RX.PA.026.CCH OCULAR DISORDERS

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) agents.

Anti-vascular endothelial growth factor agents (anti-VEGF) agents are commonly usedto 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 onthe 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.

DEFINITIONS

BRVO = Branch retinal vein occlusion
CRVO = Central retinal vein occlusion

POLICY

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.

The drugs outlined below in this policy are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:
Must meet all the criteria listed below under the respective drug:

1. Avastin (bevacizumab)

- The member must be age 18 years or older
  - EXCEPTION: No age limit for diagnosis of retinopathy of prematurity
- 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 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
  - Macular edema following retinal vein occlusion (e.g., BRVO, CRVO)
  - Diabetic Macular Edema
  - Diabetic Retinopathy
  - Myopic Choroidal Neovascularization
  - Retinopathy of Prematurity

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

- The member must be age 18 years 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 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
  - 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

3. Eylea / Eylea High-Dose (aflibercept)

- The member must be age 18 years or older
  - EXCEPTION: No age limit for diagnosis of retinopathy of prematurity
- 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 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
  - 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

4. Izervay (avacincaptad pegol)

- The member must be age 18 years or old
- 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)*
- Must not be requesting for more than 12 months total of therapy
- The member will not be using the requested drug with other compliment inhibitor therapies [such as Syfovre (pegcetacoplan)]
- The member has a documented and confirmed diagnosis of geographic atrophy secondary to age-related macular degeneration

5. Susvimo (ranibizumab implant)

- The member must be age 18 years 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 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 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

6. Syfovre (pegcetacoplan)
- The member must be age 18 years or old
- 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 will not be using the requested drug with other compliment inhibitor therapies [such as Izervay (avacincaptad pegol)]
- The member has a documented and confirmed diagnosis of geographic atrophy secondary to age-related macular degeneration

7. Vabysmo (faricimab-svoa)
- The member must be age 18 years or old
- 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 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

8. Visudyne (verteporfin)
- The member must be age 18 years or old
- 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:
    - o Age-related macular degeneration
    - o Pathologic myopia
    - o Presumed ocular histoplasmosis
- Must not have porphyria

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 the following:

- Chart documentation from the prescriber that the member's condition has improved 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)*
- The member will not be using the requested drug with other intravitreal VEGF inhibitors (e.g., Eylea, Avastin, Lucentis)

EXCEPTIONS:

- Izervay (avacincaptad pegol) is not eligible for reauthorization beyond the original 12 months of therapy.
- Vabysmo (faricimab-svoa) is not eligible for reauthorization beyond the original 6 months of therapy for the diagnosis of macular edema following RVO.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial • Izervay (avacincaptad pegol) is not eligible for authorization beyond 12 months of therapy • Vabysmo (faricimab-svoa) is not eligible for authorization beyond 6 months for RVO

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.

HCPCS Code

HCPCS 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
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

REFERENCES

1. Heier JS, Bressler NM, Avery RL, et al. Comparison of Aflibercept, Bevacizumab, and Ranibizumab for Treatment of Diabetic Macular Edema: Extrapolation of Data toClinical Practice. *JAMA Ophthalmol*. 2016;134(1):95–99. doi:10.1001/jamaophthalmol.2015.4110. https://pubmed.ncbi.nlm.nih.gov/26512939/
2. David, Turbert. American Academy of Othalmology. Anti-VEGF Treatments.03/02/2019. https://www.aao.org/eye-health/drugs/anti-vegf-treatments
3. Lanzetta P, Loewenstein A; Vision Academy Steering Committee. Fundamental principles of an anti-VEGF treatment regimen: optimal application of intravitreal anti-vascular endothelial growth factor therapy of macular diseases. *Graefes Arch Clin Exp Ophthalmol*. 2017;255(7):1259–1273. doi:10.1007/s00417-017-3647-4. https://pubmed.ncbi.nlm.nih.gov/28527040/
4. Regeneron Pharmaceuticals, Inc. Fact Sheet About Eylea (aflibercept) Injection. 03/2015. https://newsroom.regeneron.com/static-files/68dd14da-553b-4bd7-906b-7a3d6af5f1b7
5. U.S. Food and Drug Administration (FDA). Drug Approval Package: Lucentis(ranibizumab) – 125156. 06/30/2006 https://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/125156s0000_LucentisTOC.cfm
6. U.S. Food and Drug Administration (FDA). Drug Approval Package: Eylea(Aflibercept) Injection– 125387s0000. 11/18/2011. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/125387s0000toc.cfm
7. U.S. Department of Health & Human Services. National Institutes of Health. Avastinand Lucentis are equivalent in treating age-related macular degeneration.04/30/2012. https://www.nih.gov/news-events/news-releases/avastin-lucentis-are-equivalent-treating-age-related-macular-degeneration
8. Yorston D. Anti-VEGF drugs in the prevention of blindness. *Community Eye Health*. 2014;27(87):44–46. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4322736/
9. Susvimo [package insert]. South San Francisco, CA: Genentech, Inc.; April 2022.
10. Vabysmo [package insert]. South San Francisco, CA: Genentech, Inc.; January 2022.
11. Byooviz [package insert]. Cambridge, MA: Biogen Inc.; October 2023.
12. Cimerli [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; August 2022.
13. Syfovre [package insert]. Waltham, MA. Appelis Pharmaceuticals, Inc.; November 2023.
14. Visudyne [package insert]. Charleston, SC: Alcami Carolinas Corporation; February 2023.
15. Izervay [package insert]. Parsippany, NJ: IVERIC bio, Inc.;2023

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	11/2021
Addition of Susvimo & Vabysmo criteria, addition of reauthorization criteria, and requirement of appropriate dosing requirement, removal of bypass/exception criteria for Avastin prerequisite under Lucentis	09/2023
Addition of Byooviz, Cimerli, Syfovre, Visudyne Update of FDA-approved indications for Vabysmo	01/2024
Addition of Izervay Updated Vabysmo approval duration for RVO	08/2024

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

Disclaimer

CountyCare medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of CountyCare and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

CountyCare reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

These policies are the proprietary information of Evolent Health. Any sale, copying, or dissemination of said policies is prohibited.