Vascular Endothelial Growth Factor (VEGF) Inhibitors for Ophthalmic Use

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the vascular endothelial growth factor (VEGF) inhibitor drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. This policy informs prescribers of preferred products, Byooviz, Lucentis, and Vabysmo, and provides an exception process for non-preferred products, Beovu, Eylea, Eylea HD, Cimerli, and Susvimo, through prior authorization. Coverage for non-preferred products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made.

Note:

- Bevacizumab is considered medically necessary for the treatment of choroidal and retinal vascular disorders addressed within this policy and does **not require prior authorization**.
- Lucentis (ranibizumab),Byooviz (ranibizumab-nuna), and Vabysmo (faricimab) do **not require prior authorization**.

Eylea® (aflibercept) is approved by the Food and Drug Administration (FDA) for the following indications:

- Neovascular (wet) age-related macular degeneration (AMD)
- Macular edema following retinal vein occlusion (RVO)
- Diabetic macular edema (DME)
- Diabetic retinopathy (DR)
- Retinopathy of Prematurity (ROP)

Compendial use:

- Macular choroidal neovascularization (mCNV)

Eylea HD® (aflibercept) is approved by the Food and Drug Administration (FDA) for the following indications:

- Neovascular (wet) age-related macular degeneration (AMD)
- Diabetic macular edema (DME)
- Diabetic retinopathy (DR)

Lucentis® (ranibizumab) is approved by the FDA for the following indications:

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- Neovascular (wet) age-related macular degeneration (AMD)
- Diabetic macular edema (DME)
- Diabetic retinopathy (DR)
- Macular edema following retinal vein occlusion (RVO)
- Myopic choroidal neovascularization (mCNV)

Byooviz™ (ranibizumab-nuna), a biosimilar to Lucentis®, is approved by the FDA for the following indications:

- Neovascular (wet) age-related macular degeneration (AMD)
- Macular edema following retinal vein occlusion (RVO)
- Myopic choroidal neovascularization (mCNV)

Cimerli™ (ranibizumab-eqrn), a biosimilar to Lucentis®, is approved by the FDA for the following indications:

- Neovascular (wet) age-related macular degeneration (AMD)
- Macular edema following retinal vein occlusion (RVO)
- Diabetic Macular Edema (DME)
- Diabeitc Retinopathy (DR)
- Myopic choroidal neovascularization (mCNV)

Beovu® (brolucizumab-dbll) is approved by the FDA for the following indications:

- Neovascular (wet) age-related macular degeneration (AMD)
- Diabetic macular edema (DME)

Vabysmo® (faricimab-svoa) is approved by the FDA for the following indications:

- Neovascular (wet) age-related macular degeneration (AMD)
- Diabetic macular edema (DME)
- Macular edema following retinal vein occlusion (RVO)

Susvimo™ (ranibizumab) is approved by the FDA for the following indication:

- Neovascular (wet) age-related macular degeneration (AMD) in patients who have previously responded to at least two intravitreal injections of a Vascular Endothelial Growth Factor (VEGF) inhibitor.

Bevacizumab

While not FDA approved for ophthalmic use, **bevacizumab** has the support of peer reviewed literature and is considered **medically necessary** for the treatment of choroidal and retinal vascular disorders addressed within this policy.

Table. Vascular Endothelial Growth Factor (VEGF) Inhibitor Products

Medication	Generic Name
Preferred Products:	
Byooviz™	ranibizumab-nuna
Lucentis®	ranibizumab
Vabysmo®	faricimab-svoa
Targeted Products:	

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Beovu®	brolucizumab-dbll
Eylea® Eylea® HD	aflibercept
Cimerli™	ranibizumab-eqrn
Susvimo™	ranibizumab

POLICY

***Bevacizumab** is the best value VEGF inhibitor for the treatment of choroidal and retinal vascular disorders addressed within this policy, has the support of peer reviewed literature, and DOES NOT require review or prior authorization.

****Lucentis (ranibizumab), Byooviz (ranibizumab-nuna)** and **Vabysmo (faricimab)** do not require prior authorization and will be considered medically necessary for the treatment of the following:

- Neovascular (wet) AMD
- Macular edema following RVO (both BRVO and CRVO)
- Diabetic macular edema
- Proliferative diabetic retinopathy as an adjunct to photocoagulation or vitrectomy
- Diabetic retinopathy
- Choroidal neovascularization secondary to:
    - Angioid streaks
    - Central serous chorioretinopathy
    - Choroidal rupture or trauma
    - Multifocal choroiditis
    - Pathologic myopia
    - Presumed ocular histoplasmosis syndrome
    - Uveitis
    - Idiopathic choroidal neovascularization

Required Documentation

I. Submission of the following information is necessary to initiate the prior authorization review for the non-preferred products, Beovu, Eylea, Eylea HD, and Cimerli:
    - Chart notes documenting inadequate response to or an intolerable adverse event to the preferred products, Byooviz, Lucentis and Vabysmo, for an indication for which the preferred products have been FDA approved or have a compendial use for.

Preferred Drug Plan Design

Member must meet BOTH the Preferred Drug Plan Design and the Criteria for Initial Approval/Continuation of Therapy when both are applicable.

I. Criteria for initial approval for the non-preferred products will only apply when at least ONE of the following criteria are met:
    - Member has had a documented inadequate response or intolerable adverse event to one of the preferred products.

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- Member is currently receiving therapy with **a non-preferred product**, excluding when **the non-preferred product** is obtained as samples or via manufacturer's patient assistance programs, and is experiencing a positive therapeutic outcome.

Criteria for Initial Approval

I. A series of intravitreal injections with **Eylea (aflibercept)** may be considered **medically necessary** for the treatment of the following:
   - Neovascular (wet) AMD
   - Macular edema following RVO (both BRVO and CRVO)
   - Diabetic macular edema
   - Diabetic retinopathy
   - Choroidal neovascularization secondary to:
     - Angioid streaks
     - Central serous chorioretinopathy
     - Choroidal rupture or trauma
     - Multifocal choroiditis
     - Pathologic myopia
     - Presumed ocular histoplasmosis syndrome
     - Uveitis
     - Idiopathic choroidal neovascularization
   - Retinopathy of Prematurity

II. A series of intravitreal injections with **Eylea HD® (aflibercept)** may be considered **medically necessary** for the treatment of the following:
   - Neovascular (wet) AMD
   - Diabetic macular edema
   - Diabetic retinopathy

III. A series of intravitreal injections with **Cimerli (ranibizumab-eqrn)** may be considered **medically necessary** for the treatment of the following:
   - Neovascular (wet) AMD
   - Macular edema following RVO (both BRVO and CRVO)
   - Diabetic macular edema
   - Proliferative diabetic retinopathy as an adjunct to photocoagulation or vitrectomy
   - Diabetic retinopathy
   - Choroidal neovascularization secondary to:
     - Angioid streaks
     - Central serous chorioretinopathy
     - Choroidal rupture or trauma
     - Multifocal choroiditis
     - Pathologic myopia
     - Presumed ocular histoplasmosis syndrome
     - Uveitis
     - Idiopathic choroidal neovascularization

IV. A series of intravitreal injections with **Beovu (brolucizumab-dbll)** may be considered **medically necessary** for the treatment of neovascular (wet) AMD and diabetic macular edema.

V. A series of intravitreal injections with **Susvimo™ (ranibizumab)** may be considered **medically necessary** when all of the following criteria are met:

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- Member has a diagnosis of neovascular (wet) age-related macular degeneration
- Member has previously responded to at least two intravitreal injections of a Vascular Endothelial Growth Factor (VEGF) inhibitor (e.g., Byooviz, Lucentis) within the past 6 months.
- Must be used in conjunction with the Susvimo ocular implant.

Approval is for 6 months.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment of an indication listed in Criteria for Initial Approval above for members who have 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).

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD-CM diagnostic codes.

- Code(s), if applicable.
  - C9161 – Injection, aflibercept hd, 1 mg (cancelled 3-31-2024)
  - C9097 – Injection, faricimab-svoa, 0.1 mg (deleted 10-1-2022)
  - C9399 – Unclassified drugs or biologicals
  - J0177 – Injection, aflibercept hd, 1 mg (effective 4-1-2024)
  - J0178 – Injection, aflibercept, 1 mg
  - J0179 – Injection, brolucizumab, 1 mg
  - J2777 – Injection, faricimab-svoa, 0.1 mg (effective 10-1-2022)
  - J2778 – Injection, ranibizumab, 0.1 mg
  - J2779 – Injection, ranibizumab, via sustained release intravitreal implant (susvimo), 0.1 mg (effective 7/1/2022)
  - J3490 – Unclassified drugs
  - J3590 – Unclassified biologicals
  - Q5124 Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg
  - Q5128 – Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg

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POLICY HISTORY

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