



MEDICAL SURGICAL VISION CLINICAL PROTOCOL

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|--------------------------------|--|---------------------------|---------------|
| POLICY TITLE | Intravitreal anti-VEGF/Biologic Injections | | |
| CATEGORY | Medical Surgical | POLICY ID NUMBER | 300_NYS_HF_V7 |
| ORIGINAL EFFECTIVE DATE | 02/01/2026 | LAST REVIEW DATE | 10/21/2025 |
| LAST APPROVAL DATE | 10/21/2025 | LAST REVISION DATE | 10/21/2025 |
| EXCLUSIONS | Applicable to New York State, Healthfirst Plans (All LOB's) | | |

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Applicable Codes:

J0177 EYLEA HD (Aflibercept HD) injection – intravitreal injection

Aflibercept HD is a vascular endothelial growth factor (VEGF) inhibitor used for intravitreal injection

J0178 EYLEA (aflibercept) injection- intravitreal injection

Aflibercept is a vascular endothelial growth factor (VEGF) inhibitor for intravitreal injection.

J0179 BEOVU (brolucizumab-dblI)) injection-intravitreal injection

Brolucizumab-dblI is a human vascular endothelial growth factor (VEGF) inhibitor used for intravitreal injection.

J2777 VABYSMO (faricimab-svoa) injection-intravitreal injection

Faricimab-SVOA is a is a vascular endothelial growth factor (VEGF) inhibitor and angiopoietin-2 (Ang-2) inhibitor used for intravitreal injection.

J2778 LUCENTIS (ranibizumab) injection-intravitreal injection

Ranibizumab, a recombinant humanized immunoglobulin G, kappa monoclonal antibody fragment, is a vascular endothelial growth factor A (VEGF-A) antagonist used as an intravitreal injection.

J2779 SUSVIMO (ranibizumab injection) injection-intravitreal implant

Ranibizumab, a vascular endothelial growth factor (VEGF) inhibitor, is used as an injection via ocular implant.

Q5124 BYOOVIZ (ranibizumab-nuna, Biosimilar) injection-intravitreal injection

Ranibizumab-nuna is a biosimilar to the biologic known as Lucentis.

Q5128 CIMERLI (ranibizumab-EQRN, Biosimilar) injection-intravitreal injection

Ranibizumab-eqrn is a vascular endothelial growth factor (VEGF) inhibitor interchangeable to Lucentis (ranibizumab).

Q5147 PAVBLU (aflibercept-ayyh, Biosimilar) injection, intravitreal injection, 1 mg

Aflibercept-ayyh is a vascular endothelial growth factor (VEGF) inhibitor and a biosimilar to the biologic Eylea.

1 Indication and Limitations¹

1.1 Medical Necessity

- 1.1.1** Ocular Coherence Tomography (OCT) and/or fluorescein angiography (FA) test results must be interpreted and firmly establish/support diagnosis
- 1.1.2** Appropriate diagnosis and clinical findings must be well-documented to support medical necessity
 - 1.1.2.1** Secondary Choroidal Neovascularization or unlisted diagnosis may be submitted for prior authorization and is subject to all necessary criteria, including Step Therapy requirements under section 1.2.2.
 - 1.1.2.1.1** Claims will be reviewed on a case-by-case basis after the above criteria are satisfied.
- 1.1.3** Dilated examination must be performed in less than six months from prior authorization date.
 - 1.1.3.1** Records submitted for prior authorization must include the most recent dilated examination and satisfy criteria 1.1.3.

1.2 Additional Requirements (applicable for all codes)

- 1.2.1** Procedure note must include (for post-service review):
 - 1.2.1.1** Actual administered drug, dosage, injection site, & route of administration
 - 1.2.1.2** Injection lot # & expiration date
 - 1.2.1.3** Post-injection vision check \geq CF
 - 1.2.1.4** Specific notation patient has been queried/screened for contraindicating/ co-morbidities.
- 1.2.2** Avastin trial failure must clearly be indicated in chart
 - 1.2.2.1** Minimum 3-month treatment trial
 - 1.2.2.2** Fewer than 3 lines of improvement on visual acuity testing
 - 1.2.2.3** Inadequate clinical response must be indicated in chart which may include
 - 1.2.2.3.1** Fewer than 3 lines of improvement on visual acuity testing
 - 1.2.2.3.2** Failure to resolve, improve, or control fluid, edema, etc.
 - 1.2.2.4** Medical necessity for changing therapy from step-therapy drug must be noted in chart.
- 1.2.3** Informed consent stating all pertinent risks must include:
 - 1.2.3.1** Date, consent to perform/waive, patient or representative signature, surgeon/physician signature, and witness signature
- 1.2.4** Authorization Time frame
 - 1.2.4.1** given for the time period of 12 months
 - 1.2.4.2** covers up to the listed maximum of injections during the time period.
 - 1.2.4.3** Additional requested injections are subject to review
 - 1.2.4.3.1** determinations are made on a case-by-case basis and subject to medical necessity.
- 1.2.5** Services should be performed as indicated by current medical literature and/ or standards of practice.
- 1.2.6** When services are performed in excess of established parameters, they may be subject to review for medical necessity.

1.2.7 Step therapy for Part B drugs (§ 422.136)

- 1.2.7.1** Apply step therapy only to new administration of Part B drugs using at least a 365-day lookback period

2 Eylea HD

2.1 Treatment indications with approved dosage schedule:

2.1.1 Neovascular (Wet) age-related macular degeneration (nAMD)

2.1.1.1 Recommended dose

- 2.1.1.1.1** 8 mg (0.07 mL of 114.3 mg/mL solution)
- 2.1.1.1.2** administered by intravitreal injection every 4 weeks (approximately every 28 days +/- 7 days) for the first three doses,
- 2.1.1.1.3** followed by 8 mg (0.07 mL of 114.3 mg/mL solution) via intravitreal injection once every 8 to 16 weeks, +/- 1 week.

2.1.2 Diabetic macular edema (DME)

2.1.2.1 Recommended dose

- 2.1.2.1.1** 8 mg (0.07 mL of 114.3 mg/mL solution)
- 2.1.2.1.2** administered by intravitreal injection every 4 weeks (approximately every 28 days +/- 7 days) for the first three doses,
- 2.1.2.1.3** followed by 8 mg (0.07 mL of 114.3 mg/mL solution) via intravitreal injection once every 8 to 16 weeks, +/- 1 week

2.1.3 Diabetic retinopathy (DR)

2.1.3.1 Recommended dose

- 2.1.3.1.1** 8 mg (0.07 mL of 114.3 mg/mL solution)
- 2.1.3.1.2** administered by intravitreal injection every 4 weeks (approximately every 28 days +/- 7 days) for the first three doses
- 2.1.3.1.3** followed by 8 mg (0.07 mL of 114.3 mg/mL solution) via intravitreal injection once every 8 to 12 weeks, +/- 1 week.

3 Eylea & Pavblu (excluding Pavblu for ROP)

3.1 Treatment indications with approved dosage schedule:

3.1.1 Neovascular (Wet) age-related macular degeneration (AMD)

3.1.1.1 Recommended dose

3.1.1.1.1 (2) milligrams

3.1.1.1.2 administered by intravitreal injection once every 4 weeks (monthly) for the first 12 weeks (3 months),

3.1.1.1.3 THEN 2 milligrams administered by intravitreal injection once every 8 weeks [2 months]

3.1.1.1.4 Although EYLEA (aflibercept) may be dosed as frequently as 2 milligrams every 4 weeks (monthly), additional efficacy was not demonstrated when EYLEA (aflibercept) was dosed every 4 weeks as compared to every 8 weeks.

3.1.1.1.5 Some patients may require monthly injections after the initial 3-month period
Utilization Guidelines

3.1.1.1.6 Max injections per calendar year = 16

3.1.2 Diabetic macular edema (DME) & Diabetic Retinopathy (DR)

3.1.2.1 Recommended dose

3.1.2.1.1 (2) milligrams

3.1.2.1.2 administered by intravitreal injection once every 4 weeks (monthly)(approximately 28 days) for the first 5 injections

3.1.2.1.3 THEN 2 milligrams administered by intravitreal injection once every 8 weeks [2 months]

3.1.2.1.4 Some patients may require monthly injections after the initial 5-month period

3.1.3 Macular Edema Following Retinal Vein Occlusion (RVO)

3.1.3.1 Recommended dose

3.1.3.1.1 (2) milligrams

3.1.3.1.2 administered by intravitreal injection once every 4 weeks (monthly) (approximately 25 days)

3.1.4 Retinopathy of Prematurity (ROP) **NOT PAVBLU, EYLEA ONLY**

3.1.4.1 Recommended dose

3.1.4.1.1 0.4 milligrams (0.01 mL or 10 microliters of 40 mg/mL solution)

3.1.4.1.2 administered by intravitreal injection once every 4 weeks (monthly)(administered by intravitreal injection

3.1.4.1.3 may be given bilaterally on the same day

3.1.4.1.4 Injections may be repeated in each eye

3.1.4.1.5 Treatment interval between doses injected into the same eye should be at least 10 days

4 Beovu

4.1 Treatment indications with approved dosage schedule:

4.1.1 Neovascular (Wet) Age-Related Macular Degeneration (AMD)

4.1.1.1 Recommended dose

4.1.1.1.1 6 milligrams (0.05 mL of 120 mg/mL solution)

4.1.1.1.2 Administered by intravitreal injection monthly (approximately every 25-31 days) for the first three doses,

4.1.1.1.3 followed by one dose of 6 milligrams (0.05 mL) every 8-12 weeks

4.1.1.2 Utilization Guidelines

4.1.1.2.1 Max injections per calendar year = 16

4.1.2 Diabetic Macular Edema (DME)

4.1.2.1 Recommended dose

4.1.2.1.1 (6) milligrams (0.05 mL of 120 mg/mL solution)

4.1.2.1.2 Administered by intravitreal injection every six weeks (approximately every 39-45 days) for the first five doses,

4.1.2.1.3 followed by one dose of 6 milligrams (0.05 mL of 120 mg/mL solution) every 8-12 weeks

4.1.2.2 Utilization Guidelines

4.1.2.2.1 Max injections per calendar year = 16

5 Vabysmo

5.1 Treatment indications with approved dosage schedule:

5.1.1 Neovascular (Wet) Age-Related Macular Degeneration (nAMD)

5.1.1.1 Recommended dosage

5.1.1.1.1 6 mg (0.05 mL of 120 mg/mL solution)

5.1.1.1.2 administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for the first 4 doses, then

5.1.1.1.3 followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to inform whether to give a 6 mg dose via intravitreal injection on one of the following three regimens: 1) Weeks 28 and 44; 2) Weeks 24, 36 and 48; or 3) Weeks 20, 28, 36 and 44.

5.1.1.1.4 Although additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks,

5.1.1.1.5 some patients may need every 4-week (monthly) dosing after the first 4 doses. Patients should be assessed regularly.

5.1.2 Diabetic Macular Edema (DME)

5.1.2.1 Recommended dosage

5.1.2.1.1 6 mg (0.05 mL of 120 mg/mL solution)

- 5.1.2.1.2** administered by intravitreal injection every 4 weeks (approximately every 28 days \pm 7 days, monthly) for at least 4 doses.
- 5.1.2.1.3** If after at least 4 doses, resolution of edema based on the central subfield thickness (CST) of the macula as measured by optical coherence tomography is achieved, then the interval of dosing may be modified by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments based on CST and visual acuity evaluations; OR
- 5.1.2.1.4** injection can occur every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injection at intervals of every 8 weeks (2 months).
- 5.1.2.1.5** Although additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses. Patients should be assessed regularly.

5.1.3 Macular Edema Following Retinal Vein Occlusion (RVO) o

5.1.3.1 Recommended dosage

- 5.1.3.1.1** 6 mg (0.05 mL of 120 mg/mL)
- 5.1.3.1.2** administered by intravitreal injection every 4 weeks (approximately every 28 \pm 7 days, monthly) for 6 months.

5.1.3.2 Utilization Guidelines

- 5.1.3.2.1** Maximum injections per calendar year = 16
- 5.1.3.2.2** Dosing more frequent than maximum is approved at plan discretion

6 Lucentis & Cimerli

6.1 Treatment indication with approved dosage schedule:

6.1.1 Neovascular (Wet) Age-Related Macular Degeneration (AMD)

6.1.1.1 Recommended dosage

- 6.1.1.1.1** 0.5 milligrams (0.05 mL of 10 mg/mL solution)
- 6.1.1.1.2** Administered by intravitreal injection once a month (approximately 28 days)
- 6.1.1.1.3** Although not as effective, patients may be treated with 3 monthly doses followed by less frequent dosing with regular assessment.
- 6.1.1.1.4** Although not as effective, patients may also be treated with one dose every 3 months after 4 monthly doses.
- 6.1.1.1.5** Patients should be assessed regularly.

6.1.1.2 Utilization Guidelines

- 6.1.1.2.1** Maximum injections per calendar year = 26

6.1.2 Macular Edema Following Retinal Vein Occlusion (RVO)

6.1.2.1 Recommended dosage

- 6.1.2.1.1** 0.5 milligrams (0.05 mL of 10 mg/mL solution)
- 6.1.2.1.2** administered by intravitreal injection once a month (approximately 28 days)

6.1.2.2 Utilization Guidelines

6.1.2.2.1 Maximum injections per calendar year = 26

6.1.3 Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR)

6.1.3.1 Recommended dosage

6.1.3.1.1 0.3 milligrams (0.05 mL of 6 mg/mL solution)

6.1.3.1.2 administered by intravitreal injection once a month (approximately 28 days)

6.1.3.2 Utilization Guidelines

6.1.3.2.1 Maximum injections per calendar year = 26

6.1.4 Myopic Choroidal Neovascularization (mCNV)

6.1.4.1 Recommended dosage

6.1.4.1.1 0.5 mg (0.05 mL of 10 mg/mL solution) administered by intravitreal injection once a month (approximately 28 days) for up to three months.

6.1.4.1.2 Patients may be retreated if needed

6.1.4.2 Utilization Guidelines

6.1.4.2.1 Max injections per calendar year = 8

7 Susvimo (J2779)

7.1 Treatment indication with approved dosage schedule for Neovascular (wet) macular degeneration

7.1.1 Recommended dosage

7.1.1.1 2 mg (0.02 mL of 100 mg/mL solution) continuously delivered via the SUSVIMO implant with refills every 24 weeks (approximately 6 months).

7.1.1.2 Supplemental treatment with 0.5 mg intravitreal ranibizumab injection may be administered in the affected eye if clinically necessary.

7.1.1.3 Perform the initial implantation, refill-exchange, and implant removal (if necessary) procedures under strict aseptic conditions

7.2 Limitation

Patient must have responded to at least 2 prior injections of ranibizumab

8 Byooviz (Q5124)

8.1 Treatment indication with approved dosage schedule (supporting ICD-10, Biosimilar, Lucentis):

8.1.1 The recommended dose in adults is 0.5 mg given as a single intravitreal injection. This corresponds to an injection volume of 0.05 mL.

8.1.2 The interval between two doses should not be shorter than 1 month.

8.1.3 Treatment of wet AMD

8.1.3.1 Recommended dosage

8.1.3.1.1 0.5 milligrams (0.05 mL)

8.1.3.1.2 administered by intravitreal injection once a month.

8.1.3.1.3 may be reduced to one injection every 3 months after the first three injections if monthly dosing is not feasible.

- 8.1.3.1.4 Compared to monthly dosing, dosing every 3 months will lead to an approximate 5-letter (1 line) loss of visual acuity benefit, on average, over the following 9 months.
- 8.1.3.1.5 treatment is initiated with a loading phase of one injection per month for three consecutive months, followed by a maintenance phase
- 8.1.3.1.6 monitor for visual acuity on a regular basis.
- 8.1.4 Treatment of visual impairment due to macular edema secondary to retinal vein occlusion (RVO)
 - 8.1.4.1 Recommended dosage
 - 8.1.4.1.1 0.5 milligrams (0.05 mL)
 - 8.1.4.1.2 Administered by intravitreal injection given monthly and continued until maximum visual acuity is achieved
 - 8.1.4.1.3 confirmed by stable visual acuity for three consecutive monthly assessments while on Byooviz treatment.
 - 8.1.4.1.4 Thereafter patients should be monitored monthly for visual acuity.
- 8.1.5 Treatment of visual impairment due to myopic choroidal neovascularization (mCNV) secondary
 - 8.1.5.1 Recommended dosage
 - 8.1.5.1.1 0.5 mg is recommended for a single injection.
 - 8.1.5.1.2 If monitoring reveals signs of disease activity, e.g. reduced visual acuity and/or signs of lesion activity, further treatment is recommended.
 - 8.1.5.1.3 Monitoring for disease activity may include clinical examination, optical coherence tomography (OCT) or fluorescein angiography (FA).
 - 8.1.5.1.4 While many patients may only need one or two injections during the first year, some patients may need more frequent treatment.
 - 8.1.5.1.5 Monitoring is recommended monthly for the first two months and at least every three months thereafter during the first year.
 - 8.1.5.1.6 After the first year, the frequency of monitoring should be determined by the treating physician.

9 Supporting Diagnoses

9.1 For ICD-10 list please see Intravitreal Biologic Injections Appendix A

References

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- CGS Administrators, LLC. Local Coverage Article. “(A52451) Billing and Coding: Ranibizumab and biosimilars, Aflibercept, Aflibercept HD, Brolucizumab-dbl and Faricimab-svoa”. Revision date 04/01/2025.
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Review and Approval Change Log

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|-----------|--|
| July 2022 | Medical Surgical policy drafted |
| June 2023 | Scope limited to NYS medical surgical prior authorization requirement. |
| Jan 2024 | Reviewed, added aflibercept HD, updated per A52451, R17 on 01/01/24. |
| May 2024 | Reviewed, ICD-10 added to Group 4 (highlighted for approval) per R18 (A52451) On 01/11/2024 CPG updated with note C9161 has deleted and replaced with J0177 per R19 (A52451). Code C9161 remains on the CPG for reference but will be deleted on future copy. |
| Oct 2024 | Reviewed and updated per A52451, R20 updated 09/21//24, added J2779 & 67027, ICD 10 updated per LCD Article listings |
| Mar 2025 | Added Step therapy guidelines |
| Apr 2025 | Health First committee approved Step therapy guideline addition, v3 approved. |
| June 2025 | Added, Syfovre, Izervay, Mvasi, Zirabev, Byooviz, Alymsys, Cimerli, Pavblu, Enzeeva, Ahzantive. Amended step therapy guidelines. |
| July 2025 | Amended step therapy |
| Aug 2025 | Removed any drugs not on prior authorization, amended step therapy, and edited clinical information. |
| Sep 2025 | Amended step therapy to Avastin failure requirement, removed additional failure requirements (DraftV6), added 1.1.3 & 1.1.3.1 |
| Oct 2025 | Removed the administration codes |
| Oct 2025 | Client Approved |