

Byooviz™ (ranibizumab-nuna)



Pharmacy Coverage Policy

Effective Date: June 22, 2022

Revision Date: April 26, 2023

Review Date: April 19, 2023

Line of Business: Commercial, Medicaid - Kentucky, Medicaid - South Carolina, Medicaid - Ohio

Policy Type: Prior Authorization

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Products Affected

Byooviz intravitreal solution

Listed Indications

[Neovascular \(Wet\) Age-Related Exudative Macular Degeneration \(AMD\)](#)

[Macular Edema Following Retinal Vein Occlusion \(RVO\)](#)

[Myopic Choroidal Neovascularization \(mCNV\)](#)

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

Does the member meet all of the following criteria?

Criteria #1	Diagnosed with neovascular (wet) age-related macular degeneration
Criteria #2	<ul style="list-style-type: none">Has a contraindication, or intolerance to bevacizumab. OR <ul style="list-style-type: none">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).

Approval Duration

Initial Byooviz (ranibizumab-nuna) will be approved in plan year duration or as determined through clinical review.

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Macular Edema Following Retinal Vein Occlusion (RVO)

Does the member meet all of the following criteria?

Criteria #1	Diagnosed with macular edema following Retinal Vein Occlusion
Criteria #2	<ul style="list-style-type: none">Has a contraindication, or intolerance to bevacizumab. OR <ul style="list-style-type: none">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).

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Myopic Choroidal Neovascularization (mCNV)

Does the member meet all of the following criteria?

Criteria #1	Diagnosed with Myopic Choroidal Neovascularization (mCNV)
Criteria #2	<ul style="list-style-type: none">Has a contraindication, or intolerance to bevacizumab. OR

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- 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).

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Background

This is a prior authorization policy about Byooviz (ranibizumab-nuna).

Byooviz (ranibizumab-nuna) is contraindicated in patients with ocular or periocular infections.

Byooviz (ranibizumab-nuna) 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.

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 unknown, 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.

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- 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.

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

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

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

Ranibizumab-nuna is available as Byooviz:

- Single-use glass vial designed to provide 0.05 mL for intravitreal injections
 - 10 mg/mL solution (Byooviz 0.5 mg)

Provider Claim 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

Byooviz; ranibizumab-nuna; Neovascular (wet) Age Related Macular Degeneration; AMD; Intravitreal; Macular Edema, Retinal Vein Occlusion; RVO; Myopic Choroidal Neovascularization; mCNV; Pharmacy

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