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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Topical Products	**Original Policy Date:**	June 30, 2017
Subject:	Lucentis	**Page:**	1 of 6

Last Review Date: March 8, 2024

Lucentis

Description

Lucentis (ranibizumab), **Byooviz** (ranibizumab-nuna), **Cimerli** (ranibizumab-eqrn)

Preferred products: Byooviz, Cimerli

Background
Lucentis (ranibizumab) and its biosimilars are vascular endothelial growth factor (VEGF) inhibitors 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 ($VEGFR_1$ and $VEGFR_2$) on the surface of endothelial cells, reducing endothelial cell growth, vascular leakage, and new blood vessel formation (1-3).

Regulatory Status
FDA-approved indications: Lucentis (ranibizumab) and its biosimilars are vascular endothelial growth factor (VEGF) inhibitors indicated for the treatment of patients with: (1-3)

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 and its biosimilars are contraindicated in ocular or periocular infections (1-3).

Lucentis and its biosimilars 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 noted both pre-injection and post-injection (within 60 minutes) while being treated with Lucentis or its biosimilars (1-3).

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 (1-3).

Related policies
Bevacizumab, Susvimo, 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 and its biosimilars may be considered **medically necessary** if the conditions indicated below are met.

Lucentis and its biosimilars may be considered **investigational** 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. Documented baseline visual acuity test
b. **NO** ocular or periocular infection
c. **NOT** used in combination with other vascular endothelial growth factor (VEGF) inhibitors (see Appendix 1) other than Susvimo (ranibizumab)
d. **Non-preferred medications only**: Inadequate treatment response, intolerance, contraindication to **ONE** of the preferred products (Byooviz, Cimerli)

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 ALL of the following:

a. Patient has demonstrated a positive clinical response to therapy (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)
b. **NO** ocular or periocular infection
c. **NOT** used in combination with other vascular endothelial growth factor (VEGF) inhibitors (see Appendix 1) other than Susvimo (ranibizumab)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Lucentis (ranibizumab) and its biosimilars prevent 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 ranibizumab 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 and its biosimilars while maintaining optimal therapeutic outcomes.

References

1. Lucentis [package insert]. South San Francisco, CA: Genentech, Inc.; August 2023.
2. Byooviz [package insert]. Cambridge, MA: Biogen Inc.; October 2023.
3. Cimerli [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; November 2022.
4. Grudgel, Dan. Study Compares Eylea, Lucentis and Avastin for Diabetic Macular Edema. American Academy of Ophthalmology. June 2015.

Policy History

Date	Action
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)

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
September 2019	Annual review and reference update
March 2020	Annual review
March 2021	Removed the statement “This requirement only applies to patients just starting on Lucentis or initiating a prior authorization”. Revised renewal requirement from “no loss of greater than 15 letters in visual acuity” to “patient has demonstrated a positive clinical response to therapy (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)”. Also removed the letter count requirement for initiation per FEP
June 2021	Annual review. Removed Macugen from Appendix 1 due to being discontinued
March 2022	Annual review and reference update. Vabysmo and Susvimo added to Appendix 1 but added caveat that Lucentis can be used with Susvimo
June 2022	Annual review and reference update
September 2022	Annual review and reference update. Addition of biosimilars Byooviz and Cimerli to policy
December 2022	Annual editorial review. Per FEP, removed requirement to t/f Avastin
June 2023	Annual review and reference update
December 2023	Annual review. Per FEP, changed preferred products to Cimerli and Byooviz. Also removed Medex requirements. Added t/f requirement of ONE preferred agent to initiation
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.

Appendix 1 - List of VEGF Inhibitors for Ocular Indications

Generic Name	Brand Name
aflibercept	Eylea
bevacizumab	Avastin
brolucizumab-dbll	Beovu
faricimab-svoa	Vabysmo
ranibizumab	Lucentis
ranibizumab*	Susvimo*

*Dual therapy is allowed with Susvimo (ranibizumab)