EVH Clinical Guideline 5025.CC for Ocular Disorders

Guideline Number: EVH_CG_5025.CC	**Applicable Codes**	
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STATEMENT

General Information

- *It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.*

- *If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.*

Purpose

The purpose of this policy is to define the prior authorization process for products used to treat ocular disorders, such as the anti-vascular endothelial growth factor agents (anti-VEGF) and intravitreal corticosteroids.

Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan's medical benefit.

Special Note

Additional uses are included in this policy based on being supported by one or more compendia (e.g., Merative Micromedex®, UpToDate® Lexidrug™, Elsevier Clinical Pharmacology).

INITIAL REVIEW CRITERIA

The request must meet all of the criteria listed under the drug-specific sections below.

Avastin (bevacizumab)

- Must be prescribed by an ophthalmologist
- Must be 18 years of age or older
    - *EXCEPTION:* No age limit for diagnosis of retinopathy of prematurity
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved-labeling (*if being used for an FDA-approved indication*)
- The member will not be using the requested drug with other intravitreal VEGF inhibitors (e.g., aflibercept, bevacizumab, ranibizumab)
- Must have a documented and confirmed diagnosis of one or more of the following:
    - Neovascular (wet) age-related macular degeneration

- Macular edema following retinal vein occlusion (e.g., BRVO, CRVO)
- Diabetic Macular Edema
- Diabetic Retinopathy
- Myopic Choroidal Neovascularization
- Retinopathy of Prematurity

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

- Must be 18 years of age or older
- Must be prescribed by an ophthalmologist
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved-labeling (*if being used for an FDA-approved indication*)
- The member will not be using the requested drug with other intravitreal VEGF inhibitors (e.g., aflibercept, bevacizumab, ranibizumab)
- Must have a documented and confirmed diagnosis of one or more of the following:
  - Neovascular (wet) age-related macular degeneration
  - Macular edema following retinal vein occlusion
  - Diabetic Macular Edema
  - Diabetic Retinopathy
  - Myopic Choroidal Neovascularization
- The member has failed, is intolerant to, has a contraindication to Avastin (bevacizumab) **OR** has documentation supporting the use of the requested medication over Avastin for the member's diagnosis

Eylea / Eylea High-Dose (aflibercept), Ahzantive (aflibercept-mrbb), Enzeevu (aflibercept-abzv), Pavblu (aflibercept-ayyh)

- Must be prescribed by an ophthalmologist
- Must be 18 years of age or older
  - *EXCEPTION*: No age limit for diagnosis of retinopathy of prematurity
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved-labeling (*if being used for an FDA-approved indication*)
- The member will not be using the requested drug with other intravitreal VEGF inhibitors (e.g., aflibercept, bevacizumab, ranibizumab)
- Must have a documented and confirmed diagnosis of one or more of the following:

- Neovascular (wet) age-related macular degeneration
- Macular edema following retinal vein occlusion (regular dose Eylea only)
- Diabetic Macular Edema
- Diabetic Retinopathy
- Retinopathy of Prematurity (regular dose Eylea only)

- The member has failed, is intolerant to, has a contraindication to Avastin (bevacizumab) OR has documentation supporting the use of Eylea over Avastin for the member's diagnosis

Durysta (bimatoprost)

- Must be prescribed by an ophthalmologist
- Must be 18 years of age or older
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved-labeling (*if being used for an FDA-approved indication*)
- Must not have previously received Durysta implant in the requested eye
- Must have a documented and confirmed diagnosis of one or more of the following that requires intraocular pressure-lowering treatment:
  - Ocular hypertension
  - Open angle glaucoma
- Must have not have any of the following:
  - Ocular or periocular infection
  - Corneal endothelial dystrophy
  - Prior corneal transplant
  - Absent or ruptured posterior lens capsule
  - Known hypersensitivity to Durysta or any of its ingredients
- Must have tried and failed, have a contraindication, or be intolerant to ALL the following:
  - At least ONE prostaglandin (such as bimatoprost, latanoprost, travoprost)
  - At least ONE beta-adrenergic blocker (such as carteolol, levobunolol, timolol)
  - At least ONE alpha-2-agonist (such as brimonidine)

iDose TR (travoprost)

- Must be prescribed by an ophthalmologist
- Must be 18 years of age or older
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved-labeling (*if being used for an FDA-*

approved indication)

- Must not have previously received iDose TR implant in the requested eye
- Must have a documented and confirmed diagnosis of one or more of the following that requires intraocular pressure-lowering treatment:
  - Ocular hypertension
  - Open angle glaucoma
- Must have not have any of the following:
  - Ocular or periocular infection
  - Corneal endothelial dystrophy
  - Prior corneal transplant
  - Known hypersensitivity to iDOSE TR or any of its ingredients
- Must have tried and failed, have a contraindication, or be intolerant to ALL the following:
  - At least ONE prostaglandin (such as bimatoprost, latanoprost, travoprost)
  - At least ONE beta-adrenergic blocker (such as carteolol, levobunolol, timolol)
  - At least ONE alpha-2-agonist (such as brimonidine)

Illuvien (fluocinolone)

- Must be prescribed by an ophthalmologist
- Must be 18 years of age or older
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved-labeling (*if being used for an FDA-approved indication*)
- Must not have active ocular or periocular infection
- Must not have glaucoma
- Must have a diagnosis of one of the following:
  - Diabetic macular edema
  - Non-infectious uveitis affecting the posterior segment of the eye
- *For the treatment of diabetic macular edema*: Must have previously received a treatment course with corticosteroids and did not have a clinically significant rise in intraocular pressure
- *For the treatment of non-infectious uveitis:* Must have previously tried and failed intravitreal steroid injections unless contraindicated or intolerant

Izervay (avacincaptad pegol)

- Must be prescribed by an ophthalmologist
- Must be 18 years of age or old

- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved-labeling (*if being used for an FDA-approved indication*)
- The member has a confirmed diagnosis of geographic atrophy secondary to age-related macular degeneration
- The member will not be using the requested drug with other compliment inhibitor therapies [such as Syfovre (pegcetacoplan)]

Ozurdex (dexamethasone)

- Must be prescribed by an ophthalmologist
- Must be 18 years of age or older
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved-labeling (*if being used for an FDA-approved indication*)
- Must not have active ocular or periocular infection
- Must not have a torn or ruptured posterior lens capsule
- Must not have glaucoma
- Must have a diagnosis of one of the following:
    - Macular edema following branch retinal vein occlusion or central retinal vein occlusion
    - Non-infectious uveitis affecting the posterior segment of the eye
    - Diabetic macular edema
- Must have previously tried and failed intravitreal steroid injections unless contraindicated or intolerant

Retisert (fluocinolone)

- Must be prescribed by an ophthalmologist
- Must be 12 years of age or older
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved-labeling (*if being used for an FDA-approved indication*)
- Must not have active infection of the ocular structures
- Must have a diagnosis of chronic non-infectious uveitis affecting the posterior segment of the eye
- Must have previously tried and failed intravitreal steroid injections unless contraindicated or intolerant
- *For ages 18 or older*: Must have previously tried and failed Yutiq®

Susvimo (ranibizumab implant)

- Must be prescribed by an ophthalmologist
- Must be 18 years of age or older
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved-labeling (*if being used for an FDA-approved indication*)
- The member will not be using the requested drug with other intravitreal VEGF inhibitors (e.g., aflibercept, bevacizumab, ranibizumab)
- Must have a confirmed diagnosis of one of the following:
  - Diabetic Macular Edema
  - Neovascular (wet) age-related macular degeneration
- The member has documentation of previously responding to at least two injections of ONE of the following:
  - Aflibercept (Eylea)
  - Ranibizumab (Cimerli, Byooviz, Lucentis)
  - Faricimab-svoa (Vabysmo)
- The member has failed, is intolerant to, has a contraindication to Avastin (bevacizumab) OR has documentation supporting the use of Susvimo over Avastin for the member's diagnosis

Syfovre (pegcetacoplan)

- Must be prescribed by an ophthalmologist
- Must be 18 years of age or old
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved-labeling (*if being used for an FDA-approved indication*)
- The member will not be using the requested drug with other compliment inhibitor therapies [such as Izervay (avacincaptad pegol)]
- Must have a documented and confirmed diagnosis of geographic atrophy secondary to age-related macular degeneration

Vabysmo (faricimab-svoa)

- Must be prescribed by an ophthalmologist
- Must be 18 years of age or older
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved-labeling (*if being used for an FDA-approved indication*)

- The member will not be using the requested drug with other intravitreal VEGF inhibitors (e.g., aflibercept, bevacizumab, ranibizumab)
- The member has a documented and confirmed diagnosis of one or more of the following:
  - Neovascular (wet) age-related macular degeneration
  - Diabetic Macular Edema
  - Macular edema following retinal vein occlusion (RVO)
- *For macular edema following RVO ONLY*: must not be requesting more than 6 months of therapy
- The member has failed, is intolerant to, has a contraindication to Avastin (bevacizumab) OR has documentation supporting the use of Vabysmo over Avastin for the member's diagnosis

Visudyne (verteporfin)

- The member must be 18 years of age or older
- The treatment must be prescribed by an ophthalmologist
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved-labeling (*if being used for an FDA-approved indication*)
- The member has a documented and confirmed diagnosis of subfoveal choroidal neovascularization due to ONE of the following:
  - Age-related macular degeneration
  - Pathologic myopia
  - Presumed ocular histoplasmosis
- Must not have porphyria

Xipere (triamcinolone acetonide)

- Must be prescribed by an ophthalmologist
- Must be 18 years of age or older
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved-labeling (*if being used for an FDA-approved indication*)
- Must not have active ocular or periocular infection
- Must have a diagnosis of macular edema associated with uveitis
- Must have previously tried and failed triamcinolone acetonide intravitreal steroid injections (other than Xipere, such as Kenalog-10 or Triesence), unless contraindicated or intolerant

Yutiq (fluocinolone)

- Must be prescribed by an ophthalmologist
- Must be 18 years of age or older
- Must not have active ocular or periocular infection
- Must have a diagnosis of chronic non-infectious uveitis affecting the posterior segment of the eye
- Must have previously tried and failed intravitreal steroid injections unless contraindicated or intolerant

REAUTHORIZATION CRITERIA

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. The request must meet all of the criteria listed below.

- Chart documentation from the prescriber that the member's condition has improved or stabilized based upon the prescriber's assessment while on therapy
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling (*if being used for an FDA-approved indication*)
- *If the request is for a VEF inhibitor:* The member will not be using the requested drug with other intravitreal VEGF inhibitors (e.g., Eylea, Avastin, Lucentis)
- *If the request is for a complement inhibitor (e.g., Izervay, Syfovre)*: The member will not be using the requested drug with other compliment inhibitor therapies [such as Syfovre (pegcetacoplan)]

EXCEPTIONS:

- Vabysmo (faricimab-svoa) is not eligible for reauthorization beyond the original 6 months of therapy for the diagnosis of macular edema following RVO.
- Durysta and iDose TR (travoprost) are not eligible for reauthorization in the same eye that has previously received the implant (i.e., one dose per eye per lifetime).

APPROVAL DURATIONS

Initial Authorization	Up to 1 year
Reauthorization	Same as initial ● Durysta & iDose TR are not eligible for reauthorization in the same eye that has previously received the implant (i.e., one

	dose per eye per lifetime) • Vabysmo (faricimab-svoa) is not eligible for authorization beyond 6 months for RVO

CODING AND STANDARDS

Codes

Code	Brand	Description
J0177	Eylea HD	Injection, alifbercept hd, 1mg
J0178	Eylea	Injection, aflibercept, 1 mg
J2777	Vabysmo	Injection, faricimab-svoa, 0.1 mg
J2778	Lucentis	Injection, ranibizumab, 0.1 mg
J2779	Susvimo	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg
J2781	Syfovre	Injection, pegcetacoplan, intravitreal, 1 mg
J2782	Izervay	Injection, avacincaptad pegol, 0.1mg
J3396	Visudyne	Injection, verteporfin, 0.1 mg
J7311	RETISERT	INJECTION, FLUOCINOLONE ACETONIDE, INTRAVITREAL IMPLANT, 0.01 MG
J7312	OZURDEX	INJECTION, DEXAMETHASONE, INTRAVITREAL IMPLANT, 0.1 MG
J7313	ILUVIEN	INJECTION, FLUOCINOLONE ACETONIDE, INTRAVITREAL IMPLANT, 0.01 MG
J7314	YUTIQ	INJECTION, FLUOCINOLONE ACETONIDE, INTRAVITREAL IMPLANT, 0.01 MG
J7351	Durysta	Injection, bimatoprost, intracameral implant, 1 mcg
J7355	iDose TR	Injection, travoprost, intracameral implant, 1 microgram

Code	Brand	Description
J3299	XIPERE	INJECTION, TRIAMCINOLONE ACETONIDE (XIPERE), 1 MG
J9035	Avastin	Injection, bevacizumab, 10 mg
Q5124	Byooviz	Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg
Q5128	Cimerli	Injection, ranibizumab-eqrn (Cimerli), biosimilar, 0.1 mg
Q5147	Pavblu	Injection, aflibercept-ayyh (pavblu), biosimilar, 1 mg
Q5149	Enzeevu	Injection, aflibercept-azbv (enzeevu), biosimilar, 1 mg
Q5150	Ahzantive	Injection, aflibercept-mrbb (ahzantive), biosimilar, 1 mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☐	Commercial
☐	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

BACKGROUND

Anti-vascular endothelial growth factor agents (anti-VEGF) agents are commonly used to improve or stabilize vision decline caused by wet age-related macular degeneration (AMD), macular edema, diabetic retinopathy, or retinal vein occlusion. Vascular endothelial growth factors are proteins that support the development of new blood vessels. When there is an over-production of VEGF, the blood vessels in the retina grow abnormally and increase in permeability, resulting in leakiness and decreased vision. Excessive VEGF may also result in new, abnormal retinal blood vessels and capillaries on the surface of the vitreous. These new capillaries are subject to tearing and may result in a vitreous hemorrhage.

The three most common Anti-VEGF agents, Lucentis (ranibizumab), Avastin (bevacizumab), and Eylea (aflibercept) are administered through intraocular injections. Lucentis and Avastin are monoclonal antibodies that bind to VEGF. Eylea contains VEGF receptors that block the VEGF from binding with the native receptor molecules on the cell membrane. Side effects of anti-

VEGF include inflammation inside the eye, increase in eye pressure, blood clots and bleeding in the eye, corneal abrasion, cataracts, and detached retina.

Ozurdex® (dexamethasone) is indicated for the treatment of patients with:

- Macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)
- Non-infectious uveitis affecting the posterior segment of the eye
- Diabetic macular edema (DME)

Iluvien® (fluocinolone) is indicated for the treatment of patients with diabetic macular edema who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure.

Retisert® (fluocinolone) is indicated for the treatment of patients with chronic non-infectious uveitis affecting the posterior segment of the eye.

Yutiq® (fluocinolone) is indicated for the treatment of patients with chronic non-infectious uveitis affecting the posterior segment of the eye.

Xipere® (triamcinolone acetonide) is indicatied for the treatment of patients with macular edema associated with uveitis.

Definitions

BRVO = Branch retinal vein occlusion

CRVO = Central retinal vein occlusion

POLICY HISTORY

Date	Summary
June 2025	• Incorporation of Intravitreal Corticosteroids – Illuvien, Ozurdex, Retisert, Xipere, Yutiq • Removal of Izervay treatment duration • Addition of Ahzantive, Durysta, Enzeevu, iDose TR, Pavblu
August 2024	• Addition of Izervay • Updated Vabysmo approval duration for RVO
January 2024	• Addition of Byooviz, Cimerli, Syfovre, Visudyne • Update of FDA-approved indications for Vabysmo
September 2023	• Addition of Susvimo & Vabysmo criteria, addition of reauthorization criteria, and requirement of appropriate dosing requirement, removal of bypass/exception criteria for Avastin

Date	Summary
	prerequisite under Lucentis
November 2021	• New Guideline

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the *corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.*

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