CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY					
BENEFIT	**EYE CARE**	**POLICY SECTION**	**600 INJECTIONS, INSERTS & IMPLANTS**	**POLICY NO**	**600.05**
POLICY TITLE	**EYLEA® (aflibercept) INTRAVITREAL INJECTION**				
POLICY DATE	**01/01/2020**	**REVISION DATE**	**08/08/2022**	**APPROVAL DATE**	**08/10/2022**
DISCLAIMER LANGUAGE	- **Policy content and application may have state specific variance and considerations** - **Health Plan specific 'Indications and Limitations of Coverage' may apply as specified** - **Line of Business considerations (i.e., Medicaid, Medicare, Commercial) may apply as specified**				
EXCLUSIONS	- **This policy is not applicable to Medicaid in the state(s) of North Carolina, as EYLEA® does not require a prior authorization, however, must be billed appropriately with applicable diagnosis code located in Section V.**				

I. POLICY STATEMENT

Avēsis will provide coverage of EYLEA® (aflibercept) intravitreal injection when medically indicated and in accordance with applicable state requirements and, as specific to Medicare, national and local coverage determinations. To establish medical necessity for this service, Avēsis aligns its criteria with the evidence and consensus based clinical practice guidelines set forth by the American Academy of Ophthalmology (AAO). The AAO incorporates evidence based best practice and FDA approval and/or recommendations[1]. Avēsis Medical Directors and clinical staff are licensed medical professionals and review criteria and documentation submitted by requesting providers using sound medical judgment.

II. INDICATIONS AND LIMITATION OF COVERAGE

1.0 Coverage is limited to membership eligible at the time of the date of service and in accordance with continuity requirements, as applicable.

2.0 Coverage is indicated for treatment when enrollees have the following condition*:
**Note, refer to Section V for additional required detail*

- 2.1 Neovascular (Wet) age-related macular degeneration (AMD)
- 2.2 Diabetic macular edema (DME) and Diabetic Retinopathy (DR)
- 2.3 Macular edema associated with retinal vein occlusion.

4.0 Coverage will be considered only for enrollees who have completed a minimum of three (3) months of Avastin® (bevacizumab) with unsatisfactory outcome, defined as:

- 4.1 Minimum 3-month treatment trial
- 4.2 Fewer than 4 lines of improvement on visual acuity testing

5.0 EYLEA® (aflibercept) will not be covered at a frequency that exceeds what is medically reasonable and necessary.

6.0 Authorizations will be given for the time period of 12 months and will cover up to 16 injections during that time period.

- 6.1 Additional injections requested will be subject to review and determinations will be made on a case-by-case basis and subject to medical necessity.
- 6.2 When services are performed in excess of established parameters, they may be subject to peer and quality review.

III. TREATMENT RECOMMENDATIONS

1.0 The recommended dose for EYLEA® (aflibercept) is:

[1]American Academy of Ophthalmology https://www.aao.org

1.1 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months).

1.2 Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, monthly), additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks.

1.2.1 Some patients may need every 4 weeks (monthly) dosing after the first 20 weeks (5 months).

2.0 A medical screening and clearance should be considered for enrollees with medical comorbidities.

2.1 Medical clearance should also be obtained when the enrollee is scheduled for any major surgery and should include when to stop the use of EYLEA® (aflibercept) preoperatively, and when it may reasonably be restarted after surgery.

IV. MEDICAL NECESSITY REQUIREMENTS for <u>APPLICABLE HCPCS CODE J0178</u>

1.0 To establish medical necessity all criterion points referenced below must be clearly & legibly documented in the medical record and made available to Avēsis upon submission of request.

1.1 Areas where 'white out' is used are not accepted.

1.2 Areas with 'black out' or 'scribble' will not be accepted.

1.2.1 A single line through text where the text will remain readable is acceptable with provider initials and date.

2.0 Physician signature must be present on chart and procedural notes, orders, and testing interpretations.

3.0 The submitted documentation must clearly support medical necessity as outlined in Section II Indications and Limitations of Coverage.

3.1 Includes medical necessity rationale to change therapy from Avastin to EYLEA® (aflibercept)

4.0 Medical documentation must clearly state the clinical indication/medical necessity for the EYLEA® (aflibercept) injection and the frequency of its usage.

5.0 Ocular Coherence Tomography (OCT) and/or fluorescein angiography (FA) test results must be interpreted and firmly establish/support diagnosis.

6.0 Procedure note must include:

6.1 Actual administered dosage of EYLEA® (aflibercept) given

6.2 Site of injection

6.3 Route of administration

6.4 Injection Lot #

6.5 Injection expiration date

6.6 Post-injection vision ≥ CF

7.0 Medical documentation must clearly display that enrollee has been queried/screened for contraindications and/or co-morbidities:

7.1 Evidence that enrollee has been screened for medical conditions which would contraindicate the use of EYLEA® (aflibercept), including but is not limited to:

7.1.1 Gastrointestinal hemorrhage or perforations

7.1.2 Other hemorrhage occurrences

7.1.3 Wound healing complications

7.1.4 Arterial thrombo-embolic events

7.1.5 Hypertension

7.1.6 Proteinuria

7.1.7 Heart failure

8.0 Medical documentation must evidence number 7.0 above along with full informed consent, outlining all pertinent risks, inclusive of the following:

8.1 Date

8.2 Consent to perform

8.3 Consent to waive
8.4 Patient or Representative Signature
8.5 Surgeon/Physician Signature
8.6 Witness Signature

V. ICD-10 CODES SUPPORTING MEDICAL NECESSITY

1.0 For any code not listed below, please supply proper documentation with your prior authorization request, and Avēsis will review and make a determination based on medical necessity.

ICD-10 Code	Description
B39.4 – B39.9	Histoplasmosis capsulati, unspecified – Histoplasmosis, unspecified
E08.311 – E08.319	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with(out) macular edema
E08.3211 – E08.3299	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with(out) macular edema
E08.3311 – E08.3399	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with(out) macular edema
E08.3411 – E08.3499	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with(out) macular edema
E08.3511 – E08.3519	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema
E08.3591 – E08.3599	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema
E09.311 – E09.319	Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with(out) macular edema
E09.3211 – E09.3299	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with(out) macular edema
E09.3311 – E09.3399	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with(out) macular edema
E09.3411 – E09.3499	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with(out) macular edema
E09.3511 – E09.3519	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy withmacular edema
E09.3591 – E09.3599	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema
E10.311 – E10.319	Background diabetic retinopathy, Type 1, with(out) macular edema
E10.3211 – E10.3299	Mild nonproliferative diabetic retinopathy, Type 1 with(out) macular edema
E10.3311 – E10.3399	Moderate nonproliferative diabetic retinopathy, Type 1, with(out) macular edema
E10.3411 – E10.3499	Proliferative diabetic retinopathy, Type 1, with(out) macular edema
E10.3511 – E10.3519	Type 1 diabetes mellitus with proliferative diabetic retinopathy withmacular edema
E10.3591 – E10.3599	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema
E10.37X1 – E10.37X9	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment
E11.311 – E11.319	Type 2 diabetes mellitus with unspecified diabetic retinopathy with(out) macular edema
E11.3211 – E11.3299	Mild nonproliferative diabetic retinopathy, Type 2 with(out) macular edema

ICD-10 Code	Description
E11.3311 – E11.3399	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with(out) macular edema
E11.3411 – E11.3499	Severe nonproliferative diabetic retinopathy, Type 2, with(out) macular edema
E11.3511 – E11.3519	Proliferative diabetic retinopathy, Type 2, with macular edema
E11.3551 – E11.3559	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy
E11.3591 – E11.3599	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema
E11.37X1 – E11.37X9	Type 11 diabetes mellitus with diabetic macular edema, resolved following treatment
E13.311 – E13.319	Other specified diabetes mellitus with unspecified diabetic retinopathy with(out) macular edema
E13.3211 – E13.3299	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with(out) macular edema
E13.3311 – E13.3399	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with(out) macular edema
E13.3411 – E13.3499	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with(out) macular edema
E13.3511 – E13.3519	Other specified diabetes mellitus with proliferative diabetic retinopathy with1 macular edema
E13.3591 – E13.3599	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema
H34.8110 – H34.8192	Central retinal vein occlusion
H34.8310 – H34.8392	Tributary (branch) retinal vein occlusion
H35.3210 – H35.3293	Exudative age-related macular degeneration
H35.81	Retinal edema