth factor (VEGF). DME damages the central retina, which impairs color and pinpoint vision, leading to blurry, washed-out vision. DME can be classified as either focal or diffuse types. In both cases, the predominant labeled treatment for DME is macular focal/grid laser photocoagulation (cauterization of ocular blood vessels). Intravitreal steroids and anti-VEGF agents are also used off-label. (Non-diabetic causes of macular edema include: AMD, uveitis, RVO, and certain genetic disorders.) Lucentis is the first anti-VEGF agent approved for treating DME.

Provider Claims Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Lucentis; ranibizumab; Neovascular (wet) Age Related Macular Degeneration; AMD; Intravitreal; Macular Edema, Retinal Vein Occlusion; RVO; Diabetic Macular Edema; DME; Pharmacy

References

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