SmartHealth Ascension

Aflibercept (Eylea®) J0178 (1mg)

Brolucizumab-dbll (Beovu®) J0719 (1mg)

Pegaptanib (Macugen®) J2503 (active HCPCS/inactive product)

Ranibizumab (Lucentis®) J2778 (0.1mg)

Covered with prior authorization

Aflibercept (Eylea®) may be authorized when the following criteria are met:

- Diagnosis of Neovascular (Wet) Age-Related Macular Degeneration (AMD); **AND**
  - Dosing is 2 mg every 4 weeks (approximately every 28 days, monthly) for first 3 months followed by subsequent dosing of 2 mg every 8 weeks (2 months); **OR**
  - Dosing is 2 mg every 4 weeks (approximately every 28 days, monthly) continuing after the first 3 months where additional documentation is submitted to support the decreased interval; **OR**
  - Dosing is 2 mg every 4 weeks (approximately every 28 days, monthly) for the first 3 months followed by subsequent dosing of 2 mg every 8 weeks (2 months) through year 1 with dosing of 2 mg every 12 weeks (3 months) beginning in Year 2;

OR

- Diagnosis of Macular Edema Following Retinal Vein Occlusion (RVO); **AND**
  - Dosing is 2 mg once every 4 weeks (approximately every 25 days, monthly);

OR

- Diagnosis of Diabetic Macular Edema (DME); **AND**
  - Dosing is 2 mg every 4 weeks (approximately every 28 days, monthly) for the first 5 injections followed by a 2 mg dose every 8 weeks (2 months) thereafter; **OR**
  - Dosing is 2 mg every 4 weeks (approximately every 28 days, monthly) for the first 5 injections followed by a 2 mg dose every 4 weeks (monthly) thereafter where additional documentation is submitted to support the decreased interval;

OR

- Diagnosis of Diabetic Retinopathy **(DR)**; **AND**
  - Dosing is 2 mg every 4 weeks (approximately every 28 days, monthly) for the first 5 injections followed by a 2 mg dose every 8 weeks (2 months) thereafter; **OR**
  - Dosing is 2 mg every 4 weeks (approximately every 28 days, monthly) for the first 5 injections followed by a 2 mg dose every 4 weeks (monthly) thereafter where additional documentation is submitted to support the decreased interval;

AND

- Individual has had a trial and inadequate response or intolerance to at least one preferred agent; **OR**

- Request is for continuation of therapy for individual established and responding well to Aflibercept (Eylea®);

AND

- Product is prescribed by or in consultation with an ophthalmologist.

Brolucizumab-dbll (Beovu®) may be authorized when the following criteria are met:

- Diagnosis of Neovascular (Wet) Age-Related Macular Degeneration (AMD); **AND**
  - Dosing is 6 mg monthly (approximately every 25-31 days) for the first 3 doses, followed by subsequent dosing of 6 mg every 8-12 weeks**;**

OR

- Diagnosis of Diabetic Macular Edema (DME); **AND**
  - Dosing is 6 mg every six weeks (approximately every 39-45 days) for the first 5 doses, followed by subsequent dosing of 6 mg every 8-12 weeks**;**

AND

- Individual has had a trial and inadequate response or intolerance to at least one preferred agent; **OR**
- Request is for continuation of therapy for individual established and responding well to Brolucizumab-dbll (Beovu®) ;

AND

- Product is prescribed by or in consultation with an ophthalmologist.

Ranibizumab (Lucentis®) may be authorized when the following criteria are met:

- Diagnosis of Neovascular (Wet) Age-Related Macular Degeneration (AMD); **AND**
  - Dosing is 0.5 mg once a month (approximately 28 days); **OR**
  - Dosing is 0.5 mg for 3 monthly doses followed by less frequent dosing with regular assessment **OR**
  - Dosing is 0.5 mg with one dose every 3 months after 4 monthly doses;

OR

- Diagnosis of Macular Edema Following Retinal Vein Occlusion (RVO); **AND**
  - Dosing is 0.5 mg once a month (approximately 28 days);

OR

- Diagnosis of Diabetic Macular Edema (DME); **AND**
  - Dosing is 0.3 mg once a month (approximately 28 days);

OR

- Diagnosis of Diabetic Retinopathy in individuals with DMEL; **AND**
  - Dosing is 0.3 mg once a month (approximately 28 days);

OR

- Diagnosis of Myopic Choroidal Neovascularization (mCNV); **AND**
  - Dosing is 0.5 mg once a month (approximately 28 days) for up to three months;

AND

- Individual has had a trial and inadequate response or intolerance to at least one preferred agent; **OR**
- Request is for continuation of therapy for individual established and responding well to Ranibizumab (Lucentis®);

AND

- Prescribed by or in consultation with an ophthalmologist.

Pegaptanib sodium (Macugen®)
- No clinical criteria currently listed for pegaptanib sodium (Macugen®)
  - No product currently available in US
  - HCPCS code is active.

Exclusion criteria for all listed PA-Required products:
- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

Step/Alternative Therapies:
Therapeutic alternatives include preferred Vascular Endothelial Growth Factor (VEGF) Antagonists approved for ophthalmic use.

Preferred Product(s) [No PA Required]	Non-Preferred Product(s) [PA Required]
bevacizumab (Avastin®) [C9257]	aflibercept (Eylea®)
ranibizumab-nuna (Byooviz™) [Q5125]	brolucizumab-dbll (Beovu®)
	pegaptanib sodium (Macugen®) (Product not currently available in US; HCPCS code remains active)
	ranibizumab (Lucentis®)

SmartHealth ineligible products include: Vabysmo™ (faricimab-svoa), non-formulary due to NOC code and pending future TAG review.

Initial authorization for approved indications is up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Aflibercept (Eylea®), a vascular endothelial growth factor (VEGF) inhibitor, is indicated for the treatment of individuals with:
- Neovascular (Wet) Age-Related Macular Degeneration (AMD)

- Macular Edema Following Retinal Vein Occlusion (RVO)
- Diabetic Macular Edema (DME)
- Diabetic Retinopathy (DR)

Brolucizumab-dbll (Beovu®), a human vascular endothelial growth factor (VEGF) inhibitor, is indicated for the treatment of:

- Neovascular (Wet) Age-Related Macular Degeneration (AMD)
- Diabetic Macular Edema (DME)

Ranibizumab (Lucentis®), a vascular endothelial growth factor (VEGF) inhibitor, is indicated for the treatment of individuals with:

- Neovascular (Wet) Age-Related Macular Degeneration (AMD)
- Macular Edema Following Retinal Vein Occlusion (RVO)
- Diabetic Macular Edema (DME)
- Diabetic Retinopathy in individuals with DME
- Myopic Choroidal Neovascularization (mCNV)

References:

American Academy of Ophthalmology. (2019, October). *Age-Related Macular Degeneration PPP 2019*. American Academy of Ophthalmology. Retrieved April 26, 2022, from https://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp

American Academy of Ophthalmology. (2019, October). *Diabetic Retinopathy PPP 2019*. American Academy of Ophthalmology. Retrieved April 26, 2022, from https://www.aao.org/preferred-practice-pattern/diabetic-retinopathy-ppp

BEOVU® (brolucizumab-dbll). (2022, May). Accessdata.fda.gov. Retrieved June 14, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761125s008lbl.pdf

EYLEA® (aflibercept). (2019, May). Accessdata.fda.gov. Retrieved June 14, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125387s061lbl.pdf

LUCENTIS® (ranibizumab injection). (2017, January). Accessdata.fda.gov. Retrieved April 25, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125156s111lbl.pdf

OPHTHALMIC AGENTS, SELECTIVE VASCULAR ENDOTHELIAL GROWTH FACTOR ANTAGONISTS (Comparative Efficacy). (2020, September 1). Lexicomp. Retrieved June 14, 2022, from https://online.lexi.com/lco/action/doc/retrieve/docid/fc_fms_locked/6989366?cesid=6kLb7rz8exN&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3Dvascular%2Bendothelial%2Bgrowth%2Bfactor%26t%3Dname%26acs%3Dtrue%26acq%3DVascular%2Ben#

Criteria History/ Revision Information:

Date	Summary of Changes
April 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team (Ranibizumab (Lucentis®) J2778)
May 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group Ranibizumab (Lucentis®) J2778
June 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team Expanded to include Aflibercept (Eylea®) J0178 Brolucizumab-dbll (Beovu®) J0719 Pegaptanib (Macugen®) J2503 (active HCPCS/inactive product)
July 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group Expanded to include Aflibercept (Eylea®) J0178 Brolucizumab-dbll (Beovu®) J0719 Pegaptanib (Macugen®) J2503 (active HCPCS/inactive product)

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.