



Part B Prior Authorization Step Therapy Guidelines

Ophthalmic disorders – VEGF inhibitors

Non-preferred: Eylea (Aflibercept 2mg) J0178, Eylea HD (Aflibercept 8mg) J0177, Vabysmo (faricimab-svoa) J2777, Lucentis (Ranibizumab) J2778, Susvimo (ranibizumab) J2779, Beovu (Brolucizumab-dbl) J0179, Byooviz (ranibizumab-nuna) Q5124, Cimerli (ranibizumab-eqrn) Q5128, Pavblu (aflibercept-ayyh) Q5147

Preferred: Avastin (Intraocular Bevacizumab) J9035, Mvasi (Bevacizumab-awwb) Q5107, Zirabev (bevacizumab-bvzr) Q5118, Aylmsys (bevacizumab-maly) Q5126, Vegzelma (bevacizumab-adcd) Q5129

Prior Authorization Step Therapy

Medicare Part B Request Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	Standard Request– (72 Hours)	☐	Urgent Request (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ ☐ MD ☐ FNP ☐ DO ☐ NP ☐ PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

☐ Self-administered ☐ Provider-administered ☐ Home Infusion

☐ Chart notes attached. **Other important information:** _____

Diagnosis: ICD10: _____ **Description:** _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

Step Therapy

☐ Neovascular (wet) Age-Related Macular Degeneration (AMD)

☐ Preferred:

Group A: Avastin or Bevacizumab biosimilar (No PA Required)

☐ Non-Preferred:

☐ Group B: ☐ Byooviz ☐ Cimerli ☐ Lucentis

☐ Patient has tried and failed at least 3 months of Avastin or biosimilar

☐ Group C: ☐ Beovu ☐ Eylea / HD ☐ Pavblu ☐ Susvimo ☐ Vabysmo

☐ Member has tried/failed AT LEAST 3 months of a Non-preferred Group B alternative

☐ **Macular edema – Retinal Vein Occlusion (RVO)**

☐ Preferred:

Group A: Avastin or Bevacizumab biosimilar (No PA Required)

☐ Non-Preferred:

☐ Group B: ☐ Cimerli ☐ Lucentis

☐ Patient has tried and failed at least 3 months of Avastin or biosimilar

☐ Group C: ☐ Byooviz ☐ Eylea / HD ☐ Pavblu ☐ Vabysmo

☐ Member has tried and failed AT LEAST 3 months of a Non-preferred Group B alternative

☐ **Myopic Choroidal Neovascularizaion (mCNV)**

☐ Preferred:

Group A: Avastin or Bevacizumab biosimilar (No PA Required)

☐ Non-Preferred:

☐ Group B: ☐ Byooviz

☐ Patient has tried and failed at least 3 months of Avastin or biosimilar

☐ Group C: ☐ Cimerli ☐ Lucentis

☐ Member has tried and failed AT LEAST 3 months of a Preferred Group B alternative

☐ **Diabetic Macular Edema (DME)**

☐ **Diabetic Retinopathy (DR)**

☐ Preferred:

Group A: Avastin or Bevacizumab biosimilar (No PA Required)

☐ Non-Preferred:

☐ Group B: ☐ Cimerli ☐ Lucentis

☐ Patient has tried and failed at least 3 months of Avastin or biosimilar

☐ Group C: ☐ Beovu ☐ Eylea / HD ☐ Pavblu ☐ Susvimo ☐ Vabysmo

☐ Member has tried and failed AT LEAST 3 months of a Preferred Group B alternative

New Start or Initial Request: (Clinical documentation required for all requests)

☐ No concurrent ocular or periocular infection

☐ Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.

☐ **Provider has reviewed the attached Quanty Limit Chart and will treat the patient in accordance with FDA and Guideline dosing schedules.**

☐ **Optical coherence tomography (OCT) testing and report is attached.**
(Required at baseline and with every initial and continuation authorization request)

If not, please provide **clinical rationale** for formulary exception: _____

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☐ **Continuation Requests: (Clinical documentation required for all requests)**

- ☐ Patient has received the requested product in the past 365 days.
- ☐ Patient had an adequate response or significant improvement while on this medication.

☐ **Provider has reviewed the attached Quantity Limit Chart and will treat the patient in accordance with FDA and Guideline dosing schedules.**

☐ **Optical Coherence Tomography (OCT) testing and report is attached. (Required)**

If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Ophthalmic VEGF Inhibitors PA**Drug Name(s):**

ALYMSYS	AVASTIN	BEOVU
BYOOVIZ	CIMERLI	EYLEA / EYLEA (HD)
LUCENTIS	MACUGEN (discontinued)	MVASI
PAVBLU	SUSVIMO	VABYSMO
VEGZELMA	ZYRABEV	

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member has tried and failed at least ONE of the formulary alternatives: **Bevacizumab biosimilars** OR
 - There is clinical documentation stating formulary alternatives are contraindicated.
3. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan in accordance with the label.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approval will be for 6 months.

QL Chart (source-cited)

Drug	New Start QL (6mo)	Continuation QL (6mo)	Source
Vabysmo	5 vials/eye	3 vials/eye	Vabysmo Package Insert
Vabysmo (RVO)	6 vials/eye	6 vials/eye	Vabysmo Package Insert
Eylea	10 mg/eye	6 mg/eye	Eylea Package Insert
Eylea (RVO)	6 vials/eye	6 vials/eye	Eylea Package Insert
Eylea HD (AMD/DME)	32 mg/eye	24 mg/eye	Eylea HD Package Insert
Eylea HD (RVO)	40 mg/eye	16 mg/eye	Micromedex, RVO monograph
Cimerli	6 vials	4 vials	Cimerli Package Insert
Lucentis	6 vials	4 vials	Lucentis Package Insert
Byooviz	6 vials	4 vials	Byooviz Package Insert
Pavblu	10 mg/eye	6 mg/eye	Pavblu (Eylea reference label)
Beovu	30 mg/eye	18 mg/eye	Beovu Package Insert

Other Prior Authorization and Step Therapy Clinical Considerations:

All options are contraindicated in patients with ocular or periocular infections.

Requests will be reviewed according to the product- and diagnosis-specific FDA-approved dosing regimen. For Vabysmo, Eylea, Eylea HD, Pavblu, and Beovu, the FDA-approved labeling recognizes that certain patients who do not maintain an

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adequate clinical or anatomic response at an extended maintenance interval may require every-4-week (or every-6-week for Beovu) dosing. Requests for dosing more frequently than every 8 weeks must include an OCT report documenting persistent, recurrent, or worsening disease activity and failure to maintain an adequate response in OCT-measured retinal thickness or retinal fluid despite treatment at an every-8-week interval, supporting the need for more frequent dosing consistent with the FDA-approved prescribing information.

Cimerli, Lucentis, and Byooviz requests will be evaluated based on their applicable FDA-labeled monthly dosing regimens. Susvimo requests will be evaluated based on the implant fill and refill-exchange schedule specific to the approved indication. Authorization duration for Susvimo is 6 months for AMD or DME, and 9 months for DR, consistent with the FDA-approved refill-exchange interval for each indication.

Optical coherence tomography (OCT) testing and report is required at baseline and with every initial and continuation authorization request.

FDA Indications:

Byooviz, Cimerli, Eylea/Eylea HD, Lucentis, Pavblu, Vabysmo

- Exudative age-related macular degeneration
- Macular edema due to diabetes mellitus (Eylea, Lucentis, Vabysmo only)
- Macular retinal edema - Thrombosis of retinal vein (Eylea, Vabysmo only)
- Myopic choroidal neovascularization (Byooviz, Cimerli, Lucentis only)
- Retinopathy due to diabetes mellitus (Eylea, Lucentis only)

Susvima

- Exudative age-related macular degeneration

Beovu

- Exudative age-related macular degeneration
- Retinopathy due to diabetes mellitus

Off-Label Uses:

- Retinopathy of prematurity, Type 1 (Lucentis only)

Step Therapy Drug(s) and FDA Indications:

Avastin, Alymsys, Mvasi, Vegzelma, Zirabev

FDA Indications:

- Cervical cancer, Recurrent, persistent, or metastatic, in combination with paclitaxel and cisplatin or paclitaxel and topotecan
- Glioblastoma multiforme of brain, Recurrent
- Liver carcinoma, Unresectable or metastatic, in combination with atezolizumab, in patients who have not received prior systemic therapy
- Metastatic colorectal cancer, First- or second-line therapy, in combination with IV 5-fluorouracil-based chemotherapy
- Metastatic colorectal cancer, Second-line therapy, in combination with fluoropyrimidine/irinotecan- or fluoropyrimidine/oxaliplatin-based chemotherapy, in patients who have progressed on a first-line bevacizumab-containing regimen
- Metastatic renal cell carcinoma, In combination with interferon alfa
- Nonsquamous non-small cell lung cancer, Recurrent or metastatic, unresectable, locally advanced, first-line treatment in combination with paclitaxel and carboplatin
- Ovarian cancer, Fallopian tube or primary peritoneal cancer, recurrent, platinum-resistant disease, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, with no more than 2 prior chemotherapy regimens

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- Ovarian cancer, Fallopian tube or primary peritoneal cancer, recurrent, platinum-sensitive disease, in combination with carboplatin and paclitaxel or with carboplatin and gemcitabine, followed by single agent bevacizumab
- Ovarian cancer, Stage III or IV epithelial ovarian, fallopian tube or primary peritoneal cancer, first-line therapy in combination with carboplatin and paclitaxel following initial surgical resection, followed by single-agent bevacizumab

Off Label Uses:

- Age related macular degeneration - Choroidal retinal neovascularization
- Bleeding from nose - Osler hemorrhagic telangiectasia syndrome
- Branch retinal vein occlusion with macular edema
- Central retinal vein occlusion with macular edema
- Choroidal retinal neovascularization, Secondary to pathologic myopia
- Macular edema due to diabetes mellitus
- Malignant mesothelioma of pleura, Unresectable disease, first-line therapy, in combination with pemetrexed and cisplatin
- Metastatic breast cancer, HER2-negative, as first-line therapy, in combination with paclitaxel
- Metastatic breast cancer, HER2-negative, as second-line therapy in combination with other chemotherapy
- Metastatic breast cancer, In combination with capecitabine in patients previously treated with an anthracycline and a taxane
- Metastatic colorectal cancer, First-line therapy, in combination with oxaliplatin and capecitabine
- Metastatic colorectal cancer, In previously untreated elderly patients, ineligible for oxaliplatin- or irinotecan-based chemotherapy
- Necrosis of central nervous system due to exposure to ionizing radiation
- Neovascular glaucoma; Adjunct
- Nonsquamous non-small cell lung cancer, Stage IIIB/IV, continuation maintenance therapy as a single-agent following platinum-based, first-line therapy
- Nonsquamous non-small cell lung cancer, Stage IIIB/IV, first-line therapy in combination with pemetrexed and CARBOplatin
- Retinopathy due to diabetes mellitus
- Retinopathy of prematurity

Age Restrictions:

N/A

Resources:

https://careweb.careguidelines.com/ed24/ac/ac04_118.htm

https://careweb.careguidelines.com/ed24/ac/ac04_067.htm

https://careweb.careguidelines.com/ed24/ac/ac04_071.htm

https://careweb.careguidelines.com/ed24/ac/ac04_088.htm

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