

# Pharmacy Management Drug Policy

<b>SUBJECT: Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitors</b> <b>POLICY NUMBER: PHARMACY-138</b> <b>EFFECTIVE DATE: 04/2026</b> <b>LAST REVIEW DATE: 06/01/2026</b>		
<i>If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:</i>		
<b>Policy Application</b>		
<b>Category:</b>	<input checked="" type="checkbox"/> Commercial Group (e.g., EPO, HMO, POS, PPO)	<input checked="" type="checkbox"/> Medicare Advantage
	<input checked="" type="checkbox"/> On Exchange Qualified Health Plans (QHP)	<input type="checkbox"/> Medicare Part D
	<input checked="" type="checkbox"/> Off Exchange Direct Pay	<input checked="" type="checkbox"/> Essential Plan (EP)
	<input checked="" type="checkbox"/> Medicaid & Health and Recovery Plans (MMC/HARP)	<input checked="" type="checkbox"/> Child Health Plus (CHP)
	<input type="checkbox"/> Federal Employee Program (FEP)	<input type="checkbox"/> Ancillary Services
	<input checked="" type="checkbox"/> Dual Eligible Special Needs Plan (D-SNP)	

## **DESCRIPTION:**

Vascular endothelial growth factor (VEGF) is a protein produced by cells in the body which stimulates the growth of new blood vessels. Occasionally cells can produce too much VEGF causing abnormal new blood vessels to grow in the eye (neovascularization). Abnormal neovascularization can cause leakage of blood and fluids into the retina, scar the macula, and affect vision. Ophthalmic vascular endothelial growth factor (VEGF) inhibitors block the action of VEGF which reduces leaking abnormal blood vessels in the retina. This slows or stops damage from the abnormal blood vessels and slows down vision loss. In some instances, VEGF-inhibitors may also improve vision. Ophthalmic VEGF inhibitors are administered as intravitreal injections. Ophthalmic conditions treated with VEGF inhibitors include neovascular (wet) age-related macular degeneration (nAMD), diabetic retinopathy (DR), diabetic edema (DME), macular edema following retinal vein occlusion (RVO), myopic choroidal neovascularization (mCNV) and retinopathy of prematurity (ROP).

### **Neovascular (wet) Age-Related Macular Degeneration (nAMD)**

Neovascular Age-Related Macular Degeneration is a chronic, progressive disorder of the retina that is characterized by choroidal neovascularization (CNV), which is caused due to over-expression of VEGF.<sup>1</sup> When VEGF levels rise, they promote growth of abnormal vessels, vascular leakage, and hemorrhage underneath the macula, which cause the central vision to appear distorted, and if left untreated may lead to irreversible loss of vision.<sup>1</sup> Early stages of the disease are characterized by symptoms such as central vision blurring, difficulty with fine visual tasks, and metamorphopsia, defined as a type of visual distortion that causes linear objects to appear rounded.<sup>2</sup> Without medical intervention, nAMD progresses rapidly and is currently a leading cause of blindness in the older adult population in developed countries.<sup>2</sup> Introduction of intravitreal VEGF inhibitors has altered the natural disease course, reducing the rates of severe vision loss and improving outcomes of visual acuity in many patients.<sup>3</sup> According to the American Academy of Ophthalmology (AAO), anti-VEGF therapy is currently considered first line therapy for nAMD.<sup>1</sup>

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#### Diabetic Retinopathy (DR) and Diabetic Macular Edema (DME)

Diabetic Retinopathy is a complication of chronic hyperglycemia, which causes capillary dropout, ischemia, inflammation, and ultimately upregulation of VEGF.<sup>4</sup> Diabetic Macular Edema occurs due to breakdown of the blood-retina barrier and fluid accumulation inside the macula. While DME is a major cause of vision impairment in patients suffering from diabetes, randomized controlled trials indicated that therapy with intravitreal VEGF inhibitors was more effective in improving visual acuity, when compared to laser photocoagulation.<sup>5</sup> Both the American Diabetes Association (ADA) and AAO guidelines recommend anti-VEGF therapy as first-line for the treatment of center-involved DME and vision-threatening DR.<sup>4</sup>

#### Macular Edema Following Retinal Vein Occlusion (RVO)

Types of RVO include branch RVO and central RVO. Both are known to cause retinal ischemia, cystoid macular edema, and elevation of VEGF.<sup>6</sup> The most common patient presentation is a sudden, pain-free loss of vision. VEGF inhibitors are the current standard of care for macular edema following RVO, with randomized clinical trials displaying improvement in visual acuity and anatomic outcomes, as a result of VEGF inhibition.<sup>6</sup> Anti-VEGF therapy is preferred over corticosteroid, due to its superior efficacy and safety in patients suffering from RVO-associated macular edema.<sup>6</sup>

#### Myopic Choroidal Neovascularization (mCNV)

Patients with pathologic myopia are predisposed to CNV similar to that seen in patients with AMD.<sup>7</sup> Therapy with VEGF inhibitors has demonstrated superior efficacy when compared to photodynamic therapy in visual acuity and resolution of active lesions.<sup>7</sup>

#### Retinopathy of Prematurity (ROP)

In premature infants, incorrect development of retinal vascularity leads to a condition called retinopathy of prematurity, in which dysregulation of VEGF leads to neovascularization and detachment of the tractional retina. Currently, aflibercept and bevacizumab are used in specialized centers as adjunct therapy, or in cases where laser therapy is contraindicated.<sup>8,9,10</sup>

#### Ophthalmic Anti-VEGF Agents

- **Aflibercept (Eylea<sup>®</sup>, Eylea HD<sup>™</sup>, biosimilars to Eylea, Pavblu<sup>™</sup>):** approved for the treatment of nAMD, DME, DR, RVO, ROP<sup>a</sup>.
- **Bevacizumab (Avastin<sup>®</sup>, biosimilars):** compendial-approved for the treatment of nAMD, DME, DR, RVO and ROP.
- **Brolucizumab (Beovu<sup>®</sup>):** approved for the treatment of nAMD and DME.
- **Faricimab (Vabysmo<sup>®</sup>):** approved for the treatment of nAMD, DME and RVO.
- **Ranibizumab (Lucentis<sup>®</sup>, Byooviz<sup>®</sup>, Cimerli, Susvimo<sup>™</sup>):** approved for the treatment of nAMD, DME, DR, RVO, and mCNV<sup>b</sup>.
  - a. Eylea only
  - b. Lucentis, Byooviz and Cimerli only

#### Comparative Safety and Efficacy

Large comparative trials, such as CATT, VIEW, HARBOR, DRDR.net Protocol T, and TENAYA/LUCERNE, have demonstrated similar improvements in visual acuity across available agents, assuming they are being administered at the recommended dosing intervals.<sup>3,4,5,6</sup>

Differences between products appear to include flexibility of dosing interval, drying effects and safety concerns, but not significant superiority in vision outcomes. Class-wide adverse events include endophthalmitis, intraocular inflammation, retinal detachment, and increases in intraocular pressure, which appears to be transient.<sup>11</sup> Although rare thromboembolic events have been observed, there is still no clear causal association between the medication class and this adverse event.<sup>11</sup> Drug-specific

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concerns are presented with Beovu and Susvimo, with the former being associated with retinal vasculitis and occlusive vasculopathy and the latter with implant-specific complications (dislocation, conjunctival erosion, increased risk of infection).<sup>15,16</sup>

### **POLICY:**

	Neovascular (Wet) Age-Related Macular Degeneration (nAMD)	Diabetic Macular Edema (DME)	Diabetic Retinopathy (DR)	Macular Edema following Retinal Vein Occlusion (RVO)	Myopic Choroidal Neovascularization (mCNV)	Retinopathy of Prematurity (ROP)
<b>Beovu*</b> (brolucizumab)	X	X				
<b>Eylea*</b> (aflibercept)	X	X	X	X		X
<b>Pavblu*</b> (aflibercept-ayyh)	X	X	X	X		
<b>Eylea HD*</b> (aflibercept)	X	X	X	X		
<b>Byooviz*</b> (ranibizumab-nuna)	X	X	X	X	X	
<b>Cimerli*</b> (ranibizumab-eqrm)	X	X	X	X	X	
<b>Lucentis*</b> (ranibizumab)	X	X	X	X	X	
<b>Susvimo*</b> (ranibizumab)	X	X	X			
<b>Vabysmo*</b> (faricimab-svoa)	X	X		X		

\*designated as a preferred product; however, preferred status still requires prior use of a bevacizumab-containing product unless otherwise specified

1. The prescribed medication must be used for the indication(s) consistent with the population outlined in the table above **AND**
2. Must be prescribed by an ophthalmologist **AND**
3. Must be 18 years of age or older
  - a. Does not apply to Eylea for the diagnosis of Retinopathy of Prematurity (ROP) **AND**
4. For a diagnosis of Neovascular (Wet) Age-Related Macular Degeneration (nAMD), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR), Macular Edema following Retinal Vein Occlusion (RVO), and Myopic Choroidal Neovascularization (mCNV)
  - a. Patients new to treatment must have had serious side effects or drug failure (defined as at least 3 injections that results in a suboptimal clinical response) of a bevacizumab-containing product
    - i. For Susvimo
      1. For patients that achieved a positive clinical response to at least two injections of bevacizumab but subsequently experienced disease progression or loss of response, this requirement is satisfied.
      2. For patients that did not achieve a positive clinical response to at least two injections of bevacizumab, documentation must be provided confirming that the patient previously responded to at least two injections of an alternative VEGF inhibitor (e.g., aflibercept, ranibizumab, brolucizumab)
    - ii. For Eylea, Pavblu, and Eylea HD
      1. For patients with a diagnosis of DME or DR with a baseline visual acuity score of 20/50 or worse, a trial of a bevacizumab-containing product will not be required **AND**
5. Refer to individual prescribing information for approved dosing

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6. Eylea HD will not be covered for any non-FDA approved diagnoses (i.e., Retinopathy of Prematurity [ROP])
7. Approval Timeframe

Line of Business	Medical Initial	Medical Recert
SafetyNet (Medicaid, HARP, CHP, Essential Plan)	6 months	6 months
Commercial / Exchange	6 months	6 months
Medicare	2 years	2 years

#### **POLICY GUIDELINES:**

1. Prior authorization is contract dependent.
2. Utilization Management is contract dependent and coverage criteria may be dependent on the contract renewal date. Additionally, coverage of drugs listed in this policy are contract dependent. Refer to specific contract/benefit language for exclusions.
3. Unless otherwise indicated within drug specific criteria, the drugs listed in this policy are administered by a healthcare professional and therefore are covered under the medical benefit.
4. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging.
  - a. Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory finding, and other objective or subjective measures of benefit which support continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline supported treatment options).
5. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
6. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
7. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
8. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at <https://www.cms.gov/medicare-coverage-database/search.aspx>. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
9. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.

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- The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
  - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
  - The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
  - The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
  - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rationale for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration;
  - The above criteria are not applicable to requests for brand name medications that have an AB-rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
10. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: <https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html>
11. The requested site of care may impact approval timeframe and subject to review.

#### **CODES:**

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key:

Experimental/Investigational = (E/I),

Not medically necessary/ appropriate = (NMN).

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<b>HCPCS:</b>	<b>Number</b>	<b>Description</b>
	J0179	Beovu
	Q5124	Byooviz
	Q5128	Cimerli
	J0178	Eylea
	J0177	Eylea HD
	J2778	Lucentis
	Q5147	Pavblu
	J2779	Susvimo
	J2777	Vabysmo

### **UPDATES:**

<b>Date</b>	<b>Revision</b>
06/01/2026	Revised
04/15/2026	Effective and Posted
11/13/2025	P&T Committee Approval

### **REFERENCES:**

In addition to the full prescribing information for each individual drug, any references that have been utilized will be listed below.

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