



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, Macugen (Pegaptanib) J2503, Beovu (Brolucizumab-dbli) J0179, Byooviz (ranibizumab-nuna) Q5124, Cimerli (ranibizumab-eqrn) Q5128

Preferred: Avastin (Intraocular Bevacizumab) J9035, Mvasi (Bevacizumab-awwb) Q5107 Zirabev (bevacizumab-bvzr) Q5118, Alymsys (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.

Request form with checkboxes for Standard Request (72 Hours) and Urgent Request, and fields for Date Requested, Requestor, Clinic name, Phone, and 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

Table with 5 columns: 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 section with checkboxes for Neovascular (wet) Age-Related Macular Degeneration (AMD) and sub-categories like Preferred, Group A, Group B, Non-Preferred, and Member has tried and failed AT LEAST 3 months of a Preferred Group B alternative.

Part B Prior Authorization Step Therapy Guidelines

Macular edema – Retinal Vein Occlusion (RVO)

Preferred:

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

Group B: Vabysmo

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

Non-Preferred:

Byooviz Cimerli Eylea Lucentis Susvimo

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

Myopic Choroidal Neovascularizaion (mCNV)

Preferred:

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

Group B: Byooviz

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

Non-Preferred:

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)

Group B: Beovu Eylea HD Vabysmo

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

Non-Preferred:

Cimerli Eylea Lucentis Susvimo

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.

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

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.

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.

Prior Authorization Group – Ophthalmic VEGF Inhibitors PA

Drug Name(s):

ALYMSYS	AVASTIN	BEOVU
BYOOVIZ	CIMERLI	EYLEA / EYLEA (HD)
LUCENTIS	MACUGEN (discontinued)	MVASI
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: **Avastin, Mvasi, Zirabev** 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.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Byooviz, Cimerli, Eylea/Eylea HD, Lucentis

- Exudative age-related macular degeneration
- Macular edema due to diabetes mellitus (Eylea, Lucentis only)
- Macular retinal edema - Thrombosis of retinal vein (Eylea 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
-

Macugen (discontinued)

Off-Label Uses:

- Retinopathy of prematurity, Type 1 (Lucentis only)

Step Therapy Drug(s) and FDA Indications:

Avastin, Alimta, Mvasi, Vectin, 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
- 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

Other Clinical Consideration:

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

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

https://www.micromedexsolutions.com/micromedex2/librarian/CS/B6DCD7/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYN C/F64DFC/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegrat edSearch?SearchTerm=CIMERLI&UserSearchTerm=CIMERLI&SearchFilter=filterNone&navitem=searchGlobal#