

RX.PA.026.MPC Ocular Disorders

The purpose of this policy is to define the prior authorization process for drugs used for the treatment of ocular disorders.

Avastin[®] (bevacizumab), Aylmysys (bevacizumab-maly), Mvasi (bevacizumab-awwb), and Zirabev (bevacizumab-bvzr) are indicated for the treatment of:

- Age related macular degeneration – Choroidal retinal neovascularization
- Branch retinal vein occlusion with macular edema
- Central retinal vein occlusion with macular edema
- Choroidal retinal neovascularization, Secondary to pathologic myopia
- Diabetic Macular Edema (DME)
- Diabetic Retinopathy (DR)

Lucentis[®] (ranibizumab), Byooviz[®] (ranibizumab-nuna), Cimerli[®] (ranibizumab-eqrn) are indicated for the treatment of:

- Neovascular (Wet) Age-Related Macular Degeneration (AMD)
- Macular Edema following Retinal Vein Occlusion (RVO)
- Diabetic Macular Edema (DME)
- Diabetic Retinopathy (DR)
- Myopic choroidal neovascularization (mCNV)

Eylea[®] (aflibercept) is indicated for the treatment of:

- Neovascular (Wet) Age-Related Macular Degeneration (AMD)
- Macular Edema following Retinal Vein Occlusion (RVO)
- Diabetic Macular Edema (DME)
- Diabetic retinopathy (DR) associated with diabetic macular edema

Visudyne[®] (verteporfin)

- Age related macular degeneration – Choroidal retinal neovascularization
- Histoplasmosis associated with classic subfoveal choroidal neovascularization
- Myopia associated with classic subfoveal choroidal neovascularization

Vabysmo[®] (faricimab-svoa)

- Neovascular (Wet) Age-Related Macular Degeneration (nAMD)
- Diabetic Macular Edema (DME)

Syfovre[®] (pegcetacoplan)

- Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

Izervay[®] (avacincaptad pegol)

- Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

The drugs, Lucentis® (ranibizumab), Byooviz® (ranibizumab-nuna), Cimerli® (ranibizumab-eqrn), Eylea® (afibercept), Avastin® (bevacizumab), Alymsys (bevacizumab-maly), Mvasi (bevacizumab-awwb), and Zirabev (bevacizumab-bvzr), Visudyne® (verteporfin), Vabysmo® (faricimab-svoa), Syfovre® (pegcetacoplan) and Izervay® (avacincaptad pegol) are subject to the prior authorization process.

PROCEDURE

A. Initial Authorization Criteria

I. CLINICAL CRITERIA (Use for ALL Drug Requests)

Must meet all of the criteria listed under the respective product:

*****If intravenous Avastin is requested for oncology related treatment please forward to Eviti for prior authorization.**

1. **Avastin (bevacizumab)**

- Must be prescribed by an ophthalmologist
- Must be age 18 years or older
- Must have a diagnosis of 1 of the following:
 - Neovascular (wet) age-related macular degeneration
 - Branch retinal vein occlusion with macular edema
 - Central retinal vein occlusion with macular edema
 - Diabetic macular edema
 - Myopic choroidal neovascularization
 - Diabetic Retinopathy (DR)
- Must not have an active ocular or periocular infection
- Avastin is not prescribed with any other VEGF inhibitors

2. **Alymsys (bevacizumab-maly), Mvasi (bevacizumab-awwb), and Zirabev (bevacizumab-bvzr)**

- Must be prescribed by an ophthalmologist
- Must be age 18 years or older
- Must have a diagnosis of 1 of the following:
 - Neovascular (wet) age-related macular degeneration
 - Branch retinal vein occlusion with macular edema
 - Central retinal vein occlusion with macular edema
 - Diabetic macular edema
 - Myopic choroidal neovascularization
 - Diabetic Retinopathy (DR)
- Must not have an active ocular or periocular infection
- Alymsys, Mvasi, or Zirabev are not prescribed with any other VEGF inhibitors

3. **Lucentis (ranibizumab), Byooviz® (ranibizumab-nuna), Cimerli® (ranibizumab-eqrn)**

- Must be prescribed by an ophthalmologist
- Must be age 18 years or older
- Must have a diagnosis of 1 of the following:
 - Neovascular (wet) age-related macular degeneration
 - Macular edema following retinal vein occlusion
 - Diabetic macular edema
 - Diabetic retinopathy
 - Myopic choroidal neovascularization
- Must not have an active ocular or periocular infection
- Lucentis, Byooviz or Cimerli is not prescribed with any other VEGF inhibitors

4. **Eylea (aflibercept) and Eylea HD (aflibercept)**

- Must be prescribed by an ophthalmologist
- Must be age 18 years or older
- Must have a diagnosis of 1 of the following:
 - Neovascular (wet) age-related macular degeneration
 - Macular edema following retinal vein occlusion
 - Diabetic macular edema
 - Diabetic retinopathy associated with diabetic macular edema
- Must not have an active ocular or periocular infection
- Must not have active intraocular inflammation
- Eylea is not prescribed with any other VEGF inhibitors
- For members who are switching from Eylea to Eylea HD formulation: prescribers must have clinical documentation to support rationale and clinical necessity of change

5. **Visudyne (verteporfin)**

- Must be prescribed by an ophthalmologist
- Must be age 18 years or older
- Must have a diagnosis of subfoveal choroidal neovascularization due to 1 of the following:
 - Age-related macular degeneration
 - Pathologic myopia
 - Presumed ocular histoplasmosis
- Must not have porphyria
- Treatment spot size is less than or equal to 6.4 mm in diameter

6. **Vabysmo (faricimab-svoa)**

- Must be prescribed by an ophthalmologist
- Must be age 18 years or older
- Must have a diagnosis of 1 of the following:
 - Subfoveal choroidal neovascularization due to neovascular (wet) age-related macular degeneration
 - Diabetic macular edema
- Must not have an active ocular or periocular infection
- Must not have active intraocular inflammation
- Vabysmo is not prescribed with any other VEGF inhibitors

7. **Syfovre (pegcetacoplan)**

- Must be prescribed by an ophthalmologist
- Must be age 18 years or older
- Must have a diagnosis of geographic atrophy secondary to age-related macular degeneration
- Must provide documentation of baseline assessment for fundus autofluorescence (FAF) imaging
- Provider attests that conditions other than AMD have been ruled out
- Must not have an active ocular or periocular infection
- Must not have active intraocular inflammation
- Provider attests that female patients of childbearing potential utilize contraceptive methods to prevent pregnancy during treatment
- Syfovre is not prescribed in combination with other complement inhibitor therapies

8. **Izervay (avacincaptad pegol)**

- Must be prescribed by an ophthalmologist
- Must be age 18 years or older
- Must have a diagnosis of geographic atrophy secondary to age-related macular degeneration
- Must provide documentation of baseline assessment for fundus autofluorescence (FAF) imaging
- Provider attests that conditions other than AMD have been ruled out
- Must not have an active ocular or periocular infection
- Must not have active intraocular inflammation
- Izervay is not prescribed in combination with other complement inhibitor therapies

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Ocular disorder treatments will be considered investigational or experimental for any other use and will not be covered.

D. Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon:

MPC Renewal:

- Chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.
- For members who are switching from Eylea to Eylea HD formulation: prescribers must have clinical documentation to support rationale and clinical necessity of change

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria)
- Provider has a documented clinical response of the member’s condition which has stabilized or improved based upon the prescriber’s assessment

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

APPLICABLE CODES:	
CODE	DESCRIPTION
J0178	Injection, aflibercept, 1 mg
Q5124	Injection, ranibizumab-nuna, 0.1mg
J2778	Injection, ranibizumab, 0.1 mg
J3396	Injection, verteporfin, 0.1 mg
J9035	Injection, bevacizumab, 10 mg
C9142	Injection, bevacizumab-maly, biosimilar, (alymsys), 10 mg
Q5107	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg
Q5118	Injection, bevacizumab-bvzr, biosimilar, (zirabev), 10 mg
J2777	Injection, faricimab-svoa, 0.1mg
C9151	Injection, pegcetacoplan, 1 mg

REFERENCES

1. Lucentis [package insert]. South San Francisco, CA: Genentech, Inc.; April 2017.
2. Eylea [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; March 2015.
3. Visudyne [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; June 2016.
4. Avastin [package insert]. San Francisco, CA: Genentech, Inc.; January 2021.
5. Cimerli [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; August 2022.
6. Byooviz [package insert]. Cambridge, MA: Biogen, Inc.; June 2022.
7. Vabysmo [package insert]. South San Francisco, CA: Genentech, Inc.; January 2022.
8. Syfovre [package insert]. Waltham, MA: Apellis Pharmaceuticals, Inc.; February 2023.
9. Izervay [package insert]. Parsippany, NJ: Iveric bio, Inc.; August 2023.
10. American Academy of Ophthalmology Retina Panel. Preferred Pattern® Guidelines age-related macular degeneration. San Fransico, CA: American Academy of Ophthalmology; 2008. Accessed November 23, 2011. Available at: www.aao.org/ppp.
11. Alymsys (bevacizumab) [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; April 2022.
12. Mvasi (bevacizumab-awwb) [prescribing information]. Thousand Oaks, CA: Amgen Inc; November 2021.
13. Zirabev (bevacizumab-bvzr) [prescribing information]. New York, NY: Pfizer Inc; May 2021.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual review Change in Non-MPC renewal to renewal from previous insurer</i>	<i>02/2024</i>
<i>Addition of rationale and clinical necessity for members switching from Eylea to Eylea HD formulation</i>	<i>01/2024</i>
<i>Addition of Izervay® (avacincaptad pegol intravitreal) and updates to Eylea to include HD formulation. Update to Vabysmo criteria to remove DME from neovascularization requirement</i>	<i>10/2023</i>
<i>Addition of clinical criteria for Syfovre® (pegcetacoplan) and clarified specialist for prescribing (ophthalmologist)</i>	<i>07/2023</i>
<i>Annual review</i>	<i>02/2023</i>
<i>Removal of biosimilar step requirements and inclusion of diabetic retinopathy for Avastin coverage</i>	<i>02/2023</i>
<i>Selected Revision Addition of MPC vs Non-MPC Renewal, Vabysmo criteria and Lucentis interchangeable biosimilars, Avastin biosimilars</i>	<i>10/2022</i>
<i>Annual review</i>	<i>02/2022</i>
<i>Addition of dosing requirements and off-label restrictions</i>	<i>12/2021</i>
<i>Removal of step therapy requirements</i>	<i>08/2021</i>
<i>P&T Review</i>	<i>11/2020</i>