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P&T Date: 08/13/2026

Ranibizumab Products

Drug	HCPCS
Byooviz™ (ranibizumab-nuna)	Q5124
Cimerli™ (ranibizumab-eqrn)	Q5128
Lucentis® (ranibizumab)	J2778
Nufymco® (ranibizumab-leyk)	Q5168
Ranibizumab-nuna	Q5124
Ranluspec™ (ranibizumab-hkdz)	J3590
Susvimo™ (ranibizumab)	J2779

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved indication
 - b. FDA approved age
 - c. Treatment with bevacizumab or a bevacizumab biosimilar has been ineffective, not tolerated or contraindicated
 - d. For Susvimo only
 - i. Must have experienced disease stability or improvement following at least 2 injections in the same eye of either Beovu®, Eylea™, or Lucentis prior to Susvimo therapy
 - ii. Supplemental treatment is allowed only with Lucentis if ONE of the following are met:
 - 1. A decrease in visual acuity by half from the baseline visual acuity
 - 2. Increase of 150 µm or more in retinal thickness
 - e. Coverage will be provided for biosimilar products for FDA labeled indications of the innovator product when criteria are met
 - f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limits: Align with FDA recommended dosing
 - b. Authorization Period: For at least 60 days and up to one year at a time
 - i. For Susvimo only: Up to 2 supplemental Lucentis injections per affected eye allowed per 6 month refill

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- c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Intravitreal injections of anti-vascular endothelial growth factor (VEGF) have been widely used by ophthalmologists to treat a variety of ocular diseases. They are injected directly into the eye to prevent the formation of new blood vessels and reduce blood vessel leakage and inflammation. The following anti-VEGF therapies are currently available to treat the following indications:
 - Byooviz: macular edema due to retinal vein occlusion (RVO), myopic choroidal neovascularization (mCNV), and neovascular (wet) age-related macular degeneration (AMD)
 - Cimerli: diabetic macular edema (DME), diabetic retinopathy (DR), macular edema due to RVO, mCNV, and wet AMD
 - Lucentis: DME, DR, macular edema due to RVO, mCNV, and wet AMD
 - Nufymco: DME, DR, macular edema due to RVO, mCNV, and wet AMD
 - Ranluspec: DME, DR, macular edema due to RVO, mCNV, and wet AMD
 - Susvimo: neovascular AMD and DME in those who have previously responded to at least two intravitreal injections of a VEGF inhibitor
- Age-related Macular Degeneration
 - Age-related macular degeneration is a degenerative disease of the macula that results primarily in loss of central vision. Wet AMD is characterized by growth of abnormal vessels into the subretinal space. These abnormal blood vessels leak leading to collections of subretinal fluid and/or blood beneath the retina. The 2024 American Academy of Ophthalmologists (AAO) Age-Related Macular Degeneration Preferred Practice Pattern Guidelines recommend observation and early detection, antioxidant vitamin and mineral supplements, and intravitreal injections of anti-VEGF agents for the management of wet AMD. Guidelines recommend Eylea™, Avastin®, Vabysmo™, or Lucentis for treatment. The guidelines have not been updated with Beovu®, Byooviz, and Susvimo.
- Diabetic Retinopathy and Diabetic Macular Edema
 - Diabetic retinopathy and DME are common complications and the ocular manifestations of end-organ damage in diabetes mellitus. The 2025 AAO Diabetic Retinopathy Preferred Practice Pattern Guidelines state the goals of therapy for DR and DME include improvement or stabilization of visual function, improvement in vision-related quality of life, and optimal control of blood glucose, blood pressure, and other metabolic risk factors. Patients should always be treated with anti-VEGF therapy if they have severe non-proliferative DR or proliferative DR with center-involved macular edema. In cases of mild to moderate non-proliferative DR with center-involved macular edema, patients should also receive intravitreal injections.

The guidelines support the use of Lucentis, Eylea, Vabysmo, and Avastin. AAO recommendations were based on trials comparing Eylea, Avastin, and Lucentis to focal laser treatment. All trials showed that treatment with VEGF inhibitors resulted in statistically and clinically significant improvements in visual acuity in patients with DME after one to two years compared to laser treatment.

– Retinal Vein Occlusion

- Retinal vein occlusion occurs when there is partial or complete obstruction of a retinal vein. Vision loss can occur with RVO and is associated with macular ischemia or edema, retinal hemorrhages, vitreous hemorrhage, or epiretinal membrane formation. The 2025 AAO Retinal Vein Occlusions Preferred Practice Pattern Guidelines recommend anti-VEGF therapy as first-line treatment for macular edema caused by RVO. The guidelines support the use of Lucentis, Eylea, and Avastin. The guidelines state VEGF inhibitors, Eylea, Avastin, and Lucentis, are more effective than sham injection or laser therapy in maintaining or improving visual acuity in patients with macular edema secondary to RVO.

– Myopic Choroidal Neovascularization

- Myopic choroidal neovascularization is a common vision-threatening complication of myopia and pathological myopia. Naïve myopic patients who present with blurred vision, vision loss, or metamorphopsia should be referred to a retinal specialist who can diagnose mCNV. Once mCNV is diagnosed, anti-VEGF therapy should be started immediately. Lucentis has demonstrated improvements in visual acuity in patients with mCNV. A randomized controlled trial compared the effects of Lucentis to photodynamic therapy with verteporfin in patients with mCNV. At month three, treatment with Lucentis demonstrated significant improvements in visual acuity compared to photodynamic therapy with verteporfin. A Cochrane systematic review concluded that there is low to moderate-certainty evidence for the efficacy of VEGF inhibitors to treat mCNV at one year and two years. It also concluded that Lucentis and Avastin are equivalent in terms of efficacy in the treatment of patients with mCNV.

- There are very few randomized control trials that assess the efficacy of one anti-VEGF therapy over another. Of the two that are available, Avastin, Eylea, and Lucentis were all shown to be non-inferior to each other, and because of this, choice of therapy should be based on patient characteristics, side effect profiles, cost, and availability. However, a 2015 study conducted by Wells, et al. did show Eylea was superior to Avastin therapy when patients had a visual acuity of less than or equal to 20/50. In addition, a subcohort analysis of the YOSEMITE AND RHINE trials showed Vabysmo demonstrated BCVA gains similar to aflibercept, while demonstrating numerically greater improvements in anatomic outcomes at years 1 and 2. Therefore, in these scenarios Avastin should not be used prior to Eylea or Vabysmo.

– Susvimo

- In the ARCHWAY clinical trial, Susvimo was only implanted following at least 3 prior anti-VEGF intravitreal injections of either Avastin, Eylea, or Lucentis within 6 months of screening. Patients in the study had to demonstrate anatomic and visual response to anti-VEGF treatment for nAMD, therefore, Susvimo should not be administered to patients who have not had proven success with prior anti-VEGF therapy.
- Susvimo was not studied with supplemental doses of other anti-VEGF therapies and therefore, should not be administered with any other intravitreal injections other than Lucentis. Supplemental doses were given when the study participants experienced one of the following: decrease of 15 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or more from the best-recorded BCVA in the study; an increase of 150 µm or more in retinal thickness measured by central subfield thickness (CST) on spectral domain OCT (SD-OCT) from the lowest CST measurement in the study; or an increase of 100 µm or more in CST on SD-OCT from the lowest CST measurement in the study associated with a decrease of 10 ETDRS letters or more

from the best-recorded BCVA during the study. In these scenarios only should patients be considered for additional Lucentis injections. Fifteen ETDRS letters are equivalent to a decrease in visual acuity by half.

- Of the 1.6% of patients who required supplemental injections with Lucentis during the study, a maximum of 2 injections were given per affected eye within the 24 weeks between implantation of the device of the first refill. As such, there is no data available to support more than 2 supplemental injections per 6 months.

References:

1. Lucentis [prescribing information]. South San Francisco, CA: Genentech, Inc.; February 2024.
2. Byooviz [prescribing information]. Cambridge, MA: Samsung Bioepis Co., Ltd; August 2025.
3. Susvimo [prescribing information]. South San Francisco, CA: Genentech, Inc.; September 2025.
4. Cimerli [prescribing information]. Redwood City, California: Coherus BioSciences, Inc.; May 2024.
5. Avastin [prescribing information]. South San Francisco, CA: Genentech, Inc.; January 2021.
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20. Zhu Y, Zhang T, Xu G, et al. Anti-vascular endothelial growth factor for choroidal neovascularization in people with pathological myopia (Review). *The Cochrane database of systematic reviews*. 2016; 12: CD011160.

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Policy History		
#	Date	Change Description
2.7	Effective Date: 08/13/2026	Updated to include Ranluspec
2.6	Effective Date: 06/15/2026	UM medical management system update for BCBS and BCN for Ranluspec
2.5	Effective Date: 02/12/2026	Updated to include Nufymco
2.4	Effective Date: 01/07/2026	UM medical management system update for BCBS and BCN for Nufymco
2.3	Effective Date: 12/04/2025	Updated to include ranibizumab-nuna
2.2	Effective Date: 06/05/2025	Annual review of criteria was performed, no changes were made
2.1	Effective Date: 06/06/2024	Annual review of criteria was performed, no changes were made
2.0	Effective Date: 06/08/2023	Updated to add criteria stating the biosimilars will be covered for all FDA approved indications of the innovator product and add a step through Byooviz
1.9	Effective Date: 04/06/2023	New policy. This policy replaces previously approved criteria that was embedded in the Intravitreal Injections for Retinal Conditions Policy which is being split into individual drug policies and retired. The authorization period was updated from up to 1 year to at least 60 days and up to 1 year
1.8	Effective Date: 10/03/2022	UM medical management system update for BCNA and MAPPO for Cimerli
1.7	Effective Date: 09/01/2022	UM medical management system update for BCN and BCBS for Cimerli
1.6	Effective Date: 06/06/2022	UM medical management system update for BCNA and MAPPO for Byooviz
1.5	Effective Date: 04/01/2022	UM medical management system update for BCN and BCBS for Byooviz and Ranibizumab-nuna
1.4	Effective Date: 12/27/2021	UM medical management system update for MAPPO and BCNA for Susvimo
1.3	Effective Date: 11/18/2021	UM medical management system update for BCBSM and BCN for Susvimo
1.2	Effective Date: 01/01/2020	UM medical management system update for BCBS for Lucentis
1.1	Effective Date: 07/05/2017	UM medical management system update for MAPPO and BCNA for Lucentis
1.0	Effective Date: 11/08/2012	UM medical management system update for BCN for Lucentis

* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.

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Blue Cross Blue Shield/Blue Care Network of Michigan

Medication Authorization Request Form

Ranibizumab

Lucentis® (ranibizumab): J2778, Susvimo™ (ranibizumab): J2779, Byooviz® (Ranibizumab-nuna): Q5124, Cimerli™ (ranibizumab-eqrn): Q5128

Blue Cross
Blue Shield
Blue Care Network
of Michigan

This form is to be used by participating physicians to obtain coverage for Lucentis, Byooviz, Susvimo, or Cimerli. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

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PATIENT INFORMATION

PHYSICIAN INFORMATION

Name

Name

ID Number

Specialty

D.O.B.

☐ Male ☐ Female

Address

Diagnosis

City /State/Zip

Drug Name

Phone/Fax: P: () - F: () -

Dose and Quantity

NPI

Directions

Contact Person

Date of Service(s)

Contact Person Phone /
Ext.

STEP 1:

DISEASE STATE INFORMATION

1. Is this request for: ☐ Initiation ☐ Continuation *Date patient started therapy:* _____
2. Please provide the NPI number for the place of administration: _____
3. **Initiation AND Continuation of therapy:**
 - a. What eye(s) will be treated? ☐ Left eye ☐ Right eye
 - b. What is the patient's dose and frequency of requested medication?
Initiation - Dose: _____mg Frequency: ☐ 4 weeks ☐ 6 weeks ☐ 8 weeks ☐ Other: _____
Maintenance - Dose: _____mg Frequency every: ☐ 4 weeks ☐ 6 weeks ☐ 8 weeks ☐ Other: _____
 - c. What is the patient's diagnosis?
☐ Neovascular (wet) age-related macular degeneration (AMD) ☐ Diabetic retinopathy (DR)
☐ Myopic choroidal neovascularization (mCNV)
☐ Macular edema due to retinal vein occlusion (RVO) ☐ Other, Please specify: _____
☐ Diabetic macular edema (DME)
 - a. What is the visual acuity in the right eye? _____
 - b. What is the visual acuity in the left eye? _____
 - d. Has the patient tried Avastin or bevacizumab biosimilar intravitreal treatment?
☐ No
☐ Yes
 - i. Which eye was treated? ☐ Left eye ☐ Right eye
 - ii. Please enter number of Avastin or a bevacizumab biosimilar injections patient has received and in which eye? _____
 - iii. What was the patient's frequency of Avastin or bevacizumab biosimilar? ☐ 4 weeks ☐ 6 weeks ☐ 8 weeks ☐ Other: _____
 - iv. Date of the last Avastin or a bevacizumab biosimilar injection: _____
 - v. What was the patient's outcome while on Avastin or bevacizumab biosimilar therapy?
☐ Visual acuity improvement ☐ Reduction in edema ☐ Decrease in retinal thickness ☐ Condition remained the same
☐ Worsening in visual acuity ☐ Increased edema ☐ Increase in retinal thickness
☐ Intolerance to the medication: _____
☐ Other, Please list: _____
 - e. Has the patient failed treatment with other anti-VEGF therapy? ☐ Yes ☐ No
 - i. If yes, List what treatment(s) patient failed: _____
 - f. **Susvimo only:**
 - i. Has the patient experienced disease stability or improvement following at least 2 injections in the same eye of either Beovu, Eylea, or Lucentis prior to Susvimo therapy? ☐ Yes ☐ No, please explain: _____
 - ii. Is supplemental treatment needed with Lucentis while on Susvimo?
☐ No
☐ Yes
 1. Did the patient experience decrease in visual acuity by half from the baseline visual acuity?
☐ Yes ☐ No, please explain: _____
 2. Did the patient experience an of increase of 150 µm or more in retinal thickness?
☐ Yes ☐ No, please explain: _____
4. **Continuation of therapy:**
 - a. How has the patient's condition changed while on therapy?
☐ Improved; Please describe: _____
☐ Stable; Please describe: _____
☐ Worsened; Please describe: _____
☐ Other; Please describe: _____

Please add any other supporting medical information necessary for our review**Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.**☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name

Physician Signature

Date

Step 2:

Checklist

- ☐
- Form Completely Filled Out
-
- ☐
- Attached chart notes

☐ Pertinent test results

Step 3:

Submit

By Fax: BCBSM Specialty Pharmacy Mailbox
1-877-325-5979By Mail: BCBSM Specialty Pharmacy Program
P.O. Box 312320, Detroit, MI 48231-2320