Vision Clinical Criteria, Guidelines and Practice Standards

Vision Government

2025

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Introduction

Avēsis Clinical Criteria Guidelines and Practice Standards undergoes a regular revisions and an annual review by the Utilization Management Committee (UMC) and the Quality Management Committee (QMC). Our Clinical Directors developed this criteria document, with input from a participating panel of internal and external general practitioners and specialists. The standards of care and practice guidelines for dental services covered by Avēsis shall be guided by nationally recognized criteria published by experts which are grounded in sound dental clinical principles, processes, and evidence. These guidelines ensure consistent evaluation of the appropriateness of dental services that require review. Where applicable, clinical criteria will follow State, Plan, and/or Program guidelines, which will take precedence over Avēsis national guidelines contained in this document.

The clinical protocols are made publicly available to network providers to support them in making informed decisions regarding the provision of an enrollee's covered benefits.

The materials provided to you are guidelines used by the plan to authorize, modify or deny care for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual needs and the benefits covered under your contract.

Coverage and Criteria Formulation

Criteria are developed based on Medicare and State Medicaid guidelines, professional education materials, industry standards, and health plan-specific requirements. Medical necessity criteria applicable to children ages birth through twenty (20) years of age reflect EPSDT federal standards. As part of our criteria and review process, we take into account special clinical circumstances on a case-by-case basis. Clinical criteria and decision-making processes are tailored to consider individual needs, which may include factors such as: age, coexisting health conditions, treatment progress, psychosocial situations, and home or living environment, as appropriate.

- Criteria are influenced at a minimum by specialty organizations such as:
    - American Academy of Ophthalmology
    - American Optometric Association
    - Food and Drug Administration (FDA)
    - Centers for Disease Control (CDC)
    - Association National Institute of Health (NIH)

Regarding patient information upon submission, details should minimally include the following and must be clearly & legibly documented in the medical record and made available to Avēsis upon request:

- Name, sex, birth date, address, telephone number, cell phone number, email address, name of employer, work address, and telephone number.
- A detailed medical history form, including information such as the patient's current health status, physician's name and contact details, history of hospitalizations or surgeries, blood pressure history, current medications, and allergies.
    - Areas where 'white out' is used are not accepted.
    - Areas with 'black out' or 'scribble' will not be accepted.
    - A single line through text where the text will remain readable is acceptable with provider initials and date.
    - Physician signature must be present on chart and procedural notes, orders, and testing interpretations.
- Procedure note for all injections must include:
    - Actual administered dosage of injection given
    - Site of injection
    - Route of administration
    - Injection Lot #
    - Injection expiration date
    - Post-injection vision ≥ CF

- Medical documentation must clearly display that enrollee has been queried/screened for contraindications and/or co-morbidities:
- Evidence that enrollee has been screened for medical conditions which would contraindicate the use of injections.
- Medical documentation must evidence a full informed consent, outlining all pertinent risks, inclusive of the following:
    - Date
    - Consent to perform
    - Consent to waive
    - Patient or Representative Signature
    - Surgeon/Physician Signature
    - Witness Signature

Clinical records must be comprehensive, well-organized, and legible. All entries should be made in ink, signed, and dated by the treating dentist or other licensed healthcare professional who performed the services. Contracted Clinicians are required to provide copies of all member records upon request within the specified timeframe.

Progress notes serve as a legal record and must be detailed, legible, and indelible. Each entry must be signed, initialed, and dated by the person providing treatment or include unique identifiers for documentation support. Corrections or modifications to entries require the name of the person or unique identifier responsible for the changes, along with the date of the modification. Progress notes should include documentation of treatments used (or not used), specifying type, strength, and vasoconstrictor. Additionally, all prescriptions must be documented, including medication details, dosage, directions, and refills. Copies of lab prescriptions and communications should be kept in the patient's chart.

Clinical Criteria

PROVIDER ADMINISTRATIVE POLICY

PROVIDER ADMINISTRATIVE POLICY					
BENEFIT	**EYE CARE**	**POLICY SECTION**	**100 ADMINISTRATIVE**	**POLICY NO**	**100.01**
POLICY TITLE	**OFFICE VISITS – Routine, Medical and Evaluation & Management Coding**				
POLICY DATE	**01/01/2022**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**
DISCLAIMER LANGUAGE	- **Policies may be state specific or National version, see 'Applicable State'** - **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	- **DE, GA, NC, and TX:** **Table 1 in Section III.B: does not apply as S-codes are utilized for routine exams**				

I. POLICY STATEMENT

Avēsis will provide reimbursement of routine medical and specialty evaluation and management initial and subsequent office visits/examinations when core components and/or intensity of services applicable to selected code is supported by provider documentation in accordance with specified requirements. Requirements set forth are determined by the American Medical Association (AMA), specific state coverage requirements and/or national or local coverage determinations (NCD/LCD). Avēsis Medical Directors are licensed medical professionals and review criteria and documentation submitted by requesting providers against Avēsis criteria using sound medical judgment.

II. INDICATIONS AND LIMITATION OF COVERAGE

1.0 Medical documentation for routine eye or evaluation and management 'E&M' CPT code selected by the provider for submitted claims must be sufficiently detailed per requirements outlined below to support reimbursement.

1.1 Insufficient documentation or missing components in documentation submitted will result in denial of claim.

1.2 Requirements are inclusive of AMA, state requirements, and NCD/LCD, as applicable.

2.0 It is the responsibility of the provider to ensure enrollee is eligible for coverage for all dates of service.

2.1 Services provided for enrollee deemed ineligible for coverage will result in denial.

3.0 It is the responsibility of the provider to know and understand applicable compliance and rules specific to coding and requirements for appropriate medical documentation.

III. DOCUMENTATION REQUIREMENTS - GENERAL OPHTHAMOLOGICAL SERVICES and E&M EXAMINATION

A. <u>Overarching Requirements</u>

1.0 All required criterion components must be clearly and legibly documented in the patient's medical record and made available to Avēsis upon request.

2.0 Physician signature must be present on chart note, procedure note, orders, and testing interpretation.

3.0 Exam must be performed in accordance with professional standard practices of optometry and ophthalmology.

4.0 Tables 1 and 2 outline specific requirements dependent on coding selected and submitted by provider.

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

B. Routine Comprehensive Ophthalmological Examinations

Table 1

APPLICABLE CPT Code	Patient Status	Exam Intensity
92002	New	Intermediate
92012	Established	Intermediate
92004	New	Comprehensive
92014	Established	Comprehensive

Both Intermediate and Comprehensive Examinations must include all of the following requirements:

- *Medical/Eye History*

1.0 Chief Complaint 'CC'
  1.1 Any significant visual changes or complaints
2.0 History of Present Illness 'HPI'
  2.1 Location of chief complaint with duration
3.0 Current Medications
4.0 Family/Social History

- *Examination Components:*

5.0 Presenting visual acuity
  5.1 With or without correction
  5.2 Distance and near
6.0 Extra-Ocular Muscle (EOM) assessment
  6.1 Cover test
    6.1.1 Recorded at 16 inches
    6.1.2 Recorded at 20 feet
  6.2 Near point of convergence
  6.3 Versions
7.0 Gross Visual Field assessment
  7.1 List/Draw screening results
  7.2 Method (confrontation is sufficient unless defect is detected)
8.0 Refraction (Manifest)
  8.1 Objective refraction with visual acuity
  8.2 Subjective refraction must include best corrected visual acuity at distance and near
9.0 Adnexa/External
  9.1 Lids, lashes
  9.2 PALN (pre-auricular lymph nodes-if indicated)
10.0 Slit lamp exam of Anterior Segment must include:
  10.1 Cornea
  10.2 Conjunctiva
11.0 Slit lamp exam of Anterior Chamber
  11.1 Depth
  11.2 Clarity, presence of cell/flare
  11.3 Brief angle assessment prior to dilation

12.0 Slit lamp exam of Lens
- 12.1 Cataract findings must be graded
- 12.2 Media clarity

13.0 Tonometry (unless contraindicated or in child)
- 13.1 Method and Time notation
- 13.2 IOP

14.0 Pupillary Assessment (prior to dilation)
- 14.1 Size
- 14.2 Reaction
- 14.3 APD (presence or absence)

15.0 Posterior Segment Ophthalmoscopy (direct/indirect) of optic nerve must note:
- 15.1 Time of dilation unless contraindicated
- 15.2 C/D ratio
- 15.3 Appearance of nerve
- 15.4 Nerve Fiber Layer appearance
- 15.5 Posterior Segment Ophthalmoscopy of retina must notate:
  - 15.5.1 Vessels
  - 15.5.2 Macula
  - 15.5.3 Periphery
  - 15.5.4 Vitreous

16.0 Plan
- 16.1 Primary diagnosis must address the presenting chief complaint
- 16.2 Must address other exam findings
- 16.3 Must include treatment plan for ALL diagnoses, even if it is a "monitor" or "follow-up"
- 16.4 Clearly noted final spectacle Rx given (unless medically unable or inadvisable)

17.0 Patient Aftercare
- 17.1 Counseling and/or coordination of care with other providers or agencies is provided, consistent with the nature of the problem(s) and the needs of enrollee and/or family.
- 17.2 Summary of Care
- 17.3 Copy of exam findings readily available to patient following exam
- 17.4 Summary dictation should be sent to the referring doctor and the patient PCP at the completion of the exam to ensure patient continuity of care.
- 17.5 (*COMPREHENSIVE EXAM ONL*Y) Copy of spectacle Rx must be given to enrollee at check-out (even if no change) unless medically unadvisable or unable pending a follow up
  - 17.5.1 e.g., upcoming surgical consult or follow up scheduled to fine-tune final spectacle prescription.
  - 17.5.2 Spectacle Rx cannot be withheld due to pending payment or copayment.

C. <u>Specialty Consult Examination – E&M Coding* 99202 – 99205, 99211 – 99215</u>

**Note: E&M codes allow a physician to bill for face-to-face time with patient (enrollee)/family, rather than specific exam components. Although unusual in most eye clinic settings, the following criteria must be satisfied & clearly documented to bill for physician time, rather than exam components. E&M coding may be considered eligible for post service review status on a case-by-case basis, as denoted in Table 2 below. The information below preceding Table 2 provides description of required elements as outlined in Table 2.*

1.0 Medical decision making refers to the complexity of establishing a diagnosis; determining the level of decision making consists of 3 components[3]:
- 1.1 The number of diagnosis and management options
- 1.2 Amount and/or complexity of data to be reviewed
- 1.3 Risks of significant complications, morbidity, and/or mortality

[3]AMA 2021 CPT®

2.0 Patient (Enrollee) Aftercare as defined/outlined in B 17.0

3.0 'Time Spent' refers to direct face to face time (staff/testing time do not apply) and at minimum 50% of exam time must be spent on physician-patient counseling.

3.1 Time Spent must have specified "in and out" times for calculation

3.2 Extensive counseling details may be required to be present in documentation as indicated

Table 2 (continued on page 5)

E&M Code	Patient Status	Level of Decision Making	Time Spent (Minutes)	Code Specific Required Documentation Components
99204**	New	Moderate	45-59	– History and exam elements must be documented as medically appropriate, inclusive of medical diagnosis – Extensive management options for diagnosis or treatment – Extensive counseling details – Extensive amount of data to be reviewed including: ▪ Old records, physician notes ▪ Previous or current lab results ▪ Diagnostic and imaging studies – Moderate risk of complication or morbidity or mortality of patient management ▪ Co-morbidities associated with presenting problems ▪ Risk of diagnostic procedure performed ▪ Risk associated with management options – Patient Aftercare
99205**	New	High	60-74	– History and exam elements must be documented as medically appropriate, inclusive of medical diagnosis – Extensive management options for diagnosis or treatment – Extensive counseling details – Number and complexity of problems addressed: ▪ Old records, physician notes ▪ Previous or current lab results ▪ Diagnostic and imaging studies – High risk of complication or morbidity or mortality of patient management ▪ Co-morbidities associated with presenting problems ▪ Risk of diagnostic procedure performed ▪ Risk associated with management options – Patient Aftercare

E&M Code	Patient Status	Level of Decision Making	Time Spent (Minutes)	Code Specific Required Documentation Components
99213**	Established	Low	20-29	– History and exam elements must be documented as medically appropriate, inclusive of medical diagnosis – Number and complexity of problems addressed at the encounter – Limited amount of data to be reviewed including: ▪ Diagnostic and imaging studies – Low risk of complication, morbidity or mortality of patient management ▪ Stable management of a condition ▪ Minimum risk associated with treatment options – Extensive counseling details – Patient Aftercare
99214**	Established	Moderate	30-39	– History and exam elements must be documented as medically appropriate, inclusive of medical diagnosis – Extensive management options for diagnosis or treatment – Extensive counseling details – Extensive amount of data to be reviewed including: ▪ Old records, physician notes ▪ Previous or current lab results ▪ Diagnostic and imaging studies – Moderate to high risk of complication or morbidity or mortality of patient management ▪ Co-morbidities associated with presenting problems ▪ Risk of diagnostic procedure performed ▪ Risk associated with management options – Patient Aftercare
99215*	Established	High	40-54	– History and exam elements must be documented as medically appropriate, inclusive of medical diagnosis – Extensive management options for diagnosis or treatment – Extensive counseling details – Extensive amount of data to be reviewed including: ▪ Old records, physician notes ▪ Previous or current lab results ▪ Diagnostic and imaging studies – High risk of complication or morbidity or mortality of patient management ▪ Co-morbidities associated with presenting problems ▪ Risk of diagnostic procedure performed ▪ Risk associated with management options – Patient Aftercare

**Eligible for Post Service Review*

***May be eligible for Post Service Review on a case-by-case basis*

PROVIDER ADMINISTRATIVE POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY							
BENEFIT	**EYE CARE**	**POLICY SECTION**	**200 MATERIALS & LENSES**		**POLICY NO**	**200.01**	
POLICY TITLE	**VISION MATERIALS**						
POLICY DATE	**01/01/2024**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**		
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	- **There are no exclusions to this policy**						

I. POLICY STATEMENT

Coverage for Vision Materials will be provided when medically indicated and in accordance with applicable state requirements and, as specific to Medicare, national and local coverage determinations. To effectively establish medical necessity for this service, Avēsis aligns its criteria with evidence and consensus based clinical practice guidelines set forth by the American Optometric Association (AOA)[1] and the College of Optometrists in Vision Development (COVD)[2]. The AOA incorporates evidence based best practice and FDA approval and/or recommendations; COVD has a Vision Development and Rehabilitation Review Board comprised of national professional membership. 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 Reasonable and necessary for the diagnosis or treatment of condition to improve vision and the members functionality.

3.0 Meet all other applicable requirements. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity.

- 3.1 Anti-reflective coating (V2750), tints (V2744, V2745) are covered only when they are medically necessary for the individual patient and the medical necessity is documented by the treating physician. When these features are provided as a patient preference, they will be denied as not medically necessary.
- 3.2 Coverage will be considered only for enrollees who have one or more conditions following:
  - 3.2.1 Aphakia
  - 3.2.2 Photophobia
  - 3.2.3 Aniridia
  - 3.2.4 Coloboma
  - 3.2.5 Albinism
  - 3.2.6 Pigmentary retinal dystrophy
  - 3.2.7 Post-Cataract Surgery
  - 3.2.8 Keratitis
  - 3.2.9 Corneal opacity and other disorders of cornea
  - 3.2.10 An Rx of > +/- 6.00 D
  - 3.2.11 Glare

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

III. MEDICAL NECESSITY REQUIREMENTS FOR APPLICABLE CODES

Note: Unless specifically referenced by Age, criterion point applicable to both Adult and Children

1.0 To establish medical necessity, relevant CPT and HCPCS referenced below in Table 1 and all ICD-10 codes referenced below in Table 2 must be clearly & legibly documented in the medical record and made available to Avēsis upon 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.
4.0 Visual acuity and brightness acuity test results can be documented and firmly support diagnosis.
5.0 Services will be denied for prior authorization requests when:
  5.1 Documentation submitted by the requesting provider does not establish the medical necessity per requirements.
  5.2 Documentation submitted is incomplete and provider fails to respond to requests for additional clarifying information.
    5.2.1 Providers repeatedly failing to submit documentation timely will be referred to Quality.
    5.2.2 If applicable, Provider and enrollee will receive written notification of adverse determination which outlines right to appeal with instructions on request procedure and applicable timeframes.

IV. CPT/HCPCS CODES AND ICD-10 CODES

Table 1: HCPCS CODES AND DESCRIPTION

CPT/HCPCS	DESCRIPTION
V2744	Transition Lens (pair)
V2745	Tint (pair)
V2750	Antireflective Coating (pair)

Table 2: ICD-10 CODES AND DESCRIPTION

ICD-10 CODE	DESCRIPTION
E70.30 – E70.331	Albinism, unspecified – Hermansky-Pudlak syndrome
H16.101 – H16.149	Unspecified superficial keratitis – Punctate keratitis
H16.301 – H16.339	Unspecified interstitial keratitis – Sclerosing keratitis
H16.401 – H16.449	Unspecified corneal neovascularization – Deep vascularization of cornea
H16.9	Unspecified keratitis
H17.0 – H17.829	Adherent leukoma – Peripheral opacity of cornea
H17.9	Unspecified corneal scar and opacity
H27.00 – H27.03	Aphakia
H35.52	Pigmentary retinal dystrophy

ICD-10 CODE	DESCRIPTION
H53.141 – H53.149	Visual discomfort
H53.15	Visual distortions of shape and size
H53.16	Psychophysical visual disturbances
H53.71	Glare sensitivity
H53.72	Impaired contrast sensitivity
H53.9	Unspecified visual disturbance
Q13.0 – Q13.9	Coloboma of iris - Congenital malformation of anterior segment of eye, unspecified
Z98.41 – Z98.49	Cataract extraction status

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY									
BENEFIT	**EYE CARE**	**POLICY SECTION**	**200 MATERIALS & LENSES**			**POLICY NO**	**200.02**		
POLICY TITLE	**MEDICALLY NECESSARY CONTACT LENSES & FITTING**								
POLICY DATE	**01/01/2020**	**REVISION DATE**	**12/11/2024**	**APPROVAL DATE**	**01/02/2025**				
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	- **There are no exclusions to this policy**								

I. POLICY STATEMENT

Coverage for medically necessary contact lenses and fitting will be provided when medically indicated and in accordance with applicable state requirements and, as specific to Medicare, national and local coverage determinations. To effectively establish medical necessity for this service, Avēsis aligns its criteria with evidence and consensus based clinical practice guidelines set forth by the American Optometric Association (AOA)[1] and the College of Optometrists in Vision Development (COVD)[2]. The AOA incorporates evidence based best practice and FDA approval and/or recommendations; COVD has a Vision Development and Rehabilitation Review Board comprised of national professional membership. 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 Contact lenses may be fitted and dispensed for medical reasons to treat or manage diseases involving the cornea or when medically necessary in the appropriate treatment of the following conditions:
- 1.1 Keratoconus
- 1.2 Irregular Astigmatism
- 1.3 Corneal Disorders
- 1.4 Aphakia
- 1.5 Anisometropia and Aniseikonia
- 1.6 High Myopia

2.0 Medically necessary, contact lens services shall include, at a minimum:
- 2.1 Examination
- 2.2 Contact lens fitting
- 2.3 Insertion, removal, & care/cleaning training
  - 2.3.1 Written & verbal instructions
  - 2.3.2 Replacement guidelines discussed
- 2.4 Wearing schedule
  - 2.4.1 Written & verbal instructions
  - 2.4.2 Daily schedule & maintenance
- 2.5 Risk & responsibility counseling
- 2.6 Starter kit
- 2.7 Follow-up visits for a minimum of 60 days after completion of fitting
  - 2.7.1 Thorough evaluation at EACH follow up not simply a lens check
  - 2.7.2 Health, fit, tolerance should be discussed & documented

[1] American Optometric Association https://www.aoa.org/practice/clinical-guidelines/clinical-practice-guidelines?sso=y
[2] College of Optometrists in Vision Development https://www.covd.org/page/Review_Board

**Note, 2.7 in totality subject to retrospective quality medical record review*

3.0 *State specific requirements apply as outlined in sections below.*

III. MEDICAL NECESSITY REQUIREMENTS FOR APPLICABLE CODES BY STATE

Note: unless specifically referenced by Age, criterion point applicable to both Adult and Children

1.0 To establish medical necessity, relevant diagnoses referenced below in Table 1 and all criterion points referenced below in Table 2 must be clearly & legibly documented in the medical record and made available to Avēsis upon 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 Services will be denied for prior authorization requests when:

- 2.1 Documentation submitted by the requesting provider does not establish the medical necessity per requirements in Tables 1 and 2, respectively.
  - 2.1.1 Specific to select CPT and HCPCS codes as outlined below in Table 2 ***which may vary by state,*** detailed documentation, procedure note, orders and/or formal testing interpretation must be submitted.
- 2.2 Documentation submitted is incomplete and provider fails to respond to requests for additional clarifying information.
  - 2.2.1 Providers repeatedly failing to submit documentation timely will be referred to Quality.

3.0 Contact lens fitting, and dispensing, will be considered medically appropriate when submitted documentation substantiates need is specific to the treatment and/or management of disease related to the cornea:

- 3.1 Any condition (other than keratoconus) of congenital, pathological, or surgical etiology causing compromised integrity of the corneal curvature or media resulting in best correctable acuity of 20/40 or less with spectacles in one or both eyes.

4.0 Contact lens fitting, and dispensing will be considered medically appropriate when submitted documentation substantiates need is specific to the treatment and/or management for the following conditions:

- 4.1 Keratoconus
  - 4.1.2 Diagnosis confirmed by keratometry readings or corneal topography
  - 4.1.3 Best correctable visual acuity with spectacles of 20/40 or less in either eye
  - 4.1.4 Contacts improve best corrected spectacle visual acuity (standard Snellen measurement) by at least 2 lines with rigid contact lenses
- 4.2 Irregular Astigmatism
  - 4.2.1 ≥2.00 diopters of astigmatism in either eye where the principal meridians are separated by less than 90°
  - 4.2.2 Best correctable visual acuity of 20/40 or less in the affected eye with spectacles
- 4.3 Aphakia
  - 4.3.1 In one or both eyes of congenital, surgical, or traumatic etiology without implantation of an intraocular lens
- 4.4 Anisometropia and Aniseikonia
  - 4.4.1 ≥3.00 diopters difference in prescription (spherical equivalent) between right and left eye
  - 4.4.2 Unequal image size between right and left eye resulting in intermittent or constant diplopia, suppression, binocular rivalry, or less than 100° stereopsis
- 4.5 High Myopia
  - 4.5.1 Refractive error greater than (+) or (-)10.00 diopters
  - 4.5.2 Best correctable visual acuity with spectacles of 20/40 or less in either eye

4.5.3 At least 2 lines improvement in best correctable visual acuity (standard Snellen measurement) with contact lenses

5.0 If applicable, Provider and enrollee will receive written notification of adverse determination which outlines right to appeal with instructions on request procedure and applicable timeframes.

IV: ICD-10/CPT Codes Supportive of Medical Necessity – Applicable to ALL states

Table 1: ICD-10 Codes Supportive of Medical Necessity – Applicable to ALL states

ICD-10 CODE	DESCRIPTION
H18.601 – H18.609	Keratoconus, unspecified
H18.611 – H18.619	Keratoconus, stable
H18.621 – H18.629	Keratoconus, unstable
H27.00 – H27.03	Aphakia
H44.20 – H44.23	Degenerative myopia
H52.211 – H52.219	Irregular astigmatism
H52.31	Anisometropia
H52.32	Aniseikonia

Table 2: CPT/HCPCS CODES AND APPLICABLE CRITERION – NOTE: STATE SPECIFIC VARIABLES APPLY

This table outlines all codes applicable to this policy; however, codes may or may not be applicable to each participating state due to variance in state requirements. Codes which are not appliable to all states and/or which have state specific variance in requirements are denoted with an asterisk*.
Providers must confirm codes covered for state as outlined below.

Codes are representative of Managed Medicaid unless otherwise noted.

CODE	MEDICAL NECESSITY CRITERION POINT
92071*	Fitting of contact lens for treatment of ocular surface disease
92072*	Fitting of contact lens for management of keratoconus, initial fitting
V2500	Contact lens, pmma, spherical, per lens
V2501	Contact lens, pmma, toric or prism ballast, per lens
V2502*	Contact lens, pmma, bifocal, per lens
V2503*	Contact lens, pmma, color vision deficiency
V2510	Contact lens, gas permeable, spherical, per lens
V2511	Contact lens, gas permeable, toric or prism ballast, per lens
V2512*	Contact lens, gas permeable, bifocal, per lens
V2513	Contact lens, gas permeable extended wear, per lens
V2520	Contact lens, hydrophilic, spherical, per lens
V2521	Contact lens, hydrophilic, toric or prism ballast, per lens
V2522*	Contact lens, hydrophilic, bifocal, per lens
V2523	Contact lens, hydrophilic, extended wear, per lens
V2524*	Contact lens, hydrophilic, spherical, photochromic additive, per lens
V2525*	Contact lens, hydrophilic, dual focus, per lens
V2526	Contact lens, hydrophilic, with blue-violet filter, per lens
V2530	Contact lens, scleral, gas impermeable, per lens
V2531*	Contact lens, scleral, gas permeable, per lens
V2599*	Contact lens, other type (i.e., SynergEyes)

Table 3: CPT/HCPCS CODES AND APPLICABLE CRITERION – NOTE: STATE SPECIFIC VARIABLES APPLY

District of Columbia	Georgia	Illinois	Kentucky	
Medicaid	Medicaid	Medicaid & MMP	Medicaid	Medicare Advantage
92071	92071	92071	92071	92071 / 92072
92072	92072	92072	92072	92311
V2500	V2500	V2500	92310	92312
V2501	V2510	V2510	92311	92313
V2502	V2513	V2520	92312	S0592
V2503	V2520	V2531	92313	V2500
V2510	V2523	V2599	V2500	V2501
V2511			V2501	V2502
V2512			V2502	V2503
V2513			V2503	V2510
V2520			V2510	V2511
V2521			V2511	V2512
V2522			V2512	V2513
V2523			V2513	V2520
V2524			V2520	V2521
V2525			V2521	V2522
V2526			V2522	V2523
V2530			V2523	V2524
V2531			V2524	V2525
V2599			V2530	V2526
			V2531	V2530
				V2531
				V2599

Maryland	Michigan	Mississippi	North Carolina	Texas
Medicaid	MMP	Medicare Advantage	Medicaid	Medicaid
92071	92071	92071 / 92072	92310	92310 92311
92072	92072	92311 / 92312	92071	92312 92313
92310	V2500	92313	92072	92314 92315
92311	V2501	V2500	V2510	92316 92317
92312	V2510	V2501	V2520	92325 92326
92313	V2511	V2502	V2599	92071 92072
92314	V2513	V2503		V2500
S0500	V2520	V2510		V2501
V2500	V2521	V2511		V2502
V2501	V2523	V2512		V2510
V2502	V2524	V2513		V2511
V2503	V2531	V2520		V2512
V2510	V2599	V2521		V2513
V2511		V2522		V2520
V2512		V2523		V2521
V2513		V2524		V2522
V2520		V2525		V2523
V2521		V2526		V2530
V2522		V2530		V2531
V2523		V2531		V2599
V2530		V2599		
V2599				

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY					
BENEFIT	**EYE CARE**	**POLICY SECTION**	**300 DIAGNOSTIC TESTING**	**POLICY NO**	**300.01**
POLICY TITLE	**FUNDUS PHOTOGRAPHY**				
POLICY DATE	**10/01/2024**	**REVISION DATE**	**10/01/2024**	**APPROVAL DATE**	**01/02/2025**
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	- **NC: Will require appropriate use of diagnosis code listed below in Section IV. More than 1 fundus photo per billing cycle will require a prior authorization.**				

I. POLICY STATEMENT

Coverage of Fundus Photography will be provided 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 Fundus photography is indicated to document abnormalities related to disease processes affecting the eye or to follow the progress of the disease, and is considered medically necessary for conditions such as, but not limited to:

- 2.1 Macular degeneration
- 2.2 Retinal neoplasms
- 2.3 Choroid disturbances and diabetic retinopathy
- 2.4 Glaucoma
- 2.5 Identification of Multiple Sclerosis and other central nervous system abnormalities.

3.0 Fundus photography will not be considered medically necessary if performed specific to the following:

- 3.1 To document the existence or screen for existence of a condition
- 3.2 To document normal findings/absence of disease
- 3.3 For routine photographs that do not impact treatment
- 3.4 For subsequent repetitive photographs that do not demonstrate any change or new findings.

4.0 Fundus photography cannot be performed for a Medicare enrollee on the same date of service as computerized diagnostic testing (e.g., CPT codes 92132, 92133 and 92134) and extended ophthalmoscopy codes 92201 and 92202, since they are generally mutually exclusive of one another, per CMS guidelines.

5.0 It is expected that providers remain informed of current medical literature and/or standards of practice specific to requests for Fundus Photography.

- 5.1 Requests are monitored, and when services are requested/performed in excess of established parameters, the provider may be subject to retrospective quality review.

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

6.0 Services will be denied for prior authorization requests when:

6.1 Documentation submitted by the requesting provider does not establish the medical necessity per requirements outlined.

6.2 Documentation submitted is incomplete and provider fails to respond to requests for additional clarifying information.

4.2.1 Providers repeatedly failing to submit documentation timely will be referred to Quality.

6.3 Provider and enrollee will receive written notification of adverse determination which outlines right to appeal and instructions on request procedure and applicable timeframes.

III. MEDICAL NECESSITY REQUIREMENTS APPLICABLE CPT CODE 92250

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 Fundus photographs are only considered medically necessary when all of the following are met:

3.1 Results may impact the management of the patient

3.2 Baseline photographs are necessary to monitor progression

3.3 Subsequent photographs are necessary to establish/monitor progression

4.0 Medical documentation must evidence diagnostic test interpretation, inclusive of the following:

4.1 Date of test

4.2 Date of interpretation

4.3 Findings

4.4 Progression/Stable notation (unless baseline)

4.5 Diagnosis

4.6 Physician Signature

IV. ICD-10 CODES SUPPORTING MEDICAL NECESSITY

ICD-10 Code	Description
A52.15	Late syphilitic neuropathy
B20	Human immunodeficiency virus (HIV) disease
B39.4 – B39.9	Histoplasmosis capsulati, unspecified – Histoplasmosis, unspecified
B50.0 – B54	Plasmodium falciparum malaria – Unspecified malaria
B58.00 – B58.01	Toxoplasma oculopathy, unspecified – Toxoplasma chorioretinitis
B58.9	Toxoplasmosis, unspecified
C69.20 – C69.32	Malignant neoplasm of retina – Malignant neoplasm of choroid
C79.40 – C79.49	Secondary malignant neoplasm of other and unspecified parts of nervous system
D09.20 – D09.22	Carcinoma in situ of eye
D31.20 – D31.32	Benign neoplasm of retina – Benign neoplasm of choroid
D33.3	Benign neoplasm of cranial nerves
D49.81	Neoplasm of unspecified behavior of retina and choroid

ICD-10 Code	Description
D57.00 – D57.02	Hb-SS disease with crisis – Hb-SS disease with splenic sequestration
D57.1 – D57.212	Sickle-cell disease without crisis – Sickle-cell/Hb-C disease with splenic sequestration
D57.219	Sickle-cell/Hb-C disease with crisis, unspecified
D57.3 – D47.412	Sickle-cell trait – Sickle-cell thalassemia, unspecified, with splenic sequestration
D57.419	Sickle-cell thalassemia, unspecified, with crisis
D86.83	Sarcoid iridocyclitis
D86.89 – D86.9	Sarcoidosis of other sites – Sarcoidosis, unspecified
E08.311 – E08.319	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy
E08.3211– E08.3599	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema – 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
E09.3211 – E09.3599	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema – Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema
E10.A – E10.A2	Type 1 diabetes mellitus, presymptomatic
E10.311 – E10.319	Type 1 diabetes mellitus with unspecified diabetic retinopathy
E10.3211 – E10.3599	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema – Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema
E10.8	Type 1 diabetes mellitus with unspecified complications
E10.9	Type 1 diabetes mellitus without complications
E11.311 – E11.319	Type 2 diabetes mellitus with unspecified diabetic retinopathy
E11.3211– E11.3599	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema – Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema
E11.8	Type 2 diabetes mellitus with unspecified complications
E11.9	Type 2 diabetes mellitus without complications
E70.20 – E70.21	Disorder of tyrosine metabolism, unspecified – Tyrosinemia
E70.30 – E70.311	Albinism, unspecified – Autosomal recessive ocular albinism
E70.319	Ocular albinism, unspecified
E70.9	Disorder of aromatic amino-acid metabolism, unspecified
G35	Multiple Sclerosis
G93.2	Benign intracranial hypertension (pseudotumor cerebri)
H27.111 – H27.139	Subluxation of lens – Posterior dislocation of lens
H30.001 – H30.23	Unspecified focal chorioretinal inflammation – Posterior cyclitis
H30.811 – H30.819	Harada's disease
H30.90 – H30.93	Unspecified chorioretinal inflammation
H31.001 – H31.029	Unspecified chorioretinal scars – Solar retinopathy

ICD-10 Code	Description
H31.101 – H31.23	Choroidal degeneration, unspecified – Gyrate atrophy, choroid
H31.301 – H31.429	Unspecified choroidal hemorrhage – Serous choroidal detachment
H33.001 – H33.129	Unspecified retinal detachment with retinal break – Parasitic cyst of retina
H33.20 – H33.43	Serous retinal detachment – Traction detachment of retina
H34.00 – H34.9	Transient retinal artery occlusion – Unspecified retinal vascular occlusion
H35.00 – H35.079	Unspecified background retinopathy – Retinal telangiectasis
H35.101 – H35.179	Retinopathy of prematurity, stage 0 – Retrolental fibroplasia
H35.30 – H35.82	Unspecified macular degeneration – Retinal ischemia
H35.9	Unspecified retinal disorder
H36.811 – H26829	Nonproliferative sickle-cell retinopathy – Proliferative sickle-cell retinopathy
H40.001 – H40.839	Preglaucoma, unspecified – Aqueous misdirection
H40.9	Unspecified glaucoma
H43.00 – H43.319	Vitreous prolapse – Vitreous membranes and strands
H43.811 – H43.829	Vitreous degeneration – Vitreomacular adhesion
H43.9	Unspecified disorder of vitreous body
H44.001 – H44.329	Unspecified purulent endophthalmitis – Siderosis of eye
H44.40 – H44.829	Unspecified hypotony of eye – Luxation of globe
H44.9	Unspecified disorder of globe
H46.00 – H46.3	Optic papillitis – Toxic optic neuropathy
H46.9 – H47.039	Unspecified optic neuritis – Optic nerve hypoplasia
H47.10 – H47.239	Unspecified papilledema – Glaucomatous optic atrophy
H47.311 – H47.339	Coloboma of optic disc – Pseudopapilledema of optic disc
H47.41 – H47.9	Disorders of optic chiasm – Unspecified disorder of visual pathways
H53.50 – H53.55	Unspecified color vision deficiencies – Tritanomaly
L93.0 – L93.1	Discoid lupus erythematosus – Subacute cutaneous lupus erythematosus
M05.20, M05.29	Rheumatoid vasculitis with rheumatoid arthritis, of unspecified (multiple) site(s)
M05.40, M05.49	Rheumatoid myopathy with rheumatoid arthritis, of unspecified (multiple) site(s)
M05.50, M05.59	Rheumatoid polyneuropathy with rheumatoid arthritis, of unspecified (multiple) site(s)
M05.60, M05.69	Rheumatoid arthritis of unspecified (multiple) site(s) with involvement of other organs and systems
M05.70, M05.79	Rheumatoid arthritis with rheumatoid factor of unspecified (multiple) site(s) without organ or systems involvement
M05.9	Rheumatoid arthritis with rheumatoid factor, unspecified
M06.00, M06.09	Rheumatoid arthritis without rheumatoid factor, unspecified (multiple) sites(s)
M06.4	Inflammatory polyarthropathy
M06.9	Rheumatoid arthritis, unspecified
M08.00, M08.09	Unspecified juvenile rheumatoid arthritis, unspecified (multiple) sites(s)
M08.1	Juvenile ankylosing spondylitis
M08.20, M08.29	Juvenile rheumatoid arthritis with systemic onset, unspecified (multiple) sites(s)
M08.3	Juvenile rheumatoid polyarthritis (seronegative)

ICD-10 Code	Description
M08.90, M08.99	Juvenile arthritis, unspecified, unspecified (multiple) sites(s)
M32.0	Drug-induced systemic lupus erythematosus
M32.10	Systemic lupus erythematosus, organ or system involvement unspecified
M32.9	Systemic lupus erythematosus, unspecified
P35.0	Congenital rubella syndrome
Q14.3	Congenital malformation of choroid
Z79.899	Other long term (current) drug therapy (utilized for Plaquenil toxicity)

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY					
BENEFIT	**EYE CARE**	**POLICY SECTION**	**300 DIAGNOSTIC TESTING**	**POLICY NO**	**300.02**
POLICY TITLE	**Scanning Computerized Ophthalmic Diagnostic Imaging (SCODI)**				
POLICY DATE	**10/01/2024**	**REVISION DATE**	**10/01/2024**	**APPROVAL DATE**	**01/02/2025**
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	- **There are no exclusions to this policy**				

I. POLICY STATEMENT

Coverage for Scanning Computerized Ophthalmic Diagnostic Imaging (SCODI) will be provided when medically indicated and in accordance with applicable state Medicaid 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 SCODI is a non-invasive, non-contact imaging technique which produces high resolution, cross-sectional tomographic images of ocular structures and is used for the evaluation of conditions involving the anterior segment, optic nerve, and retina.

2.0 SCODI includes the following tests:

- 2.1 Confocal Laser Scanning Ophthalmoscopy
- 2.2 Scanning Laser Polarimetry, nerve fiber analyzer
- 2.3 Optical Coherence Tomography (OCT)

3.0 SCODI requires a medical diagnosis to establish medical necessity; the following codes/procedures would generally not be considered necessary to be performed on the same date of service as SCODI, unless documentation justifies and supports:

- 3.1 92250 – Fundus photography with interpretation and report
  - 3.1.1 Fundus photography cannot be performed on the same date of service as computerized diagnostic testing (e.g., CPT codes 92132, 92133 and 92134) since they are generally mutually exclusive of one another, per CMS guidelines.
- 3.2 92201 – Ophthalmoscopy, extended with retinal drawing and scleral depression of peripheral retinal disease (e.g., for retinal tear, retinal detachment, retinal tumor) with interpretation and report, unilateral or bilateral.
- 3.3 99202 – Ophthalmoscopy, extended with drawing of optic nerve or macula (e.g., for glaucoma, macular pathology, tumor) with interpretation and report, unilateral or bilateral.
- 3.4 76512 – B-scan (with or without superimposed non-quantitative A-scan)

4.0 SCODI will be covered at the following frequencies as per condition:

- 4.1 Glaucoma/glaucoma suspicion
  - 4.1.1 Baseline
  - 4.1.2 Annually
- 4.2 Retinal Disorders – (active or inactive disease, without treatment)
  - 4.2.1 Baseline
  - 4.2.2 1 scan per eye every 2 months

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

4.3 Retina Disorders – (active AMD and diabetic retinopathy currently undergoing treatment)
4.3.1 Baseline
4.3.2 One scan per eye, per month (as justified and medically necessary)
4.4 Retinal Disorders – (active disease currently undergoing intravitreal injection)
4.4.1 Baseline
4.4.2 One scan per eye, per month (as justified and medically necessary)

5.0 It is expected that providers remain informed of current medical literature and/or standards of practice specific to requests for SCODI.

5.1 Requests are monitored, and when services are requested/performed in excess of established parameters, the provider may be subject to retrospective quality review.
5.1.1 In order to determine medical necessity, Avēsis may request clinical records, which must justify the diagnosis listed on claim and the reason(s) procedure(s) were necessary for planning therapy and monitoring the progress of the disease diagnosed.
5.1.2 When the documentation guidelines do not meet the criteria for the service rendered, or the documentation does not establish the medical necessity for the services, such services will be retrospectively denied as not reasonable and necessary.

III. MEDICAL NECESSITY REQUIREMENTS for CPT 92132

1.0 To establish medical necessity all criterion points referenced below and applicable diagnosis support as outlined in Table 1 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 SCODI may be considered medically necessary when any of the following are substantiated by medical record submission:

2.1 A documented disorder of the optic nerve or the neurological visual pathway
2.2 Documentation of narrow angles
2.3 Documentation of other condition of the angles (i.e., tumor of the angles)

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

4.0 A current, pertinent history, physical examination, appropriate diagnostic testing, and progress notes describing and supporting the covered indication.

4.1 Chart note must clearly order test, specify medical necessity (diagnosis), frequency, and need for monitoring/ongoing therapy

5.0 Medical documentation must evidence diagnostic test interpretation, inclusive of the following:

5.1 Date of test
5.2 Date of interpretation
5.3 Findings
5.4 Progression/Stable notation (unless baseline)
5.5 Diagnosis
5.6 Physician Signature

6.0 Copy of tests, computer analysis of data, and appropriate storage for future comparison on follow up exam must be maintained in the patient file.

IV. TABLE 1 - ICD-10 CODES SUPPORTING MEDICAL NECESSITY

The following ICD-10-CM codes may support medical necessity of CPT 92132	
ICD-10 Code	Description
H18.20 – H18.239	Unspecified corneal edema – Secondary corneal edema

H20.041 – H20.049	Secondary noninfectious iridocyclitis
H21.231 – H21239	Degeneration of iris (pigmentary)
H21.40 – H21.43	Pupillary membranes
H21.521 – H21.529	Goniosynechiae
H21.551 – H21.559	Recession of chamber angle
H21.81 – H21.82	Floppy iris syndrome – Plateau iris syndrome (post-iridectomy) (postprocedural)
H21.9	Unspecified disorder of iris and ciliary body
H40.001 – H40.069	Preglaucoma, unspecified – Primary angle closure without glaucoma damage
H40.1310 – H40.1394	Pigmentary glaucoma
H40.20X0 – H40.839	Unspecified primary angle-closure glaucoma – Aqueous misdirection
H40.211 – H40.219	Acute angle-closure glaucoma
H40.2210 – H40.2294	Chronic angle-closure glaucoma
H40.231 – H40.249	Intermittent angle-closure glaucoma – Residual stage of angle-closure glaucoma
H40.30X0 – H40.63X4	Glaucoma secondary to eye trauma – Glaucoma secondary to drugs
H40.9	Unspecified glaucoma

The following ICD-10-CM codes may support medical necessity of CPT 92133	
ICD-10 Code	Description
A79.82	Anaplasmosis [A. phagocytophilum]
D75.838 – D75.839	Other thrombocytosis – Thrombocytosis, unspecified
G92.00 – G92.05	Immune effector cell-associated neurotoxicity syndrome
G92.8 – G92.9	Other toxic encephalopathy – Unspecified toxic encephalopathy
G93.2	Benign intracranial hypertension
H20.041 – H20.049	Secondary noninfectious iridocyclitis
H21.231 – H21239	Degeneration of iris (pigmentary)
H21.40 – H21.43	Pupillary membranes
H21.521 – H21.529	Goniosynechiae
H21.551 – H21.559	Recession of chamber angle
H40.001 – H40.069	Preglaucoma, unspecified – Primary angle closure without glaucoma damage
H40.10X0 – H40.1194	Open-angle glaucoma – Primary open-angle glaucoma, unspecified eye
H40.1210 – H40.1294	Low-tension glaucoma
H40.1310 – H40.1394	Pigmentary glaucoma
H40.1410 – H40.1494	Capsular glaucoma with pseudoexfoliation of lens
H40.151 – H40.159	Residual stage of open-angle glaucoma
H40.20X0 – H40.20X4	Unspecified primary angle-closure glaucoma
H40.211 – H40.219	Acute angle-closure glaucoma
H40.2210 – H40.2294	Chronic angle-closure glaucoma
H40.231 – H40.249	Intermittent angle-closure glaucoma – Residual stage of angle-closure glaucoma

H40.30X0 – H40.63X4	Glaucoma secondary to eye trauma – Glaucoma secondary to drugs
H40.811 – H40.839	Glaucoma with increased episcleral venous pressure – Aqueous misdirection
H42	Glaucoma in diseases classified elsewhere
H44.511 – H44.519	Absolute glaucoma
H46.00 – H46.3	Optic papillitis - Toxic optic neuropathy
H47.011 – H47.039	Ischemic optic neuropath – Optic nerve hypoplasia
H47.10 – H47.239	Unspecified papilledema – Glaucomatous optic atrophy
H47.311 – H47.339	Coloboma of optic disc – Pseudopapilledema of optic disc
H47.9	Unspecified disorder of visual pathways
H53.131 – H53.139	Sudden visual loss
H53.15	Visual distortions of shape and size
H53.40 – H53.439	Unspecified visual field defects – Sector or arcuate defects
H53.481 – H53.489	Generalized contraction of visual field
Q14.2	Congenital malformation of optic disc
Q15.0, Q15.9	Congenital glaucoma, Congenital malformation of eye, unspecified
R11.15	Cyclical vomiting syndrome unrelated to migraine
S04.011A, S04.011D	Injury of optic nerve, right eye
S04.012A, S04.012D	Injury of optic nerve, left eye
S06.A0XA – S06.A0XS	Traumatic brain compression without herniation
S06.A1XA – S06.A1XS	Traumatic brain compression with herniation
Z79.899	Other long term (current) drug therapy

The following ICD-10-CM codes may support medical necessity of CPT 92134	
ICD-10 Code	Description
B39.4 – B39.9	Histoplasmosis capsulati, unspecified – Histoplasmosis, unspecified
C69.20 – C69.32	Malignant neoplasm of unspecified retina – Malignant neoplasm of choroid
D18.09	Hemangioma of other sites
D31.20 – D31.32	Benign neoplasm of retina – Benign neoplasm of choroid
D57.09	Hb-SS disease with crisis with other specified complication
D57.459	Sickle-cell thalassemia beta plus with crisis, unspecified
E10.A – E10.A2	Type 1 diabetes mellitus, presymptomatic
E10.311 – E10.319	Type 1 diabetes mellitus with unspecified diabetic retinopathy
E10.3211 – E10.3599	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema – 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
E11.3211 – E11.3599	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema – Type 2 diabetes mellitus with stable proliferative diabetic retinopathy

E11.37X1 – E11.37X9	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment
E70.310 – E70.311	X-linked ocular albinism – Autosomal recessive ocular albinism
E70.319	Ocular albinism, unspecified
G45.3	Amaurosis fugax
H30.001 – H30.819	Unspecified focal chorioretinal inflammation – Harada's disease
H30.90 – H30.93	Unspecified chorioretinal inflammation
H31.001 – H31.029	Unspecified chorioretinal scars – Solar retinopathy
H31.101 – H31.23	Choroidal degeneration, unspecified – Gyrate atrophy, choroid
H31.301 – H31.429	Unspecified choroidal hemorrhage – Serous choroidal detachment
H32	Chorioretinal disorders in diseases classified elsewhere
H33.001 – H33.129	Unspecified retinal detachment with retinal break – Parasitic cyst of retina
H33.20 – H33.43	Serous retinal detachment – Traction detachment of retina
H34.00 – H34.9	Transient retinal artery occlusion – Unspecified retinal vascular occlusion
H35.00 – H35.079	Unspecified background retinopathy – Retinal telangiectasis
H35.30 – H35.52	Unspecified macular degeneration – Pigmentary retinal dystrophy
H35.54 – H35.82	Dystrophies primarily involving the retinal pigment epithelium – Retinal ischemia
H36.811 – H36.829	Nonproliferative sickle-cell retinopathy – Proliferative sickle-cell retinopathy
H43.811 – H43.829	Vitreous degeneration – Vitreomacular adhesion
H44.111 – H44.119	Panuveitis
H44.20 – H44.2D9	Degenerative myopia – Degenerative myopia with foveoschisis
H47.9	Unspecified disorder of visual pathways
H53.131 – H53.139	Sudden visual loss
H53.15	Visual distortions of shape and size
H53.40 – H53.439	Unspecified visual field defects – Sector or arcuate defects
H53.461 – H53.469	Homonymous bilateral field defects
H53.481 – H53.489	Generalized contraction of visual field
H59.031 – H59.039	Cystoid macular edema following cataract surgery
Q14.1	Congenital malformation of retina
Q14.3	Congenital malformation of choroid
Z79.633	Long term (current) use of mitotic inhibitor
Z79.899	Other long term (current) drug therapy
Z85.840	Personal history of malignant neoplasm of eye

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY							
BENEFIT	**EYE CARE**	**POLICY SECTION**	**300 DIAGNOSTIC TESTING**		**POLICY NO**	**300.03**	
POLICY TITLE	**VISUAL EVOKED POTENTIAL (VEP) TESTING**						
POLICY DATE	**01/01/2024**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**		
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	- **There are no exclusions to this policy**						

I. POLICY STATEMENT

Coverage of Visual Evoked Potential (VEP) Testing will be provided only 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 that review criteria and documentation submitted by requesting providers using sound medical judgment.

II. INDICATIONS AND LIMITATION OF COVERAGE for CPT CODE 95930

1.0 Visual Evoked Potentials (VEPs) are electrophysiologic responses to stimulation by either patterned or unpatterned visual stimuli.

2.0 Visual Evoked Potentials (VEPs) are considered medically necessary for ANY of the following indications:

- 2.1 Multiple Sclerosis or Neuromyelitis Optica (NMO)
- 2.2 Suspected disorder of the Optic Nerve, Optic Chiasm or Optic Radiations not explained by MRI, CT, infectious diseases, or metabolic disorders

3.0 Visual Evoked Potential Testing will be covered annually for the patient who has or is suspected of having the conditions outlined in Sections II and III of this policy.

4.0 In order to determine medical necessity, Avēsis may request a copy of the clinical records, which must justify the diagnosis listed on the claim and the reason(s) procedure(s) were necessary for planning therapy and monitoring the progress of the disease diagnosed.

5.0 Services will be denied for prior authorization requests when:

- 5.1 Documentation submitted by the requesting provider does not establish the medical necessity per requirements outlined.
- 5.2 Documentation submitted is incomplete and provider fails to respond to requests for additional clarifying information.
  - 6.2.1 Providers repeatedly failing to submit documentation timely will be referred to Quality.
- 5.3 Provider and enrollee will receive written notification of adverse determination which outlines right to appeal and instructions on request procedure and applicable timeframes.

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

III. MEDICAL NECESSITY REQUIREMENTS for CPT CODE 95930

1.0 To establish medical necessity all criterion points referenced below and applicable information in Table 1 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 A copy of tests, computer analysis of data, and appropriate storage for future comparison on follow up exam must be maintained in the medical record.

4.0 Medical documentation must evidence diagnostic test interpretation, inclusive of the following:

- 4.1 Date of test
- 4.2 Date of interpretation
- 4.3 Findings
- 4.4 Progression/Stable notation (unless baseline)
- 4.5 Diagnosis
- 4.6 Physician Signature

IV. TABLE 1: ICD-10 CODES SUPPORTING MEDICAL NECESSITY

ICD-10 Code	Description
A39.82	Meningococcal retrobulbar neuritis
A79.32	Anaplasmosis [A. phagocytophilum]
C70.0 – C70.9	Malignant neoplasm of cerebral meninges – Malignant neoplasm of meninges, unspecified
C72.0 – C72.9	Malignant neoplasm of spinal cord – Malignant neoplasm of central nervous system, unspecified
C79.31 – C79.32	Secondary malignant neoplasm of brain – Secondary malignant neoplasm of cerebral meninges
C79.49	Secondary malignant neoplasm of other parts of nervous system
D32.0 – D32.9	Benign neoplasm of cerebral meninges – Benign neoplasm of meninges, unspecified
D33.2 – D33.7	Benign neoplasm of brain, unspecified – Benign neoplasm of other specified parts of central nervous system
D42.0 – D42.9	Neoplasm of uncertain behavior of cerebral meninges – Neoplasm of uncertain behavior of meninges, unspecified
D43.2 – D43.4	Neoplasm of uncertain behavior of brain, unspecified – Neoplasm of uncertain behavior of spinal cord
D44.4 – D44.5	Neoplasm of uncertain behavior of craniopharyngeal duct – Neoplasm of uncertain behavior of pineal gland
D49.6	Neoplasm of unspecified behavior of brain
F44.0 – F44.9	Dissociative amnesia – Dissociative and conversion disorder, unspecified
F68.11	Factitious disorder with predominantly psychological signs and symptoms
G11.0 – G11.4	Congenital nonprogressive ataxia – Hereditary spastic paraplegia
G11.9	Hereditary ataxia, unspecified
G23.0 – G23.2	Hallervorden-Spatz disease – Striatonigral degeneration
G32.81	Cerebellar ataxia in diseases classified elsewhere

ICD-10 Code	Description
G35	Multiple sclerosis
G36.0	Neuromyelitis optica
G37.0 – G37.5	Diffuse sclerosis of central nervous system – Concentric sclerosis [Balo] of central nervous system
G37.9	Demyelinating disease of central nervous system, unspecified
G93.1	Anoxic brain damage, not elsewhere classified
G93.82	Brain death
G95.9	Disease of spinal cord, unspecified
G97.81 – G97.82	Other intraoperative complications of nervous system – Other postprocedural complications and disorders of nervous system
H35.54	Dystrophies primarily involving the retinal pigment epithelium
H46.00 – H46.3	Optic papillitis – Toxic optic neuropathy
H46.9	Unspecified optic neuritis
H47.011 – H47.039	Ischemic optic neuropathy – Optic nerve hypoplasia
H47.10 – H47.239	Unspecified papilledema associated with increased intracranial pressure – Glaucomatous optic atrophy
H47.311 – H47.339	Coloboma of optic disc – Pseudopapilledema of optic disc
H47.41 – H47.9	Disorders of optic chiasm – Unspecified disorder of visual pathways
H53.001 – H53.16	Unspecified amblyopia – Psychophysical visual disturbances
H53.30 – H53.439	Unspecified disorder of binocular vision – Sector or arcuate defects
H53.461 – H53.55	Homonymous bilateral field defects – Tritanomaly
H53.60 – H53.63	Unspecified night blindness – Congenital night blindness
H53.71 – H53.72	Glare sensitivity – Impaired contrast sensitivity
H54.0X33 – H54.8	Blindness, both eyes – Legal blindness, as defined in USA
P84	Other problems with newborn
P91.60 – P91.63	Hypoxic ischemic encephalopathy [HIE], unspecified – Severe hypoxic ischemic encephalopathy [HIE]
R40.20	Unspecified coma
R48.3	Visual agnosia
S01.90XA	Unspecified open wound of unspecified part of head, initial encounter
S04.011A – S04.049A	Injury of optic nerve, right eye – Injury of visual cortex, unspecified eye [initial encounters]
S06.0X0A	Concussion without loss of consciousness, initial encounter
S06.0X1A	Concussion with loss of consciousness of 30 minutes or less, initial encounter
S06.0X9A	Concussion with loss of consciousness of unspecified duration, initial encounter
S06.1X0A – S06.1X9A	Traumatic cerebral edema without loss of consciousness – Traumatic cerebral edema with loss of consciousness of unspecified duration [initial encounters]
S06.330A – S06.339A	Contusion and laceration of cerebrum, unspecified, without loss of consciousness – Contusion and laceration of cerebrum, unspecified, with loss of consciousness of unspecified duration [initial encounters]

ICD-10 Code	Description
S06.360A – S06.389A	Traumatic hemorrhage of cerebrum, unspecified, without loss of consciousness – Contusion, laceration, and hemorrhage of brainstem with loss of consciousness of unspecified duration [initial encounters]
S06.4X0A – S06.4X9A	Epidural hemorrhage without loss of consciousness – Epidural hemorrhage with loss of consciousness of unspecified duration [initial encounters]
S06.5X0A – S06.5X9A	Traumatic subdural hemorrhage without loss of consciousness – Traumatic subdural hemorrhage with loss of consciousness of unspecified duration [initial encounters]
S06.6X0A – S06.6X9A	Traumatic subarachnoid hemorrhage without loss of consciousness – Traumatic subarachnoid hemorrhage with loss of consciousness of unspecified duration [initial encounters]
S06.9X0A – S06.9X6A	Unspecified intracranial injury without loss of consciousness – Unspecified intracranial injury with loss of consciousness greater than 24 hours without return to pre-existing conscious level with patient surviving [initial encounters]
S06.9X9A	Unspecified intracranial injury with loss of consciousness of unspecified duration, initial encounter

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY					
BENEFIT	**EYE CARE**	**POLICY SECTION**	**300 DIAGNOSTIC TESTING**	**POLICY NO**	**300.04**
POLICY TITLE	**VISUAL FIELD TESTING**				
POLICY DATE	**01/01/2024**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**
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	- **There are no exclusions to this policy**				

I. POLICY STATEMENT

Coverage for Visual Field Testing will be provided 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 The purpose of a visual field is to aid in the diagnosis and management (track progression, stability) of a condition, and for all diagnoses, visual field assessment by confrontation should be performed prior to performing formal visual field testing.

2.0 The level and frequency of visual field testing performed should be commensurate with the type and severity of the related condition.

3.0 Visual fields for patients may be indicated and appropriate when there is glaucoma suspicion, previous glaucoma diagnosis, or presence of any factor from column A, or any two (2) factors from column B:

Column I (any 1 complete factor)	Column II (any full 2 factors)
A. Optic Nerve Findings	
i. Segmental thinning of neuroretinal rim	i. C/D ratio > 0.5
ii. Flame hemorrhage of optic disc	ii. C/D ratio difference of > 0.1 between cups
iii. Bared circumlinear vessel/NFL thin or wedge defect	
iv. Atrophy/Pallor	
v. C/D ratio > 0.6	
vi. C/D ratio difference of >0.2 between cups	
B. Intra Ocular Pressure (IOP)	
i. >25 with applanation tonometry/ Icare tonometer	i. >23 with applanation tonometry/ Icare tonometer

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

Column I (any 1 complete factor)	Column II (any full 2 factors)
C. Risk Factors	
i. Previous diagnosis of glaucoma or glaucoma suspect	i. African American race
ii. Previous treatment as glaucoma suspect due to injury	ii. Positive family history of glaucoma
iii. Visual field defect or constriction by patient report, family	iii. History of blunt force ocular trauma/hyphema
	iv. Angle recession
	v. Pseudoexfoliation of lens/heavily pigmented TM on gonioscopy

4.0 It is expected that providers remain informed of current medical literature and/or standards of practice specific to requests for Visual Field Testing.

4.1 Requests are monitored, and when services are requested/performed in excess of established parameters, the provider may be subject to retrospective quality review.

4.1.1 When two (2) or more examinations are performed per year, the medical record must establish the medical necessity for the service and the increased frequency.

5.0 Frequency of examinations for a diagnosis of macular generation or an experienced central vision loss (or to evaluate the results of a surgical intervention or for the possible need for surgical intervention) is dictated by stage of disease or degree of risk factors, just as with glaucoma evaluation.

6.0 Services will be denied for prior authorization requests when:

6.1 Documentation submitted by the requesting provider does not establish the medical necessity per requirements outlined.

6.2 Documentation submitted is incomplete and provider fails to respond to requests for additional clarifying information.

6.2.1 Providers repeatedly failing to submit documentation timely will be referred to Quality.

6.3 Provider and enrollee will receive written notification of adverse determination which outlines right to appeal and instructions on request procedure and applicable timeframes.

III. MEDICAL NECESSITY REQUIREMENTS

1.0 To establish medical necessity all criterion points referenced below and applicable information in Tables 1 and 2 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 Visual Field Testing may be considered medically necessary when any of the following are substantiated by medical record submission:

2.1 Disorder of the eyelids potentially affecting the visual field

2.2 A documented disorder of the optic nerve or the neurological visual pathway

2.3 A recent intracranial hemorrhage, an intracranial mass or a recent measurement of increased intracranial pressure with or without visual symptomatology

2.4 A recently documented occlusion and/or stenosis of cerebral and precerebral arteries, a

recently diagnosed transient cerebral ischemia or giant cell arteritis

2.5 A history of a cerebral aneurysm, pituitary tumor, occipital tumor or other condition potentially affecting the visual fields.

2.6 A visual field defect demonstrated by gross visual field testing (e.g., confrontation testing)

2.7 An initial workup for buphthalmos, congenital ptosis, congenital anomalies of the posterior segment

2.8 A disorder of the orbit, potentially affecting the visual field

2.9 A significant eye injury

2.10 Unexplained visual loss which may be described as "trouble seeing or vision going in and out."

2.11 A pale or swollen optic nerve documented by a recent examination

2.12 New functional limitations which may be due to visual fields loss (i.e., reports by family that patient is running into things).

2.13 Medication treatment (e.g., Plaquenil) which has a high risk of potentially affecting the visual system.

2.14 Initial evaluation for macular degeneration related to central vision loss or has experienced such loss resulting in vision measured at or below 20/70

2.15 Diagnosis and monitoring visual field loss due to blepharoptosis or to disease involving the cornea, lens, retina, optic nerve and intracranial visual pathway.

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

4.0 A current, pertinent history, physical examination (including IOP), appropriate diagnostic testing, and progress notes describing and supporting the covered indication

5.0 Chart note must clearly order test, specify medical necessity (diagnosis), frequency, and need for monitoring/ongoing therapy

6.0 Medical documentation must evidence diagnostic test interpretation, inclusive of the following:

6.1 Date of test

6.2 Date of interpretation

6.3 Findings

6.4 Progression/Stable notation (unless baseline)

6.5 Diagnosis

6.6 Physician Signature

7.0 Comparison on follow-up exam must be maintained in the patient file

IV. TABLE 1 - ICD-10 CODES SUPPORTING MEDICAL NECESSITY

ICD-10 Code	Description
A18.53	Tuberculous chorioretinitis
A52.14 – A52.15	Late syphilitic encephalitis – Late syphilitic neuropathy
A52.71	Late syphilitic oculopathy
B45.1	Cerebral cryptococcosis
B58.00 – B58.09	Toxoplasma oculopathy – Toxoplasmosis, unspecified
C69.20 – C69.32	Malignant neoplasm of retina – Malignant neoplasm of choroid
C69.60 – C69.92	Malignant neoplasm of orbit – Malignant neoplasm of unspecified site of eye
C70.0	Malignant neoplasm of cerebral meninges
C71.0 – C71.9	Malignant neoplasm of cerebrum, except lobes and ventricles - Malignant neoplasm of brain, unspecified
C72.30 – C72.32	Malignant neoplasm of optic nerve
C73	Malignant neoplasm of thyroid gland
C75.1	Malignant neoplasm of pituitary gland

ICD-10 Code	Description
C79.32	Secondary malignant neoplasm of cerebral meninges
D09.20 – D09.22	Carcinoma in situ of eye
D18.02	Hemangioma of intracranial structures
D31.20 – D31.32	Benign neoplasm of retina – Benign neoplasm of choroid
D32.0	Benign neoplasm of cerebral meninges
D33.3	Benign neoplasm of cranial nerves
D34	Benign neoplasm of thyroid gland
D35.2	Benign neoplasm of pituitary gland
D42.0	Neoplasm of uncertain behavior of cerebral meninges
D43.3	Neoplasm of uncertain behavior of cranial nerves
D45	Polycythemia vera
D49.6 – D49.81	Neoplasm of unspecified behavior of brain – Neoplasm of unspecified behavior of retina and choroid
E05.11	Thyrotoxicosis with toxic single thyroid nodule with thyrotoxic crisis or storm
E08.3211 – E08.3599	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema – Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema
E08.37X1 – E08.37X9	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment
E08.65	Diabetes mellitus due to underlying condition with hyperglycemia
E09.311 – E09.319	Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy
E09.3211 – E09.3599	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema – Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema
E09.37X1 – E09.37X9	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment
E09.65	Drug or chemical induced diabetes mellitus with hyperglycemia
E10.311 – E10.319	Type 1 diabetes mellitus with unspecified diabetic retinopathy
E10.3211 – E10.3599	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema – 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
E10.65	Type 1 diabetes mellitus with hyperglycemia
E11.311 – E11.319	Type 2 diabetes mellitus with unspecified diabetic retinopathy
E11.3211 – E11.3599	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema - Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema
E11.37X1 – E11.37X9	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment
E11.65	Type 2 diabetes mellitus with hyperglycemia
E24.1	Nelson's syndrome
E50.0 – E50.9	Vitamin A deficiency with conjunctival xerosis – Vitamin A deficiency, unspecified
E64.1	Sequelae of vitamin A deficiency

ICD-10 Code	Description
F07.81	Postconcussional syndrome
G00.0 – G00.9	Hemophilus meningitis – Bacterial meningitis, unspecified
G01 – G02	Meningitis in bacterial diseases classified elsewhere – Meningitis in other infectious and parasitic diseases classified elsewhere
G03.0 – G03.9	Nonpyogenic meningitis - Meningitis, unspecified
G04.00 – G04.32	Acute disseminated encephalitis and encephalomyelitis (ADEM) – Postimmunization acute necrotizing hemorrhagic encephalopathy
G04.90 – G04.91	Encephalitis and encephalomyelitis, unspecified – Myelitis, unspecified
G05.3	Encephalitis and encephalomyelitis in diseases classified elsewhere
G24.5	Blepharospasm
G35	Multiple sclerosis
G36.0 – G36.1	Neuromyelitis optica [Devic] – Acute and subacute hemorrhagic leukoencephalitis [Hurst]
G36.9	Acute disseminated demyelination, unspecified
G37.0 – G37.5	Diffuse sclerosis of central nervous system – Concentric sclerosis [Balo] of central nervous system
G43.101 – G43D1	Migraine without aura, not intractable – Abdominal migraine
G43.901 – G43.919	Migraine, unspecified, not intractable – Migraine, unspecified, intractable
G45.0	Vertebro-basilar artery syndrome
G45.9	Transient cerebral ischemic attack, unspecified
G46.3 – G46.6	Brain stem stroke syndrome – Pure sensory lacunar syndrome
G80.2	Spastic hemiplegic cerebral palsy
G81.00 – G81.94	Flaccid hemiplegia – Hemiplegia, unspecified
G82.20 – G82.54	Paraplegia – Quadriplegia
G91.0 – G91.4	Communicating hydrocephalus – Hydrocephalus in diseases classified elsewhere
G92.00 – G92.05	Immune effector cell-associated neurotoxicity syndrome
G93.0 – G93.2	Cerebral cysts – Benign intracranial hypertension
G93.40 – G93.41	Encephalopathy, unspecified – Metabolic encephalopathy
G93.5	Compression of brain
H02.31, H02.34	Blepharochalasis, right upper eyelid, Blepharochalasis, left upper eyelid
H02.401 – H02.439	Unspecified ptosis of eyelid – Paralytic ptosis of eyelid
H02.831, H02.834	Dermatochalasis of right upper eyelid, Dermatochalasis of left upper eyelid
H05.011 – H05.049	Cellulitis of orbit – Tenonitis of orbit
H05.111 – H05.119	Granuloma of orbit
H05.211 – H05.269	Displacement (lateral) of globe – Pulsating exophthalmos
H05.311 – H05.829	Atrophy of orbit – Myopathy of extraocular muscles
H30.001 – H30.819	Unspecified focal chorioretinal inflammation – Harada's disease
H30.90 – H30.93	Unspecified chorioretinal inflammation
H31.001 – H31.029	Unspecified chorioretinal scars – Solar retinopathy
H31.101 – H31.23	Unspecified choroidal degeneration – Gyrate atrophy, choroid
H31.301 – H31.429	Unspecified choroidal hemorrhage – Serous choroidal detachment
H31.9	Unspecified disorder of choroid

ICD-10 Code	Description
H32	Chorioretinal disorders in diseases classified elsewhere
H33.001 – H33.129	Unspecified retinal detachment with retinal break – Parasitic cyst of retina
H33.20 – H33.43	Serous retinal detachment – Traction detachment of retina
H34.00 – H34.9	Transient retinal artery occlusion – Unspecified retinal vascular occlusion
H35.011 – H35.079	Changes in retinal vascular appearance – Retinal telangiectasis
H35.171 – H35.179	Retrolental fibroplasia
H35.30 – H35.52	Unspecified macular degeneration – Pigmentary retinal dystrophy
H35.54	Dystrophies primarily involving the retinal pigment epithelium
H35.60 – H35.82	Retinal hemorrhage – Retinal ischemia
H35.9	Unspecified retinal disorder
H36.811 – H36.829	Nonproliferative sickle-cell retinopathy – Proliferative sickle-cell retinopathy
H40.001 – H40.839	Preglaucoma, unspecified – Aqueous misdirection
H42	Glaucoma in diseases classified elsewhere
H44.321 – H44.329	Siderosis of eye
H44.511 – H44.519	Absolute glaucoma
H46.00 – H46.3	Optic papillitis – Toxic optic neuropathy
H46.9	Unspecified optic neuritis
H47.011 – H47.039	Ischemic optic neuropathy – Optic nerve hypoplasia
H47.10 – H47.239	Unspecified papilledema – Glaucomatous optic atrophy
H47.311 – H47.339	Coloboma of optic disc – Pseudopapilledema of optic disc
H49.00 – H49.43	Third [oculomotor] nerve palsy – Progressive external ophthalmoplegia
H51.0 – H51.23	Palsy (spasm) of conjugate gaze – Internuclear ophthalmoplegia
H53.001 – H53.039	Unspecified amblyopia – Strabismic amblyopia
H53.10 – H53.16	Unspecified subjective visual disturbances – Psychophysical visual disturbances
H53.2	Diplopia
H53.40 – H53.439	Unspecified visual field defects – Sector or arcuate defects
H53.461 – H53.489	Homonymous bilateral field defects – Generalized contraction of visual field
H53.51 – H53.55	Achromatopsia - Tritanomaly
H53.60 – H53.63	Unspecified night blindness – Congenital night blindness
H53.71	Glare sensitivity
H53.72	Impaired contrast sensitivity
H53.9	Unspecified visual disturbance
H54.0X33 – H54.8	Blindness right eye category 3, blindness left eye category 3 – Legal blindness, as defined in USA
H55.00 – H55.04	Unspecified nystagmus – Dissociated nystagmus
H55.81	Saccadic eye movements
H57.01	Argyll Robertson pupil, atypical
H59.40 – H59.43	Inflammation (infection) of postprocedural bleb
I60.00 – I60.7	Nontraumatic subarachnoid hemorrhage from carotid siphon and bifurcation – Nontraumatic subarachnoid hemorrhage from unspecified intracranial artery
I60.9	Nontraumatic subarachnoid hemorrhage, unspecified

ICD-10 Code	Description
I61.0 – I61.6	Nontraumatic intracerebral hemorrhage in hemisphere, subcortical – Nontraumatic intracerebral hemorrhage, multiple localized
I61.9	Nontraumatic intracerebral hemorrhage, unspecified
I62.00 – I62.9	Nontraumatic subdural hemorrhage – Nontraumatic intracranial hemorrhage, unspecified
I63.00 – I63.6	Cerebral infarction due to thrombosis of unspecified precerebral artery – Cerebral infarction due to cerebral venous thrombosis, nonpyrogenic
I65.01 – I65.9	Occlusion and stenosis of vertebral artery – Occlusion and stenosis of unspecified precerebral artery
I66.01 – I66.9	Occlusion and stenosis of middle cerebral artery – Occlusion and stenosis of unspecified cerebral artery
I67.1 – I67.2	Cerebral aneurysm, nonruptured – Cerebral atherosclerosis
I67.841	Reversible cerebrovascular vasoconstriction syndrome
I67.9	Cerebrovascular disease, unspecified
I68.0 – I68.2	Cerebral amyloid angiopathy – Cerebral arteritis in other diseases classified elsewhere
M31.5	Giant cell arteritis with polymyalgia rheumatica
Q10.0	Congenital ptosis
Q14.2	Congenital malformation of optic disc
Q15.0	Congenital glaucoma
Q85.00 – Q85.01	Neurofibromatosis, unspecified – Neurofibromatosis, type 1
Q85.03	Schwannomatosis
R44.1	Visual hallucinations
R48.3	Visual agnosia
R51.0 – R51.9	Headache with orthostatic component, not elsewhere classified – Headache, unspecified
S04.011A – S04.12XA	Injury of optic nerve and pathways, initial encounter – Injury of oculomotor nerve, left side, initial encounter (Initial encounters only)
Z76.5	Malingerer [conscious simulation]
Z79.51 – Z79.52	Long term (current) use of inhaled steroids – Long term (current) use of systemic steroids
Z79.899	Long term (current) use of drugs (Plaquenil)

V. TABLE 2 – APPLICABLE CPT CODES

CPT Code	Description
92081	Limited Examination – single stimulus level e.g., tangent screen, Autoplot, Arc perimeter and Octopus 3 or 7
92082	Intermediate Examination – at least 2 isopters e.g., Goldmann perimeter, Semi-quantitative Suprathreshold screening program, Humphrey Suprathreshold automated test, Octopus program 33 and Visual Field automated screener
92083	Comprehensive Examination – static determination of central 30° e.g., Quantitative automated threshold perimetry, Octopus program G-1, 32, or 42, Humphrey visual field analyzer threshold programs 30-2, 24-2, 30/60-2, 10-2 and Macular Red Quantitative Testing

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY					
BENEFIT	**EYE CARE**	**POLICY SECTION**	**300 DIAGNOSTIC TESTING**	**POLICY NO**	**300.05**
POLICY TITLE	**Tear Osmolarity Testing**				
POLICY DATE	**01/01/2024**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**
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	- **Appropriate diagnosis must be utilized, even when/if the test does not require a prior authorization.**				

I. POLICY STATEMENT

Coverage for Tear Osmolarity Testing will be provided 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 and/or MEDICAL NECESSITY

1.0 Tear Osmolarity Testing is "microfluidinic analysis utilizing an integrated collection and analysis device" which is used to manage ocular surface disease associated with dry eyes. Avēsis considers Tear Osmolarity Testing medically necessary when patient presents with signs or symptoms of dry eye as determined by the physician/clinician.

1.1 The code is unilateral and should be billed with a modifier:

1.1.1 Right eye – RT

1.1.2 Left eye – LT

III. MEDICAL NECESSITY REQUIREMENTS for <u>APPLICABLE CPT/HCPCS CODE 83861</u>

1.0 All coverage criteria must be clearly & legibly documented in the patient's medical record and made available to Avēsis upon request.

2.0 Documentation must support the medical necessity of this service as outlined in the Indications and Limitations of Coverage and/or Medical Necessity section of this policy.

3.0 Physician signature on chart note, procedure note, orders, and testing interpretation.

4.0 Medical necessity supported by clinic/progress notes and clinical findings.

5.0 The sign or symptom of disease that prompted the ordering of the test must be documented.

6.0 "Tear osmolarity" must be specifically identified in the medical record and the numerical result of testing and indication of normal or abnormal.

7.0 Medical action taken as a result of the test with reference of test results in the treatment plan.

8.0 The ordering physician must also be the managing physician of patient's medical.

9.0 Test interpretation note must include:

9.1 Date of test

9.2 Findings

9.3 Progression/Stable notation (unless baseline)

9.4 Diagnosis

9.5 Physician signature

10.0 In order to determine medical necessity, Avēsis may request a copy of the clinical records, which must justify the diagnosis listed on the claim and the reason(s) procedure(s) were necessary for planning therapy and monitoring the progress of the disease diagnosed. When the documentation guidelines do not meet the criteria for the service rendered, or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary.

IV. UTILIZATION GUIDELINES

1.0 Physicians are responsible for knowing applicable payer coverage, coding, and reimbursement requirements and policies.

2.0 Generally, Tear Osmolarity Testing is expected to be performed no more than bi-annually, however will be reimbursed if medically necessary.

3.0 CLIA Waiver Certificate must be up-to-date and on file with Avēsis, and available upon request.

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 consider and make a determination based on medical necessity.

ICD-10 Code	Description
H04.121 – H04.129	Dry eye syndrome of lacrimal gland
H11.141 – H11.149	Conjunctival xerosis, unspecified
H16.101 – H16.109	Unspecified superficial keratitis
H16.121 – H16.129	Filamentary keratitis
H16.141 – H16.149	Punctate keratitis
H16.211 – H16.219	Exposure keratoconjunctivitis
H16.221 – H16.229	Keratoconjunctivitis sicca, not specified as Sjögren's
H16.231 – H16.239	Neurotrophic keratoconjunctivitis
H18.831 – H18.839	Recurrent erosion of cornea
M35.00	Sjögren syndrome, unspecified
M35.01	Sjögren syndrome with keratoconjunctivitis

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY							
BENEFIT	**EYE CARE**	**POLICY SECTION**	**300 DIAGNOSTIC TESTING**		**POLICY NO**	**300.06**	
POLICY TITLE	**Electroretinography Testing (ERG)**						
POLICY DATE	**01/01/2024**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**		
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	- **There are no exclusions to this policy**						

I. POLICY STATEMENT

Coverage of Electroretinography (ERG) Testing will be provided only 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 that review criteria and documentation submitted by requesting providers using sound medical judgment.

II. INDICATIONS AND LIMITATION OF COVERAGE for ERG Testing (CPT codes 92273, 92274, and 0509T)

1.0 The full field electroretinogram (ERG) is used to detect loss of retinal function or distinguish between retinal and optic nerve lesions. ERG measures the electrical activity generated by neural and non-neuronal cells in the retina in response to a light stimulus. (CPT 92273)

2.0 Multi-focal electroretinography (mfERG) is a higher resolution form of ERG, enabling assessment of ERG activity in small areas of the retina. (CPT 92274)

3.0 Pattern ERG (PERG) to assess retinal ganglion cell (RGC) function in glaucoma is being investigated.

4.0 ERGs are considered medically necessary for any of the following to diagnose loss of retinal function or distinguish between retinal lesions and optic nerve lesions:

- 4.1.1 Toxic retinopathies, including those caused by intraocular metallic foreign bodies, Vigabatrin and Chlorpromazine
- 4.1.2 Diabetic retinopathy
- 4.1.3 Retinal vascular disease [e.g., Central Retinal Artery Occlusion (CRAO), Central Retinal Vein Occlusion (CRVO), Branch Vein Occlusion (BVO), and sickle cell retinopathy]
- 4.1.4 Autoimmune retinopathies [e.g., Cancer Associated Retinopathy (CAR), Melanoma Associated Retinopathy (MAR), and Acute Zonal Occult Outer Retinopathy (AZOOR)]
- 4.1.5 Retinal detachment
- 4.1.6 Assessment of retinal function after trauma [e.g., vitreous hemorrhage, dense cataracts, and other conditions where the fundus cannot be visualized]
- 4.1.7 Retinitis pigmentosa and related hereditary degenerations
- 4.1.8 Retinitis punctata albescens
- 4.1.9 Leber's congenital amaurosis
- 4.1.10 Choroideremia
- 4.1.11 Gyrate atrophy of the retina and choroid
- 4.1.12 Goldman-Favre syndrome
- 4.1.13 Congenital stationary night blindness

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

4.1.14 X-linked juvenile retinoschisis
4.1.15 Achromatopsia
4.1.16 Cone dystrophy
4.1.17 Disorders mimicking retinitis pigmentosa
4.1.18 Usher Syndrome
4.1.19 Retinal Dystrophies (e.g., Stargardt's disease, Fundus Flavimaculata, North Carolina macular dystrophy, Best's Vitelliform dystrophy, Sorsby's macular dystrophy)

5.0 To detect chloroquine (Aralen) and hydroxychloroquine (Plaquenil) toxicity (mfERG) per AAO guidelines, which does not recommend mfERG for routine primary screening, but can provide objective confirmation of suspected visual loss.

6.0 Pattern ERG (CPTIII code 0509T) may be used to evaluate ganglion cell function for signs of possible glaucoma and other optic neuropathies.

7.0 The use of full field or multifocal ERG (either diagnosis or management) is considered experimental and investigational as the available published clinical evidence does not support clinical value. Therefore, the use of full field and multifocal ERG for glaucoma is non- covered and will be denied as not reasonable and necessary.

8.0 ERG will be covered annually for the patient who is suspected of having the condition outlined in this policy.

9.0 In order to determine medical necessity, Avēsis may request a copy of the clinical records, which must justify the diagnosis listed on the claim and the reason(s) procedure(s) were necessary for planning therapy and monitoring the progress of the disease diagnosed.

10.0 Services will be denied for prior authorization requests when:

10.1 Documentation submitted by the requesting provider does not establish the medical necessity per requirements outlined.
10.2 Documentation submitted is incomplete and provider fails to respond to requests for additional clarifying information.

III. MEDICAL NECESSITY REQUIREMENTS for CPT CODES 92273, 92274

1.0 All coverage criteria must be clearly and legibly documented in the patients record and made available to Avēsis upon request.

2.0 Documentation must support the medical necessity of this service as outlined in the Indications and Limitations of Coverage and /or Medical Necessity section of this policy.

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

4.0 A copy of tests, computer analysis of data, and appropriate storage for future comparison on follow up exam must be maintained in the medical record.

5.0 Medical documentation must evidence diagnostic test interpretation, inclusive of the following.

5.1 Date of test
5.2 Date of interpretation
5.3 Findings
5.4 Progression/Stable notation (unless baseline)
5.5 Diagnosis
5.6 Physician Signature

See pages 3 and 4 for Table 1

IV. TABLE 1: ICD-10 CODES SUPPORTING MEDICAL NECESSITY

***Electroretinogram or electroretinography (ERG)*:**	
CPT codes covered if selection criteria are met:	
92273	Electroretinography (ERG), with interpretation and report; full field (ie, ffERG, flash ERG, Ganzfeld ERG)
ICD-10 codes covered if selection criteria are met:	
D18.09	Hemangioma of other sites [retina]
E08.311	Diabetes mellitus with diabetic retinopathy with macular edema
E08.3211 – E08.3219	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema
E08.3311 – E08.3319	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema
E08.3411 – E08.3419	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema
E08.3511 – E08.3559	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema – Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy
E09.311	Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with macular edema
E09.3211 – E09.3219	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E09.3311 – E09.3319	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E09.3411 – E09.3419	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E09.3511 – E09.3559	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema – Drug or chemical induced diabetes mellitus with stable proliferative diabetic retinopathy
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.3211 – E10.3219	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E10.3311 – E10.3319	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E10.3411 – E10.3419	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E10.3511 – E10.3559	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema – Type 1 diabetes mellitus with stable proliferative diabetic retinopathy
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E11.3211 – E11.3219	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E11.3311 – E11.3319	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E11.3411 – E11.3419	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E11.3511 – E11.3559	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema – Type 2 diabetes mellitus with stable proliferative diabetic retinopathy

E13.311	Other specified diabetes mellitus with unspecified diabetic retinopathy with macular edema
E13.3211 – E13.3219	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E13.3311 – E13.3319	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E13.3411 – E13.3419	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E13.3511 – E13.3559	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema – Other specified diabetes mellitus with stable proliferative diabetic retinopathy
H30.001 – H30.819	Unspecified focal chorioretinal inflammation – Harada's disease
H30.90 – H30.93	Unspecified chorioretinal inflammation
H31.001 – H31.029	Unspecified chorioretinal scars – Solar retinopathy
H31.101 – H31.23	Unspecified choroidal degeneration – Gyrate atrophy, choroid
H31.301 – H31.429	Unspecified choroidal hemorrhage – Serous choroidal detachment
H33.001 – H33.119	Unspecified retinal detachment with retinal break – Cyst of ora serrata
H33.20 – H33.43	Serous retinal detachment – Traction detachment of retina
H34.00 – H34.9	Transient retinal artery occlusion – Unspecified retinal vascular occlusion
H35.00 – H35.079	Unspecified background retinopathy – Retinal telangiectasis
H35.101 – H35.179	Retinopathy of prematurity, unspecified – Retrolental fibroplasia
H35.30 – H35.82	Unspecified macular degeneration – Retinal ischemia
H36.811 – H36.829	Nonproliferative sickle-cell retinopathy – Proliferative sickle-cell retinopathy
H43.00 – H43.319	Vitreous prolapse – Vitreous membranes and strands
H43.811 – H43.829	Vitreous degeneration – Vitreomacular adhesion
H46.00 – H46.3	Optic papillitis – Toxic optic neuropathy
H47.011 – H47.039	Ischemic optic neuropathy – Optic nerve hypoplasia
H47.10 – H47.239	Unspecified papilledema – Glaucomatous optic atrophy
H47.311 – H47.339	Coloboma of optic disc – Pseudopapilledema of optic disc
H53.51	Achromatopsia
H53.63	Congenital night blindness
L10.4	Pemphigus erythematosus (e.g., Senear-Usher syndrome)
Z79.899	Other long term (current) drug therapy (e.g. chloroquine (Aralen) and hydroxychloroquine (Plaquenil toxicity)

CPT codes covered if selection criteria are met:	
92274	Electroretinography (ERG), with interpretation and report; multifocal (mfERG)
ICD-10 codes covered if selection criteria are met:	
B50.0 – B50.9	Plasmodium falciparum malaria with cerebral complications – Plasmodium falciparum malaria, unspecified
T37.2X1A – T37.2X6S	Poisoning by antimalarials and drugs acting on other blood protozoa, accidental (unintentional) – Underdosing of antimalarials and drugs acting on other blood protozoa
Z79.899	Other long term (current) drug therapy [detecting chloroquine (Aralen) and hydroxychloroquine (Plaquenil toxicity]

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY									
BENEFIT	**EYE CARE**	**POLICY SECTION**	**400 STANDARD PROCEDURES**			**POLICY NO**	**400.01**		
POLICY TITLE	**NASOLACRIMAL DUCT PROBING and PUNCTUM DILATION**								
POLICY DATE	**01/01/2024**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**				
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	- **There are no exclusions to this policy**								

I. POLICY STATEMENT

Coverage for Nasolacrimal Duct Probing and Punctum Dilation will be provided 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 Nasolacrimal punctal dilation and nasolacrimal duct probing may be reasonable and necessary when:
- 2.1 Obstruction at or distal to the lacrimal puncta is reasonably suspected to be causing or contributing to symptoms, e.g., excessive tearing (epiphora) or chronic dacryocystitis;
- 2.2 When such measures are required to alleviate symptoms and reduce the likelihood of infection or damage to the lacrimal drainage apparatus.

3.0 Probing of the nasolacrimal duct and/or dilation of the nasolacrimal punctum can be carried out for any of the following indications:
- 3.1 Epiphora (excessive tearing) due to acquired obstruction within the nasolacrimal sac and duct
- 3.2 A mucocele of the lacrimal sac
- 3.3 Chronic dacryocystitis or conjunctivitis due to lacrimal sac obstruction
- 3.4 Lacrimal sac infection that must be relieved before intra-ocular surgery
- 3.5 Other conditions which require probing or dilation for diagnosis or treatment

4.0 In order to determine medical necessity, Avēsis may request a copy of the clinical records, which must justify the diagnosis listed and the reason(s) procedure(s) were necessary for planning therapy and monitoring the progress of the disease diagnosed.

5.0 Coverage and/or reimbursement for performance of a bilateral procedure may be denied or reduced to a unilateral procedure if:
- 5.1 Medical record documentation fails to support that both eyes had qualifying signs or symptoms and lack of proper pre-procedural evaluation.

6.0 Services will be denied for prior authorization requests when:

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

6.1 Documentation submitted by the requesting provider does not establish the medical necessity per requirements outlined.
6.2 Documentation submitted is incomplete and provider fails to respond to requests for additional clarifying information.
6.2.1 Providers repeatedly failing to submit documentation timely will be referred to Quality.
6.3. Provider and enrollee will receive written notification of adverse determination which outlines right to appeal and instructions on request procedure and applicable timeframes.

III. MEDICAL NECESSITY REQUIREMENTS

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 Procedure note must include:
5.1 Procedure performed (name)
5.2 Site
5.3 Anesthetics/meds administered
5.4 Complications, if any
5.5 Post procedure care and precautions taken
4.0 Informed consent stating all pertinent risks must include:
4.1 Date
4.2 Consent to perform
4.3 Consent to waive
4.4 Enrollee or Representative Signature
4.5 Surgeon/Physician Signature
4.6 Witness Signature

IV. UTILIZATION GUIDELINES

1.0 The following listed tests are considered part of a general ophthalmological examination or E&M service will be denied if billed separately:
1.1 Tear production measurement (Schirmer test)
1.2 Tear break-up time (TBUT)
1.3 Jones dye testing or saccharine testing
1.4 Surface staining (fluorescein, rose bengal, lissamine green)

V. ICD-10/CPT CODES SUPPORTING MEDICAL NECESSITY

Table 1: ICD-10 CODES SUPPORTING MEDICAL NECESSITY

ICD-10 Code	Description
H04.201 – H04.209	Unspecified epiphora, lacrimal gland
H04.221 – H04.229	Epiphora due to insufficient drainage, lacrimal gland
H04.411 – H04.419	Chronic dacryocystitis of lacrimal passage
H04.421 – H04.429	Chronic lacrimal canaliculitis of lacrimal passage
H04.431 – H04.439	Chronic lacrimal mucocele of lacrimal passage

ICD-10 Code	Description
H04.541 – H04.549	Stenosis of lacrimal canaliculi
H04.551 – H04.559	Acquired stenosis of nasolacrimal duct
H04.561 – H04.569	Stenosis of lacrimal punctum
H10.401 – H10.409	Unspecified chronic conjunctivitis
H10.421 – H10.429	Simple chronic conjunctivitis
H10.431 – H10.439	Chronic follicular conjunctivitis

Table 2: CPT CODES

CPT Code	Description and Additional Specifics
68801	Dilation of lacrimal punctum, with or without irrigation; reimbursement is limited to only the specific eye(s), right or left, for which these procedures are considered reasonable and necessary.
68810	Probing of nasolacrimal duct, with or without irrigation; reimbursement is limited to only the specific eye(s), right or left, for which these procedures are considered reasonable and necessary.
68811	Probing of nasolacrimal duct, with or without irrigation; requiring general anesthesia
68815	Probing of nasolacrimal duct, with or without irrigation; with insertion of tube or stent
68816	Probing of nasolacrimal duct, with or without irrigation; with transluminal balloon catheter dilation
68840	Probing of lacrimal canaliculi, with or without irrigation
These are unilateral codes and must be billed with appropriate modifiers: • Right eye – RT • Left eye – LT • 50 (if applicable)	

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY					
BENEFIT	**EYE CARE**	**POLICY SECTION**	**400 STANDARD PROCEDURES**	**POLICY NO**	**400.02**
POLICY TITLE	**PUNCTAL OCCLUSION by PLUGS**				
POLICY DATE	**01/01/2024**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**
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	- **There are no exclusions to this policy**				

I. POLICY STATEMENT

Coverage for Punctal Plugs will be provided 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 Punctal occlusion is defined as "closure of the lacrimal punctum; by plug, each"; the word "each" refers to each plug that is placed in a punctum, the opening in the lacrimal canaliculi.

- 2.1 There are 4, located on the upper and lower eyelid margins near the nose, on both eyes. (Excerpt from CMS, AMA CPT® definition.)
- 2.2 Patient qualifies for up to 4 punctal plugs since there are two puncta in each eye; however only the appropriate number of plugs should be placed, as medically necessary. (Refer to Table 2.)

3.0 Use of lacrimal punctum plugs is indicated for:

- 3.1 Dry eye syndrome not adequately responding to conservative treatment with:
  - 3.1.1 artificial tears
  - 3.1.2 warm compresses
  - 3.1.3 ophthalmic cyclosporine
  - 3.1.4 oral Omega-3 supplements
- 3.2 Dry eye symptoms include complaints of:
  - 3.2.1 Dryness
  - 3.2.2 Redness
  - 3.2.3 Burning /discomfort/foreign body sensation
- 3.3 Dry eye symptoms may be contributed to or exacerbated by:
  - 3.3.1 Systemic medications
  - 3.3.2 General health issues (e.g., Sjogren's Syndrome, Rheumatoid Arthritis);
  - 3.3.3 Environmental issues (e.g., cold weather, decreased humidity)
  - 3.3.4 Hormonal/endocrine fluctuations

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

4.0 One temporary plug (collagen) per punctum will be reimbursed, if placed prior to permanent plug (silicone) to determine efficacy of punctal occlusion.

5.0 After placement of collagen plugs, enrollee must report significant improvement in symptoms or show quantitative improvement of clinical findings on follow up exam in order to proceed with permanent plug (silicone) placement.

6.0 Current global period is ten (10) calendar days for punctal plug placement.

6.1 After the 10th day, visits relating to the dry eye syndrome or punctal plug complaints may be appropriately billed as an Evaluation and Management service.

7.0 Repetitive use of temporary lacrimal punctum plugs for treatment of dry eye syndrome when permanent treatment is indicated *will not be reimbursed*.

8.0 Punctal plug placement (collagen or silicone) prior to refractive surgery, without the presence of clinical findings and enrollee complaints as noted above, *will not be reimbursed.*

9.0 Punctal plug placement in patients with any of the following contraindications, *will not be reimbursed*.

9.1 Signs and symptoms of an infection
9.2 Inflammation of eyelids, blepharitis
9.3 Dacryocystitis
9.4 Allergies to bovine collagen or silicone
9.5 Insufficient presence of ocular surface disease, dry eye syndrome, enrollee complaints related to dry eye syndrome.

10.0 Services will be denied for prior authorization requests when:

10.1 Documentation submitted by the requesting provider does not establish the medical necessity per requirements outlined.
10.2 Documentation submitted is incomplete and provider fails to respond to requests for additional clarifying information.
10.2.1 Providers repeatedly failing to submit documentation timely will be referred to Quality.
10.3 Provider and enrollee will receive written notification of adverse determination which outlines right to appeal and instructions on request procedure and applicable timeframes.

III. MEDICAL NECESSITY REQUIREMENTS

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 Evidence of ≥ three (3) of the following clinical findings must be documented:

3.1 Tear break up time < 10 seconds
3.2 Increased tear osmolarity ocular surface dye staining (corneal or bulbar conjunctival)
3.3 Schirmer's test results ≤5mm with anesthesia
3.4 Evidence of corneal decomposition by slit lamp exam

4.0 Evidence of ≥ two (2) of the following clinical findings must be documented:

4.1 Enrollee report of significant lifestyle compromise due to excessive regimen and/or persistent discomfort despite current regimen of conservative treatment (including tears, ophthalmic cyclosporine, warm compresses, etc.)
4.2 Enrollee reports minimum/no improvement in dry eye symptoms with conservative treatment of an adequate trial period

4.3 Clinical findings show minimal/no improvement despite patient compliance with conservative treatment of an adequate trial period
4.4 Enrollee presents with worsening symptoms and/or worsening clinical findings during conservative treatment of an adequate trial period

5.0 Procedure note must include:
5.1 Site of placement
5.2 Punctal plug lot #
5.3 Any difficulties in placement or intolerance to procedure
5.4 Physician signature if separate from progress note

6.0 Informed consent stating all pertinent risks must include:
6.1 Date
6.2 Consent to perform
6.3 Consent to waive
6.4 Enrollee or Representative Signature
6.5 Surgeon/Physician Signature
6.6 Witness Signature

IV. ICD-10 CODES SUPPORTING MEDICAL NECESSITY

ICD-10 Code	Description
H04.121 – H04.129	Dry eye syndrome
H11.141 – H11.149	Conjunctival xerosis, unspecified
H16.001 – H16.029	Unspecified corneal ulcer - Ring corneal ulcer
H16.041 – H16.109	Marginal corneal ulcer - Unspecified superficial keratitis
H16.121 – H16.129	Filamentary keratitis
H16.141 – H16.149	Punctate keratitis
H16.211 – H16.239	Exposure keratoconjunctivitis - Neurotrophic keratoconjunctivitis
H18.831 – H18.839	Recurrent erosion of cornea
M35.00 – M35.01	Sjögren syndrome, unspecified – Sjögren syndrome with keratoconjunctivitis

V. APPLICABLE CPT CODES

CPT Code	Description and Additional Specifics
68761 **Note:** *CPT code 68761 does not differentiate between collagen plugs and silicone plugs. The same code should be billed for either type of plug*	Punctal occlusion is defined as "closure of the lacrimal punctum; by plug, each." The word "each" refers to each plug that is placed in a punctum, the opening in the lacrimal canaliculi. There are 4, located on the upper and lower eyelid margins near the nose, on both eyes. (Excerpt from CMS, AMA CPT® definition.) Patient qualifies for up to 4 punctal plugs since there are two puncta in each eye; however only the appropriate number of plugs should be placed, as medically necessary. **MODIFIERS** It is appropriate to bill for each plug that is placed (one per line) with the appropriate modifier as follows: i. **E1:** Left upper lid ii. **E2:** Left lower lid iii. **E3:** Right upper lid iv. **E4:** Right lower lid

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY							
BENEFIT	**EYE CARE**	**POLICY SECTION**	**400 STANDARD PROCEDURES**		**POLICY NO**	**400.03**	
POLICY TITLE	**VISION THERAPY**						
POLICY DATE	**01/01/2024**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**		
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	- **There are no exclusions to this policy**						

I. POLICY STATEMENT

Coverage for Vision Therapy will be provided when medically indicated and in accordance with applicable state requirements and, as specific to Medicare, national and local coverage determinations. To effectively establish medical necessity for this service, Avēsis aligns its criteria with evidence and consensus based clinical practice guidelines set forth by the American Optometric Association (AOA)[1] and the College of Optometrists in Vision Development (COVD)[2]. The AOA incorporates evidence based best practice and FDA approval and/or recommendations; COVD has a Vision Development and Rehabilitation Review Board comprised of national professional membership. Avēsis Medical Directors and clinical staff are licensed medical professionals and review documentation submitted by requesting providers using sound medical judgment.

II. INDICATIONS AND LIMITATION OF COVERAGE

1.0 Vision therapy is a term used by eye care professionals and refers to orthoptic eye exercises as prescribed by pediatric ophthalmologists and optometrists in the treatment of symptomatic convergence insufficiency and other ocular motor dysfunctions
  1.1 The vision therapy program is based on the results of standardized binocular tests, the needs of the enrollee, and the enrollee's signs and symptoms.

2.0 Vision therapy visits are payable at a maximum of 24 visits per year.

3.0 *State specific requirements apply as outlined in sections below.*

III. MEDICAL NECESSITY REQUIREMENTS FOR APPLICABLE CODES BY STATE

Note: unless specifically referenced by Age, criterion point applicable to both Adult and Children

1.0 To establish medical necessity, relevant diagnoses referenced below in Table 1, page 2 and all criterion points referenced below in Table 2, page 3 must be clearly & legibly documented in the medical record and made available to Avēsis upon 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 Services will be denied for prior authorization requests when:
  2.1 Documentation submitted by the requesting provider does not establish the medical necessity per requirements in Tables 1 and 2, respectively.
    2.1.1 Specific to select E&M codes as outlined below in Table 2 which may vary by state, formal test type, interpretation, and report must be present in chart note.

[1] American Optometric Association https://www.aoa.org/practice/clinical-guidelines/clinical-practice-guidelines?sso=y
[2] College of Optometrists in Vision Development https://www.covd.org/page/Review_Board

2.2 Documentation submitted is incomplete and provider fails to respond to requests for additional clarifying information.
2.2.1 Providers repeatedly failing to submit documentation timely will be referred to Quality.

3.0 The primary eye care practitioner must submit:
3.1 Comprehensive eye examination notes
3.2 Standardized binocular test results
3.3 Treatment plan clearly stating:
3.3.1 Anticipated goals of treatment
3.3.2 Duration of treatment
3.3.3 Frequency of visits
3.3.4 Therapy activities:
i. Performed in office during therapy appointment
ii. Performed and practiced at home by patient

4.0 Formal interpretations and report summaries for certain codes, as defined in the body of this protocol and by certifying state and clinical bodies.

5.0 If applicable, Provider and enrollee will receive written notification of adverse determination which outlines right for appeal and instructions on request procedure and applicable timeframes.

6.0 Providers submitting documentation for post service review for service rendered which exceeds 'Indications and Limitation of Coverage' in Section 1 or documentation submitted does not support medical necessity as outlined in this policy will be denied payment.
6.1 The enrollee must be held harmless; the provider is prohibited from billing enrollee.
6.2 Provider has right to request dispute resolution per policy.

IV. ICD-10 Codes and CPT Codes

Table 1: ICD-10 Codes Supportive of Medical Necessity – Applicable to ALL states

ICD-10 CODE	DESCRIPTION
F80.0 – F80.82	Phonological disorder – Social pragmatic communication disorder
F81.0	Specific reading disorder
F81.81	Disorder of written expression
F81.9	Developmental disorder of scholastic skills, unspecified
F84.0	Autistic disorder
F89	Unspecified disorder of psychological development
H49.00 – H49.43	Third [oculomotor] nerve palsy – Progressive external ophthalmoplegia
H50.011 – H50.042	Monocular esotropia – Monocular esotropia with other noncomitancies
H50.05 – H50.08	Alternating esotropia – Alternating esotropia with other noncomitancies
H50.111 – H50.142	Monocular exotropia – Monocular exotropia with other noncomitancies
H50.15 – H50.18	Alternating exotropia – Alternating exotropia with other noncomitancies
H50.311 – H50.43	Intermittent monocular esotropia – Accommodative component in esotropia
H50.51 – H50.55	Esophoria – Alternating heterophoria
H50.611 – H50.612	Brown's sheath syndrome
H50.621 – H50.689	Inferior oblique muscle entrapment – Extraocular muscle entrapment, unspecified
H50.811 – H50.812	Duane's syndrome
H51.11 – H51.12	Convergence insufficiency - Convergence excess

ICD-10 CODE	DESCRIPTION
H52.511 – H52.539	Internal ophthalmoplegia (complete) (total) – Spasm of accommodation
H53.011 – H53.039	Deprivation amblyopia – Strabismic amblyopia
H53.10	Unspecified subjective visual disturbances
H53.121 – H53.16	Transient visual loss – Psychophysical visual disturbances
H53.2 – H53.34	Diplopia – Suppression of binocular vision
H55.01 – H55.03	Congenital nystagmus – Visual deprivation nystagmus
H55.81	Saccadic eye movements
H93.25	Central auditory processing disorder
R48.0	Dyslexia and alexia
R48.3	Visual agnosia
R94.113	Abnormal oculomotor study

Table 2: CPT CODE AND APPLICABLE CRITERION – NOTE: STATE SPECIFIC VARIABLES APPLY

STATE	District of Columbia	Delaware	Georgia	Illinois Medicaid	Illinois MMP	Kentucky	New Hampshire	North Carolina	Texas
Program	**Medicaid**	**Medicaid**	**Medicaid**	**Medicaid**	**MMP**	**Medicaid & Medicare**	**Medicaid**	**Medicaid**	**Medicaid & CHIP**
CODES	92060 92065 96112 96113 96116 97110 97112 97530	92060 92065 92066 96112 97110 97112 97530	92060 92065 96112 96113 96116 97110 97112 97530	92060 92065 92066 96112 96113 97110 97112 97530	92060 92065 92066 96112 96113 97110 97112 96116 97530	92060 92065 92066 96112 96113 96116 97110 97112 97530	92060 96112 96113 96116 97110 97112 97530	92060 96112 96113 96116 97110 97112 97530	92060 92065 96112 96113 93116 97110 97112 97530

CODE	MEDICAL NECESSITY CRITERION POINT
92060	Sensorimotor examination with multiple measurements of ocular deviation with interpretation and report
92065*	Orthoptic training; performed by a physician or other qualified health care professional ***No additional requirements***
92066*	Orthoptic training; performed under supervision of a physician or other qualified health care professional ***No additional requirements***
96112*	Developmental test administration (including fine and/or gross motor and/or executive level functions) by physician or other qualified health care professional, with interpretation and report; first hour. ***Specific to this code, refer to Section III, 2.1.1 for New Hampshire only***
96113*	Developmental test administration (including fine and/or gross motor and/or executive level functions) by physician or other qualified health care professional, with interpretation and report; each additional 30 minutes. ***Specific to this code, refer to Section III, 2.1.1 for all states above except New Hampshire***

96116*	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, e.g., acquired knowledge, attention, language, memory, planning and problem solving, and visual special abilities) per hour of the psychologist's or physician's time, both face-to-face time with the patient and time interpreting test results preparing report. Performed generally after a screening or questionnaire has revealed an area of deficit or concern. The test requires an interpretation and a formal report outlining the treatment plan. This testing is not billable if performance does not directly influence treatment plan. ***Specific to this code, refer to Section III, 2.1.1 for New Hampshire only***
97110	Therapeutic exercises to develop strength and endurance, range of motion and flexibility. This could be used for working with convergence insufficiency or accommodative dysfunctions
97112	Neuromuscular reeducation of movement, balance coordination, kinesthetic sense, posture and proprioception. This is often used for eccentric fixation training
97530	Therapeutic activities utilized to restore a patient's functional performance with dynamic activities, such as training in specific functional movements or activities performed during daily living routines. This could be used to train a patient with oculomotor/saccadic dysfunctions that are impacting performance. (excerpt from CMS, AMA CPT® definition.)

This table outlines all codes applicable to this policy; however, codes may or may not be applicable to each participating state due to variance in state requirements. Codes which are not appliable to all states and which have state specific variance in requirements are denoted with an asterisk*.
Providers must confirm codes covered for state as outlined above.

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY							
BENEFIT	**EYE CARE**	**POLICY SECTION**	**500 SURGICAL PROCEDURES**		**POLICY NO**	**500.01**	
POLICY TITLE	**ADULT STRABISMUS SURGERY**						
POLICY DATE	**01/01/2024**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**		
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	- **There are no exclusions to this policy**						

I. POLICY STATEMENT

Coverage of Strabismus surgery in adults ≥21 years will be provided when medically indicated and in accordance with applicable state requirements and, as specific to Medicare, national and local coverage determinations. To establish medical necessity Avēsis aligns its criteria with the evidence and consensus based clinical practice guidelines set forth by the American Academy of Ophthalmology (AAO)[1]. The AAO incorporates evidence based best practice and FDA approval and/or recommendations. Avēsis Medical Directors and clinical staff are licensed medical professionals and review criteria and documentation submitted by requesting providers against Avēsis criteria using sound medical judgment.

II. INDICATIONS AND LIMITATION OF COVERAGE

1.0 Strabismus surgery is an inability of one eye to attain binocular vision with the other because of imbalances of muscles of the eyeball; goals of strabismus surgery are to obtain normal visual acuity in each eye, to obtain or improve fusion, to eliminate any associated sensory adaptations or diplopia, and to improve visual fields.

2.0 Repair of strabismus when there is no expected improvement of fusion and visual acuity is considered cosmetic in nature and therefore is excluded from coverage.

3.0 Avēsis will reimburse Strabismus Corrective Surgery one time per eye, per adult, per Enrollee lifetime.

4.0 In order to determine medical necessity, Avēsis may request a copy of the clinical records, which must justify the diagnosis listed on the claim and the reason(s) procedure(s) were necessary for planning therapy and monitoring the progress of the disease diagnosed.

4.1 When the documentation guidelines do not meet the criteria for the service rendered, or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary.

5.0 Services will be denied for prior authorization requests when:

5.1 Documentation submitted by the requesting provider does not establish the medical necessity per requirements outlined.

5.2 Documentation submitted is incomplete and provider fails to respond to requests for additional clarifying information.

5.2.1 Providers repeatedly failing to submit documentation timely will be referred to Quality.

5.3 Provider and enrollee will receive written notification of adverse determination which outlines right for appeal and instructions on request procedure and applicable timeframes.

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

III. MEDICAL NECESSITY REQUIREMENTS

1.0 To establish medical necessity, relevant diagnoses referenced below in Table 1 and all criterion points referenced below must be clearly and legibly documented in the medical record and made available to Avēsis upon request to bill for applicable CPT codes listed in Table 2.

- 1.1 Areas where 'white out' is used are not accepted.
- 1.2 Areas that are 'blacked out' or 'scribbled' 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 Documentation must support Diplopia, or if there is an impairment of peripheral vision due to esotropia or exotropia:

- 2.1 Subjective-patient complaint (frequency, duration, related activities)
- 2.2 Correctable deviation (diopter, direction of prism)

3.0 Surgeon must notate his expectations of restoration of fusion and visual function following corrective surgery to restore alignment.

4.0 Evidence of informed consent stating all pertinent risks and inclusive of the following:

- 4.1 Date
- 4.2 Consent to perform
- 4.3 Consent to waive
- 4.4 Patient or Representative Signature
- 4.5 Surgeon/Physician Signature
- 4.6 Witness Signature

V. ICD-10/CPT Codes SUPPORTING MEDICAL NECESSITY

For any code not listed below, please supply proper documentation with your Prior Authorization request, and Avēsis will consider and make a determination based on medical necessity.

Table 1: APPLICABLE DIAGNOSIS CODES

ICD-10 CODE	DESCRIPTION
C69.90 – C69.92	Malignant neoplasm of eye and adnexa
C71.0 – C71.9	Malignant neoplasm of brain
C79.31 – C79.32	Secondary malignant neoplasm of brain and cerebral meninges
C79.40 – C79.49	Secondary malignant neoplasm of other and unspecified parts of nervous system
D09.20 – D09.22	Carcinoma in situ of eye
D31.40 – D31.42	Benign neoplasm of ciliary body
D33.2	Benign neoplasm of brain, unspecified
D33.3	Benign neoplasm of cranial nerves
D33.4	Benign neoplasm of spinal cord
E05.00 – E05.91	Thyrotoxicosis [hyperthyroidism]
H05.20	Unspecified exophthalmos
H46.2 – H46.3	Nutritional optic neuropathy – Toxic optic neuropathy
H47.011 – H47.019	Ischemic optic neuropathy
H49.00 – H49.03	Paralytic strabismus, Third [oculomotor] nerve palsy
H49.20 – H49.23	Paralytic strabismus, Sixth [abducent] nerve palsy
H50.00 – H50.9	Unspecified esotropia – Unspecified strabismus
H53.19	Other subjective visual disturbances

ICD-10 CODE	DESCRIPTION
H53.2	Diplopia
I60.00 – I60.9	Nontraumatic subarachnoid hemorrhage
I61.0 – I68.2	Nontraumatic intracerebral hemorrhage – Cerebral arteritis in other diseases classified elsewhere
S02.0XXA – S02.11FS	Fracture of vault of skull – Type III occipital condyle fracture, left side
S02.30XA – S02.32XS	Fracture of orbital floor
S05.20XA – S05.22XS	Ocular laceration and rupture with prolapse or loss of intraocular tissue
S05.30XA – S05.32XS	Ocular laceration without prolapse or loss of intraocular tissue
S05.40XA – S05.42XS	Penetrating wound of orbit with or without foreign body
S05.50XA – S05.52XS	Penetrating wound with foreign body of eyeball
S05.60XA – S05.62XS	Penetrating wound without foreign body of eyeball
S05.70XA – S05.72XS	Avulsion of eye
S05.90XA – S05.92XS	Unspecified injury of eye and orbit
S09.0XXA – S09.12XS	Injury of blood vessels of head, not elsewhere classified – Laceration of muscle

TABLE 2: APPLICABLE CPT CODES

CPT	DESCRIPTION
67311	Strabismus surgery, recession or resection procedure: one horizontal muscle
67312	Two horizontal muscles
67314	One vertical muscle (excluding superior oblique)
67316	Two or more vertical muscles (excluding superior oblique)
67318	Strabismus surgery, any procedure, superior oblique muscle
67320	Transposition procedure (e.g., for paretic extraocular muscle), any extraocular muscle (specify) (List separately in addition to code for primary procedure)
67331	Strabismus surgery on patient with previous eye surgery or injury that did not involve the EOM (List separately in addition to code for primary procedure)
67332	Strabismus surgery on patient with scarring of EOM (e.g., prior ocular injury, strabismus or retinal detachment surgery) or restrictive myopathy (e.g., dysthyroid ophthalmopathy) (List separately in addition to code for primary procedure)
67334	Strabismus surgery by posterior fixation suture technique, with or without muscle resection (List separately in addition to code for primary procedure)
67335	Placement of adjustable suture(s) during strabismus surgery including postoperative adjustments of suture(s) – (List separately in addition to code for primary procedure)
67340	Strabismus surgery involving exploration and/or repair of detached EOM (List separately in addition to code for primary procedure)
67343	Release of extensive scar tissue without detaching EOM (separate procedure)
67345	Chemodenervation of EOM

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY							
BENEFIT	**EYE CARE**	**POLICY SECTION**	**500 SURGICAL PROCEDURES**		**POLICY NO**	**500.02**	
POLICY TITLE	**BLEPHAROPLASTY AND PTOSIS REPAIR**						
POLICY DATE	**01/01/2024**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**		
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	- **There are no exclusions to this policy.**						

I. POLICY STATEMENT

Coverage of Blepharoplasty and Ptosis Repair will be provided when medically indicated and in accordance with applicable state requirements and, as specific to Medicare, national and local coverage determinations. To establish medical necessity Avēsis aligns its criteria with the evidence and consensus based clinical practice guidelines set forth by the American Academy of Ophthalmology (AAO)[1]. The AAO incorporates evidence based best practice and FDA approval and/or recommendations. 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 Blepharoplasty and Ptosis Repair are surgical interventions performed on the eyelids, brows, muscles, and surrounding skin to correct functional/physical abnormalities or impairments.

2.0 Blepharoplasty and Ptosis Repair are considered reasonable and necessary when the enrollee:

- 2.1 Has an appropriate medical diagnosis
- 2.2 Presents with a functional/physical impairment and the complaint is directly related to an abnormality of the eyelid(s), position of the eyelid(s), or brow ptosis
- 2.3 When abnormality compromises functionality and patient field of vision

3.0 Generally, Blepharoplasty and Ptosis Repair are expected to be performed no more than once in an enrollee's lifetime, however additional requests will be reviewed and/or reimbursed if medically necessary.

III. ESTABLISHING MEDICAL NECESSITY

1.0 To establish medical necessity, relevant diagnoses referenced below in Table 1, page 2 and all criterion points referenced below and in Table 2, pages 2 and 3 must be clearly & legibly documented in the medical record and made available to Avēsis upon 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 Submitted documentation must include evidence of Informed Consent stating all pertinent risks:

- 2.1 Date
- 2.2 Consent to perform
- 2.3 Consent to waive

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

2.4 Enrollee or Representative Signature
2.5 Surgeon/Physician Signature
2.6 Witness Signature

3.0 Services will be denied for prior authorization requests when:
3.1 Documentation submitted by the requesting provider does not establish the medical necessity per requirements outlined in Table 2, pages 2 and 3.
3.2 Documentation submitted is incomplete and provider fails to respond to requests for additional clarifying information.
3.2.1 Providers repeatedly failing to submit documentation timely will be referred to Quality.

4.0 Provider and enrollee will receive written notification of adverse determination which outlines right for appeal and instructions on request procedure and applicable timeframes.

V. ICD-10/CPT CODES SUPPORTING MEDICAL NECESSITY

TABLE 1: ICD-10 CODES SUPPORTING MEDICAL NECESSITY

For any code not listed below, please supply proper documentation with your Prior Authorization request, and Avēsis will consider and make a determination based on medical necessity.

ICD-10 CODE	DESCRIPTION
H02.31	Blepharochalasis, right upper eyelid
H02.34	Blepharochalasis, left upper eyelid
H02.401 – H02.439	Unspecified ptosis of eyelid – Paralytic ptosis of eyelid
H02.531	Eyelid retraction, right upper eyelid
H02.534	Eyelid retraction, left upper eyelid
H02.831	Dermatochalasis, right upper eyelid
H02.834	Dermatochalasis, left upper eyelid
H57.811	Brow Ptosis, right eye
H57.812	Brow Ptosis, left eye
H57.813	Brow Ptosis, bilateral
L90.5	Scar conditions and fibrosis of skin
Q10.0	Congenital ptosis

Table 2: CPT CODE AND APPLICABLE MEDICAL CRITERION

This table outlines all codes applicable to this policy; however, codes may or may not be applicable to each participating state due to variance in state requirements.
Codes listed below are applicable to all states; however, state specific variance in requirements are denoted with an asterisk*. Providers must confirm codes covered for state as outlined below.

See Next Page

CPT	DESCRIPTION	CODE SPECIFIC MEDICAL CRITERION
15820	Blepharoplasty, lower eyelid	Non-cosmetic reasons
15821	Blepharoplasty, lower eyelid w/ exten herniated fat pad	Non-cosmetic reasons
15822	Blepharoplasty, upper eyelid	1. A pre-operative photograph operative photograph taken of full face, straight on, with pupil reflex) to document the lid is 2mm above the pupil midline (MRD – 1 is 2mm or less), ***and/or*** 2. Automated visual field testing, with lids taped and untaped, showing improvement of at least 30% in the superior visual field points seen, ***and/or*** 3. Excess skin (dermatochalasis/blepharochalasis) touches the lashes
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid	
67900*	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)	1. Other possible causes of ptosis are ruled out such as recent Botox injections; ***and*** 2. Two pre-operative photographs must be present: a. 1st photo – must show eyebrow below the bony superior orbital rim; ***and/or*** b. 2nd photo – must show a taped brow that eliminates the visual field defect; ***and/or*** 3. Automated visual field testing, with lids taped and untaped, showing improvement of at least 30% in the superior visual field points seen
		DELAWARE SPECIFIC REQUIREMENTS: 1. Other possible causes of ptosis are ruled out such as recent Botox injections; ***and*** 2. Pre-operative photographs must be present: a. Good quality frontal photos with gaze in primary position, looking straight ahead; ***and*** b. Must demonstrate a distance of ≤ 2mm from the central corneal reflex to the upper eyelid margin or skin that overhangs the eyelid margin. 3. Automated visual field testing, with lids taped and untaped, showing improvement of at least 30% in the superior visual field points seen
67901	Repair of blepharoptosis, frontalis muscle	Other possible causes of ptosis are ruled out such as recent Botox injections; and A pre-operative photo (full face straight on with pupil reflex) to document the lid is 2mm above the pupil midline (MRD-1 is 2mm or less), and Automated visual field testing, with lids taped and untaped, showing improvement of at least 30% in the superior visual field points seen
67902	Repair of blepharoptosis, frontalis w/ sling	
67903	Repair of blepharoptosis, levator resection, internal approach	
67904	Repair of blepharoptosis, levator resection, external approach	
67906	Blepharoptosis, superior rectus w/ fascial sling	
67908	Blepharoptosis, Fasanella-Sevat type	
67909	Reduction of over correction of ptosis	

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY						
BENEFIT	**EYE CARE**	**POLICY SECTION**	**500 SURGICAL PROCEDURES**		**POLICY NO**	**500.03**
POLICY TITLE	**CATARACT EXTRACTION with INSERTION of IOL**					
POLICY DATE	**01/01/2024**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**	
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	- **There are no exclusions to this policy**					

I. POLICY STATEMENT

Coverage of Cataract Extraction with insertion of IOL (intraocular lens) will be provided when medically indicated and in accordance with applicable state requirements and, as specific to Medicare, national and local coverage determinations. To establish medical necessity Avēsis aligns its criteria with the evidence and consensus based clinical practice guidelines set forth by the American Academy of Ophthalmology (AAO)[1]. The AAO incorporates evidence based best practice and FDA approval and/or recommendations. 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 Cataract Extraction with insertion of IOL is considered reasonable and necessary based on the following:

- 1.1 Cataract causing symptomatic (i.e., causing the patient to seek medical attention) impairment of visual function not correctable with a tolerable change in glasses or contact lenses, lighting, or non-operative means resulting in specific activity limitations and/or participation restrictions including, but not limited to reading, viewing television, driving, or meeting vocational or recreational needs.
- 1.2 Concomitant intraocular disease (e.g., diabetic retinopathy, or intraocular tumor) requiring monitoring or treatment that is prevented by the presence of cataract.
- 1.3 Lens-induced disease threatening vision or ocular health (including, but not limited to, phacomorphic or phacolytic glaucoma).
- 1.4 High probability of accelerating cataract development as a result of a concomitant or subsequent procedure (e.g., pars plana vitrectomy, iridocyclectomy, procedure for ocular trauma) and treatments such as external beam irradiation.
- 1.5 Cataract interfering with the performance of vitreoretinal surgery.
- 1.6 Intolerable anisometropia or aniseikonia uncorrectable with glasses or contact lenses exists as a result of lens extraction in the first eye (despite satisfactorily corrected monocular visual acuity).

2.0 Services will be denied for prior authorization requests when:

- 2.1 Documentation submitted by the requesting provider does not establish the medical necessity per requirements outlined.
- 2.2 Documentation submitted is incomplete and provider fails to respond to requests for additional clarifying information.
  - 2.2.1 Providers repeatedly failing to submit documentation timely will be referred to Quality.
- 2.3 Provider and enrollee will receive written notification of adverse determination which outlines right for appeal and instructions on request procedure and applicable timeframes.

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

III. ESTABLISHING MEDICAL NECESSITY

1.0 To establish medical necessity, relevant diagnoses referenced below in Table 1 and all criterion points referenced below must be clearly & legibly documented in the medical record and made available to Avēsis upon request to bill for applicable CPT codes listed in Table 2.

- 1.1 Areas where 'white out' is used are not accepted.
- 1.2 Areas that are 'blacked out' or 'scribbled' 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 Specific to Section II, 1.1 and 1.2; the procedure will be considered medically necessary when *all of the following* subjective criteria are met:

- 2.1 Enrollee perceives ability to carry out needed or desired activities is impaired, based on:
  - 2.1.1 Enrollee's own assessment of visual disability at distance (e.g., impact on driving, viewing television, and occupational needs) and near disability (e.g., reading, occupational activities requiring near vision);
  - 2.1.2 Enrollee's perception of the disability on lifestyle (e.g., loss of independence, loss of income);
  - 2.1.3 Enrollee's complaints of reduced vision due to glare.
    - i. Confirmation of the reduction of vision from glare should be documented by means consistent with the standards of ophthalmological medical practices.
    - ii. The loss of best corrected acuity due to glare should be verified before the member is considered a candidate for cataract surgery.

3.0 Specific to Section II, 1.1 only; the procedure will be considered medically necessary when all of the following objective criteria is met:

- 3.1 Provider validates that the enrollee's medical and mental health permit the surgery to be performed safely.

4.0 Specific to Section II, 1.2 only; the procedure will be considered medically necessary when all of the following objective criteria is met:

- 4.1 There is a significant loss of visual acuity in bright ambient light or glare
- 4.2 The eye examination confirms that the cataract is the limiting factor for improvement of vision
- 4.3 Provider validates that the enrollee's medical and mental health permit the surgery to be performed safely.

5.0 Specific to Section II, 1.1 only; the procedure will be considered when all of the following educational criteria is met:

- 5.1 Enrollee has been educated about the risks and benefits of cataract surgery, including alternatives to treatment, and determines the expected improvement in visual function outweighs the potential risk, cost, and inconvenience of surgery.

6.0 Specific to Section II, 1.2 only; the procedure will be considered medically necessary when all of the following educational criteria are met:

- 6.1 Enrollee has been educated about the risks and benefits of cataract surgery, including alternatives to treatment, and determines that the expected reduction in disability outweighs the potential risk, cost, and inconvenience of surgery.

7.0 Specific to Section II, 1.3 only;

- 7.1 Enrollee has lens-induced disease (e.g., phacomorphic glaucoma, phacolytic glaucoma, phacoanaphylactic endophthalmitis, dislocated or subluxated lens), or;
- 7.2 There is a need to visualize the fundus (retina):
  - 7.2.1 Diabetes with inability to adequately assess and treat diabetic retinopathy
  - 7.2.2 To facilitate vitrectomy for treatment of other diseases of the retina and vitreous
  - 7.2.3 To prepare for surgical repair of retinal detachment; or
  - 7.2.4 When other testing demonstrates the need for better visualization of the retina to allow diagnosis and treatment of ocular disease.

8.0 Specific to all Indications referenced in Section II, 1.0 – 1.3:

8.1 Best corrected visual acuities must be documented and meet applicable criteria listed above

8.2 Impairment of daily function and extent of impairment must be noted in enrollee's chart

8.3 A complete evaluation and comprehensive eye exam must be performed and submitted with surgical request for authorization.

IV. ICD-10/CPT CODES SUPPORTING MEDICAL NECESSITY

Table 1: ICD-10/CPT CODES SUPPORTING MEDICAL NECESSITY

For any code not listed below, please supply proper documentation with your Prior Authorization request, and Avēsis will consider and make a determination based on medical necessity.

ICD-10 CODE	DESCRIPTION
E08.36	Diabetes mellitus due to underlying condition with diabetic cataract
E09.36	Drug or chemical induced diabetes mellitus with diabetic cataract
E10.36	Type 1 diabetes mellitus with diabetic cataract
E11.36	Type 2 diabetes mellitus with diabetic cataract
H25.011 – H25.819	Cortical age-related cataract – Combined forms of age-related cataract
H25.9	Unspecified age-related cataract
H26.001 – H26.069	Unspecified infantile and juvenile cataract – Combined forms of infantile
H26.101 – H26.139	Unspecified traumatic cataract – Total traumatic cataract
H26.20 – H26.239	Unspecified complicated cataract – Glaucomatous flecks (subcapsular)
H26.30 – H26.33	Drug-induced cataract
H26.9	Unspecified cataract
Q12.0	Congenital cataract

TABLE 2: CPT CODE AND APPLICABLE MEDICAL CRITERION

CPT	DESCRIPTION
66982	Extracapsular cataract removal with insertion of IOL prosthesis (one stage procedure), manual or mechanical technique, complex requiring devices or techniques not generally used in routine cataract surgery or performed on patients in the amblyogenic development stage; without endoscopic cyclophotocoagulation
66983	Intracapsular cataract with insertion of IOL prosthesis (one stage procedure)
66984	Extracapsular cataract removal with insertion of IOL prosthesis (one stage procedure), manual or mechanical technique; without endoscopic cyclophotocoagulation
66987	Extracapsular cataract removal with insertion of IOL prosthesis (one stage procedure), manual or mechanical technique, complex requiring devices or techniques not generally used in routine cataract surgery or performed on patients in the amblyogenic development stage; with endoscopic cyclophotocoagulation
66988	Extracapsular cataract removal with insertion of IOL prosthesis (one stage procedure), manual or mechanical technique; with endoscopic cyclophotocoagulation
66989	Extracapsular cataract rmvl w/ insert of IOL (eg, trabecular meshwork, supraciliary, suprachoroidal) ant seg aqueous drainage device, w/out extraocular reservoir, internal approach, one or more
66991	Extracapsular cataract rmvl w/ insert of IOL (eg, trabec meshwork, supraciliary, suprachoroidal) ant seg aqueous drainage device, w/out extraocular reservoir, internal approach, one or more

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY					
BENEFIT	**EYE CARE**	**POLICY SECTION**	**500 SURGICAL PROCEDURES**	**POLICY NO**	**500.05**
POLICY TITLE	**YAG (Yittrium-Aluminum Garnet) LASER SURGERY**				
POLICY DATE	**01/01/2024**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**
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	- **There are no exclusions to this policy**				

I. POLICY STATEMENT

Coverage for YAG laser surgery will be provide when medically indicated and in accordance with applicable state requirements and, as specific to Medicare, national and local coverage determinations. To establish medical necessity Avēsis aligns its criteria with the evidence and consensus based clinical practice guidelines set forth by the American Academy of Ophthalmology (AAO)[2]. The AAO incorporates evidence based best practice and FDA approval and/or recommendations. 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 YAG Laser Capsulotomy is considered medically indicated according to the level of visual impairment
- 1.1 Opacification affecting functional needs and the potential visual outcome is expected to alleviate the visual complaints.
- 1.2 Documentation exists that best correct visual acuity of 20/30 or worse (secondary to capsular opacification) OR;
- 1.3 Documentation exists of loss of 2 or more lines of acuity since cataract surgery was performed secondary to capsular opacification, with associated enrollee complaints and lifestyle impairments.
- 1.4 Documentation shows results of glare testing evidence a loss of 2 or more lines of visual acuity.
- 1.5 It is expected that this procedure be performed only once per eye per lifetime of an enrollee, unless there is a specific medically necessary need identified.

2.0 YAG Laser Iridotomy/iridectomy (LPI) is considered medically indicated when:
- 2.1 Documentation indicates Angle closed or capable of closure
- 2.2 Findings/history indicative of attacks of narrow angle glaucoma (NAG)

3.0 YAG Laser Trabeculoplasty (SLT) is considered medically indicated when:
- 3.1 It is considered the primary treatment modality for enrollee intolerant to topical and/or systemic medical therapy (e.g., drug allergy)
- 3.2 Primary open angle glaucoma exists which demonstrates progression of optic nerve damage and/or visual field loss despite topical and/or systemic medical therapy.

4.0 Services will be denied for prior authorization requests when:
- 4.1 Documentation submitted by the requesting provider does not establish the medical necessity per requirements outlined.
- 4.2 Documentation submitted is incomplete and provider fails to respond to requests for additional clarifying information.
  - 5.2.1 Providers repeatedly failing to submit documentation timely will be referred to Quality.
- 4.3 Provider and enrollee will receive written notification of adverse determination which outlines right for appeal and instructions on request procedure and applicable timeframes.

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

III. MEDICAL NECESSITY REQUIREMENTS

1.0 To establish medical necessity, relevant diagnoses referenced below in Table 1a, b, c and all criterion points referenced below must be clearly and legibly documented in the medical record and made available to Avēsis upon request to bill for applicable CPT codes listed in Table 2.

- 1.1 Areas where 'white out' is used are not accepted.
- 1.2 Areas that are 'blacked out' or 'scribbled' 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 Documentation for YAG Laser Capsulotomy must support indications for treatment outlined in Section II, 1.0 in full, and all of the following:

- 2.1 Impairment of daily function and extent of impairment due to capsular opacification must be noted in chart history;
- 2.2 A complete evaluation and comprehensive eye exam must be performed.

3.0 Documentation for YAG Laser Iridotomy/iridectomy (LPI) must support indications for treatment outlined in Section II, 2.0 in full, and all of the following:

- 3.1 Slit lamp examination of ocular media
- 3.2 Slit lamp examination of iris (neovascularization, pupillary block)
- 3.3 Gonioscopy findings including detailed description of angle depth and approach for entire angle

4.0 Documentation for YAG Laser Trabeculoplasty (SLT) must support indications for treatment outlined in Section II, 3.0 in full, and all of the following:

- 4.1 Comprehensive eye examination including a gonioscopy and documented progression of optic nerve changes in a dilated fundus exam, if any;
- 4.2 Visual Field testing with interpretation should document progression of field loss, if any.

IV. ICD-10 CODES AND CPT CODES

TABLE 1: ICD-10 CODES SUPPORTING MEDICAL NECESSITY

For any code not listed below, please supply proper documentation with your prior authorization request (if applicable), and Avēsis will consider and make a determination based on medical necessity.

1a: YAG Laser Capsulotomy

ICD-10 CODE	DESCRIPTION
H26.40	Unspecified secondary cataract
H26.411 – H26.419	Soemmering's ring
H26.491 – H26.493	Other secondary cataract

1b: YAG Peripheral Iridotomy/Iridectomy (LPI):

ICD-10 CODE	DESCRIPTION
H40.031 – H40.039	Anatomical narrow angle
H40.061 – H40.069	Primary angle closure without glaucoma damage
H40.20X0 – H40.20X4	Unspecified primary angle-closure glaucoma
H40.211 – H40.219	Acute angle-closure glaucoma
H40.2210 – H40.2294	Chronic angle-closure glaucoma

ICD-10 CODE	DESCRIPTION
H40.231 – H40.239	Intermittent angle-closure glaucoma
H40.241 – H40.249	Residual stage of angle-closure glaucoma

1c: YAG Laser Trabeculoplasty (SLT):

ICD-10 CODE	DESCRIPTION
H40.011 – H40.019	Open angle with borderline findings, low risk
H40.021 – H40.029	Open angle with borderline findings, high risk
H40.051 – H40.059	Ocular hypertension
H40.10X0 – H40.10X4	Unspecified open-angle glaucoma
H40.1110 – H40.1194	Primary open-angle glaucoma
H40.1210 – H40.1294	Low-tension glaucoma
H40.1310 – H40.1394	Pigmentary glaucoma
H40.1410 – H40.1494	Capsular glaucoma with pseudoexfoliation of lens
H40.151 – H40.159	Residual stage of open-angle glaucoma
H40.60X0 – H40.63X4	Glaucoma secondary to drugs
Q15.0	Congenital glaucoma

TABLE 2: APPLICABLE CPT CODES

CPT	DESCRIPTION
66821	Discission of secondary membranous cataract (opacified posterior lens capsule and/or anterior hyaloid); laser surgery (e.g., YAG Laser Capsulotomy) (1 or more stages)
66761	Iridotomy/iridectomy by laser surgery (e.g., for glaucoma) (per session) (LPI)
65855	Trabeculoplasty by laser surgery (SLT)

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY					
BENEFIT	**EYE CARE**	**POLICY SECTION**	**600 INJECTIONS, INSERTS & IMPLANTS**	**POLICY NO**	**600.01**
POLICY TITLE	**BEOVU® (brolucizumab-dbll) INTRAVITREAL INJECTION**				
POLICY DATE	**01/01/2024**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**
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 Delaware, as BEOVU® is not a covered benefit.** - **This policy is not applicable to Medicaid in the state(s) of North Carolina, as BEOVU® 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 BEOVU® (brolucizumab-dbll) 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)

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

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

4.0 BEOVU® (brolucizumab-dbll) will not be covered at a frequency that exceeds what is medically reasonable and necessary.

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

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

6.0 Physicians are responsible for knowing applicable payer coverage, coding, and reimbursement requirements and policies.

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

III. TREATMENT RECOMMENDATIONS

1.0 The recommended dose for BEOVU® (brolucizumab-dbll) is:
  1.1 One (1) dose of 6 mg (0.05 mL of 120 mg/ml solution) administered by intravitreal injection, approximately every 25-31 days) for the first three (3) injections followed by one (1) dose of 6 mg (0.05 mL of 120 mg/ml solution) once every 8-12 weeks.
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 BEOVU® (brolucizumab-dbll) preoperatively, and when it may reasonably be restarted after surgery.
  2.2 Some published data excluded patients with a history of myocardial infarction or uncontrolled hypertension.
3.0 Endophthalmitis and retinal detachments may occur following intravitreal injections.
  3.1 Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay.
4.0 Increases in intraocular pressure (IOP) have been seen within 30 minutes of an intravitreal injection.
5.0 There is a potential risk of arterial thromboembolic events (ATE) following intravitreal use of VEGF inhibitors.

IV. MEDICAL NECESSITY REQUIREMENTS for <u>APPLICABLE HCPCS CODE J0179</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 BEOVU® (brolucizumab-dbll)
4.0 Medical documentation must clearly state the clinical indication/medical necessity for the BEOVU® (brolucizumab-dbll) 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 BEOVU® (brolucizumab-dbll) 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 BEOVU® (brolucizumab-dbll), 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
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with(out) 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

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY					
BENEFIT	**EYE CARE**	**POLICY SECTION**	**600 INJECTIONS, INSERTS & IMPLANTS**	**POLICY NO**	**600.02**
POLICY TITLE	**BOTOX® (botulinum toxin) INJECTION**				
POLICY DATE	**01/01/2024**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**
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 BOTOX® does not require a prior authorization, however, must be billed appropriately with applicable diagnosis code located in Section V.**				

I. POLICY STATEMENT

Coverage of BOTOX® (botulinum toxin) injection will be provided 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 may be indicated for treatment when enrollees have the following ocular conditions:

- 2.1 Blepharospasm
- 2.2 Chronic Migraine
- 2.3 Orofacial Dyskinesia

3.0 BOTOX® (botulinum toxin) injections will not be covered at a frequency that exceeds what is medically reasonable and necessary.

4.0 It is usually considered not medically necessary to give botulinum toxin injections for spastic conditions more frequently than every 90 days.

- 4.1 There may be slight variation based on FDA indications for a particular product.

5.0 Authorizations will cover up to 600 units per treatment.

- 5.1 Additional injections requested will be considered a new request for service, requiring prior authorization review and determinations made on a case-by-case basis and subject to medical necessity.

6.0 It is expected that providers remain informed of current medical literature and/or standards of practice specific to requests for BOTOX® (botulinum toxin) injections.

- 6.1 Requests are monitored, and when services are requested/performed in excess of established parameters, the provider may be subject to retrospective quality review.

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

III. TREATMENT RECOMMENDATIONS AND PARAMETERS

1.0 Botulinum toxins are potent neuromuscular blocking agents that are useful in treating various focal muscle spastic disorders and excessive muscle contractions, such as dystonia, spasms, and twitches.
- 1.1 These agents produce a presynaptic neuromuscular blockade by preventing the release of acetylcholine from the nerve endings.
  - 1.1.1 Since the resulting chemical denervation of muscle produces local paresis or paralysis, selected muscles can be treated.
  - 1.1.2 The agents are used in the treatment of overactive skeletal muscles (e.g., hemifacial spasm, dystonia and spasticity).

2.0 The patient who has a spastic or excessive muscular contraction condition is usually started with a low dose of botulinum toxin.
- 2.1 Other spastic or muscular contraction conditions, such as eye muscle disorders, (e.g., blepharospasm) may require lesser amounts of botulinum toxin.

3.0 For larger muscle groups, it is generally agreed that once a maximum dose per site has been reached and there is no response, the treatment is discontinued.
- 3.1 The treatments may be resumed at a later date.

4.0 With response, the effect of the injections generally lasts for three months at which time the patient may require repeat injections to control the spastic or excessive muscular condition.

5.0 Migraine headaches are described as an intense pulsing or throbbing pain in one area of the head.
- 5.1 The headaches are often accompanied by nausea, vomiting, and sensitivity to light and sound.
- 5.2 Migraines usually begin with intermittent headache attacks 14 days or fewer each month (episodic migraine), but some patients go on to develop the more disabling chronic migraine.
- 5.3 To treat chronic migraines, botulinum toxin is given approximately every 12 weeks as multiple injections around the head and neck to try to dull future headache symptoms.
- 5.4 Botulinum toxin has not been shown to work for the treatment of migraine headaches that occur 14 days or less per month, or for other forms of headache.

IV. MEDICAL NECESSITY REQUIREMENTS for APPLICABLE HCPCS CODE J0585

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 A baseline visual status (visual acuity) must be provided.

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

5.0 Specific to Migraine Protocol, the following must be documented:
- 5.1 Headache frequency clearly noting headaches on most days of the month
- 5.2 Chronic presence of migraines, clearly noted by history
- 5.3 Anticipated frequency must clearly be noted
- 5.4 Subsequent evaluation & support of the clinical effectiveness of BOTOX® (botulinum toxin)

6.0 Procedure note must include:
- 6.1 Dosage (number of units) of BOTOX® (botulinum toxin) given
- 6.2 Site of injection
- 6.3 Route of administration
- 6.4 Injection Lot Number

6.5 Injection expiration date
6.6 Physician Signature

7.0 Medical documentation must evidence full informed consent, outlining all pertinent risks, inclusive of the following:

7.1 Date
7.2 Consent to perform
7.3 Consent to waive
7.4 Patient or Representative Signature
7.5 Surgeon/Physician Signature
7.6 Witness Signature

V. ICD-10 CODES SUPPORTING MEDICAL NECESSITY

ICD-10 Code	Description
G24.4	Idiopathic orofacial dystonia
G24.5	Blepharospasm
G43.011 – G43.019	Migraine without aura, intractable
G43.101 – G43.109	Migraine with aura, not intractable
G43.111 – G43.119	Migraine with aura, intractable
G43.701 - G43.709	Chronic migraine without aura, not intractable
G43.711 – G43.719	Chronic migraine without aura, intractable
G43.E01 – G43.E09	Chronic migraine with aura, not intractable
G43.E11 – G43.E19	Chronic migraine with aura, intractable
G51.2	Melkersson's syndrome
G51.31 – G51.39	Clonic hemifacial spasm
G51.4	Facial myokymia
G81.10 – G81.14	Spastic hemiplegia
H02.041 – H02.046	Spastic entropion of eyelid
H02.141 – H02.146	Spastic ectropion of eyelid
H49.00 – H49.03	Third [oculomotor] nerve palsy
H49.10 – H49.13	Fourth [trochlear] nerve palsy
H49.20 – H49.23	Sixth [abducent] nerve palsy
H49.30 – H49.33	Total (external) ophthalmoplegia
H49.40 – H49.43	Progressive external ophthalmoplegia
H49.811 – H49.819	Kearns-Sayre syndrome
H49.9	Unspecified paralytic strabismus
H51.20 – H51.23	Internuclear ophthalmoplegia

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY					
BENEFIT	**EYE CARE**	**POLICY SECTION**	**600 INJECTIONS, INSERTS & IMPLANTS**	**POLICY NO**	**600.03**
POLICY TITLE	**DEXTENZA® (fluocinolone acetonide) OPHTHALMIC INSERT**				
POLICY DATE	**01/01/2022**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**
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 Delaware, District of Columbia, Kentucky and Texas, as DEXTENZA® is not a covered benefit.** - **This policy is not applicable to Medicaid in the state(s) of North Carolina, as DEXTENZA® does not require a prior authorization, however, must be billed appropriately with applicable diagnosis code located in Section IV.**				

I. POLICY STATEMENT

Coverage of DEXTENZA® (dexamethasone) ophthalmic Insert will be provided 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 that 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 DEXTENZA® is a preservative-free intracanalicular insert that is inserted in the lower lacrimal punctum, a natural opening in the eye lid, and into the canaliculus. DEXTENZA® is designed to deliver a tapered dose of steroid (dexamethasone) to the ocular surface for up to 30 days. Following treatment, DEXTENZA® resorbs and exits the nasolacrimal system without the need for removal.

3.0 DEXTENZA® is designed to deliver a dexamethasone 0.4 mg dose to the ocular surface for up to 30 days without preservatives.

4.0 Avēsis considers the use of DEXTENZA® reasonable and necessary for the following conditions.

- 4.1 The treatment of ocular inflammation and pain following cataract surgery.
- 4.2 The treatment of ocular itching associated with allergic conjunctivitis under the following conditions:
  - 4.2.1 A chief complaint of itching of the eyes consistent with seasonal or other allergies, AND
  - 4.2.2 A documented history of failure of decrease in symptoms using OTC or prescription allergy drops AND
  - 4.2.3 A documented history of failure of steroid eye drops OR
  - 4.2.4 Inability to administer any prescribed eye drops.
  - 4.2.5 Clinical findings that correlate with symptoms such as extreme conjunctival hyperemia or significant follicular reaction.

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

5.0 DEXTENZA® is contraindicated in patients with active corneal, conjunctival or canalicular infections, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella; mycobacterial infections; fungal diseases of the eye, and dacryocystitis.

6.0 Patients should be closely monitored for adverse reactions for the treatment of:

6.1 Ocular Inflammation and Pain following ophthalmic surgery including but not limited to iritis, IOP increase, visual acuity reduction, CME, corneal edema, eye pain and conjunctival hyperemia

6.2 Itching associated with allergic conjunctivitis including but not limited to increased IOP, increased lacrimation, eye discharge and reduced visual acuity.

III. MEDICAL NECESSITY REQUIREMENTS for <u>APPLICABLE HCPCS CODE J1096</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.

1.2.1.1 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.

4.0 Medical documentation must fill informed consent, outlining all pertinent risks, inclusive of the following:

4.1 Date

4.2 Consent to perform

4.3 Consent to waive

4.4 Patient or Representative Signature

4.5 Surgeon/Physician Signature

4.6 Witness Signature

IV. HCPCS/ICD-10 CODES SUPPORTING MEDICAL NECESSITY

***DEXTENZA® (dexamethasone) OPHTHALMIC INSERT*:**	
HCPCS codes covered if selection criteria are met:	
J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg
ICD-10 codes covered if selection criteria are met:	
G89.18	Other acute postprocedural pain [ocular pain following ophthalmic surgery]
H10.10 - H10.13	Acute atopic conjunctivitis
H10.45	Other chronic allergic conjunctivitis
H57.10 - H57.13	Ocular pain [ocular pain following ophthalmic surgery]

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY					
BENEFIT	**EYE CARE**	**POLICY SECTION**	**600 INJECTIONS, INSERTS & IMPLANTS**	**POLICY NO**	**600.04**
POLICY TITLE	**DURYSTA™ (Bimatoprost Implant) IMPLANT**				
POLICY DATE	**01/01/2024**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**
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 Delaware and Louisiana, as DURYSTA™ is not a covered benefit.** - **This policy is not applicable to Medicaid in the state(s) of North Carolina, as DURYSTA™ does not require a prior authorization, however, must be billed appropriately with applicable diagnosis code located in Section IV.**				

I. POLICY STATEMENT

Coverage of DURYSTA™ (Bimatoprost implant) will be provided only 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 that 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.

1.1 New enrollee ninety (90) day continuity applies.

2.0 DURYSTA™ (Bimatoprost implant) is a biodegradable sustained-release implant that continuously delivers the prostaglandin analog Bimatoprost within the eye to reduce and maintain intraocular pressure (IOP).

2.1 The implant contains ten (10) micrograms of Bimatoprost administered via bicameral implant and absorbs naturally over time.

3.0 DURYSTA™ (Bimatoprost implant) will be considered for coverage in the following:

3.1 For enrollees with established diagnosis of:

3.1.1 open angle glaucoma

3.1.2 ocular hypertension;

3.2 For enrollees who:

3.2.1 demonstrate an inability to use eyedrops for the treatment of glaucoma; or,

3.2.2 have a significant medical condition that would prevent the instillation of eye drops for the treatment of glaucoma.

4.0 Coverage for DURYSTA™ (Bimatoprost implant) is limited to a frequency of one implant per eye per lifetime.

5.0 It is expected that providers remain informed of current medical literature and/or standards of practice specific to requests for DURYSTA™ (Bimatoprost implant).

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

III. MEDICAL NECESSITY REQUIREMENTS for APPLICABLE HCPCS CODE J7351

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.

4.0 Medical documentation must clearly evidence that enrollee has been screened for the following medical conditions that would contraindicate the use of DURYSTA™ including but are not limited to:
- 4.1 Active or suspected ocular infection
- 4.2 Diagnosis of corneal endothelial cell dystrophy (e.g., Fuchs Dystrophy)
- 4.3 History of corneal transplantation or endothelial cell transplant
- 4.4 Absent or posterior lens capsule
- 4.5 Hypersensitivity to Bimatoprost or any other component of DURYSTA™.

5.0 Medical documentation must clearly evidence that the following tests have been conducted and interpreted to firmly establish supporting diagnosis:
- 5.1 Visual field testing
- 5.2 Optical Coherence Tomography (OCT)
- 5.3 Intraocular Pressure
- 5.4 Gonioscopy and evaluation of the optic nerve

6.0 Procedure note must include:
- 6.1 Actual administered dosage of DURYSTA™ 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 evidence number 7.0 above along with full informed consent, outlining all pertinent risks, inclusive of the following:
- 7.1 Date
- 7.2 Consent to perform
- 7.3 Consent to waive
- 7.4 Patient or Representative Signature
- 7.5 Surgeon/Physician Signature
- 7.6 Witness Signature

IV. 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
H40.051 – H40.059	Ocular hypertension
H40.10X0 – H40.10X4	Unspecified open-angle glaucoma
H40.1110 – H40.1194	Primary open-angle glaucoma, right eye – unspecified eye
H40.1310 – H40.1394	Pigmentary glaucoma, right eye – unspecified eye
H40.1410 – H40.1494	Capsular glaucoma with pseudoexfoliation of lens, right eye – unspecified eye

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) or EYLEA® HD (aflibercept) INTRAVITREAL INJECTION**				
POLICY DATE	**04/01/2024**	**REVISION DATE**	**06/05/2024**	**APPROVAL DATE**	**01/02/2025**
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) or EYLEA® HD (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 (MEfRVO)

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

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

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

5.0 Authorizations will be given for the time period of 12 months and will cover up to 26 injections for EYLEA® (aflibercept) and up to 16 injections for EYLEA® HD (aflibercept) during that time period.

- 5.1 Additional injections requested will be subject to review and determinations will be made on a case-by-case basis and subject to medical necessity.
- 5.2 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.

3.0 The recommended dose for EYLEA® HD (aflibercept) is:

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

3.1.1 8 mg (0.07 mL of 114.3 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days +/- 7 days) for the first three doses, followed by 8 mg (0.07 mL of 114.3 mg/mL solution) via intravitreal injection once every 8 to 16 weeks, +/- 1 week.

3.2 Diabetic Macular Edema (DME)

3.2.1 8 mg (0.07 mL of 114.3 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days +/- 7 days) for the first three doses, followed by 8 mg (0.07 mL of 114.3 mg/mL solution) via intravitreal injection once every 8 to 16 weeks, +/- 1 week.

3.3 Diabetic Retinopathy (DR)

3.3.1 8 mg (0.07 mL of 114.3 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days +/- 7 days) for the first three doses, followed by 8 mg (0.07 mL of 114.3 mg/mL solution) via intravitreal injection once every 8 to 12 weeks, +/- 1 week.

IV. MEDICAL NECESSITY REQUIREMENTS for <u>APPLICABLE HCPCS CODES J0177 and 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) or EYLEA® HD (aflibercept)

4.0 Medical documentation must clearly state the clinical indication/medical necessity for the EYLEA® (aflibercept) or EYLEA® HD (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) or EYLEA® HD (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) or EYLEA® HD (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

ICD-10 Code	Description
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
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 with 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

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY									
BENEFIT	**EYE CARE**	**POLICY SECTION**	**600 INJECTIONS, INSERTS & IMPLANTS**			**POLICY NO**	**600.06**		
POLICY TITLE	**ILUVIEN® (fluocinolone acetonide) INTRAVITREAL IMPLANT**								
POLICY DATE	**01/01/2020**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**				
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 Delaware as ILUVIEN® is not a covered benefit.** - **This policy is not applicable to Medicaid in the state(s) of North Carolina, as ILUVIEN® does not require a prior authorization, however, must be billed appropriately with applicable diagnosis code located in Section V.**								

I. POLICY STATEMENT

Coverage of Iluvien® (fluocinolone acetonide) Intravitreal Implant will be provided 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 that 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 Iluvien® (fluocinolone acetonide) Intravitreal Implant is a non-bioerodable intravitreal implant in a drug delivery system containing 0.19 mg fluocinolone acetonide, designed to release fluocinolone acetonide at an initial rate of 0.25 µg/day and lasting 36 months.

3.0 Iluvien® (fluocinolone acetonide) Intravitreal Implant contains a corticosteroid and is indicated for the treatment of diabetic macular edema in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure.

4.0 Iluvien® (fluocinolone acetonide) Intravitreal Implant will be considered only when evidence is provided that the enrollee Avastin trial for a minimum of three months and showed fewer than four (4) lines of improvement in visual acuity.

- 4.1 Detailed documentation of medical necessity for switch from Avastin to Iluvien® (fluocinolone acetonide) Intravitreal Implant is required.
- 4.2 Avēsis may request clinical documentation to justify the diagnosis listed on the request and the reason(s) procedure(s) were necessary for planning therapy and monitoring the progress of the disease diagnosed.
- 4.3 This service may be subject to retrospective review for validation purposes.

5.0 Iluvien® (fluocinolone acetonide) Intravitreal Implant will be considered only when evidence is provided that the enrollee has history of corticosteroid use without onset of intraocular pressure (IOP).

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

6.0 It is expected that providers remain informed of current medical literature and/or standards of practice specific to requests for Iluvien® (fluocinolone acetonide) Intravitreal Implant

III. TREATMENT RECOMMENDATIONS

1.0 Patient post-injection assessment & monitoring for endophthalmitis & IOP may consist of:
- 1.1 Monitoring intraocular pressure (IOP) for minimum thirty (30) minutes post injection
- 1.2 Optic nerve perfusion notation
- 1.3 Bio-microscopy 2-7 days post injection
- 1.4 Provision of patient counseling specific to risk for endophthalmitis and 'red flag' symptoms

IV. MEDICAL NECESSITY REQUIREMENTS for <u>APPLICABLE HCPCS CODE J7313 (0.01 milligram)</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 Iluvien® (fluocinolone acetonide) Intravitreal Implant.

4.0 Medical documentation must clearly state the clinical indication/medical necessity for Iluvien® (fluocinolone acetonide) Intravitreal Implant.

5.0 Procedure note must include:
- 5.1 Actual administered dosage of Iluvien® (fluocinolone acetonide) Intravitreal Implant given
- 5.2 Site of injection
- 5.3 Route of administration
- 5.4 Injection Lot #
- 5.5 Injection expiration date
- 5.6 Post-injection vision ≥ CF

6.0 Medical documentation must evidence number 7.0 above along with full informed consent, outlining all pertinent risks, inclusive of the following:
- 6.1 Date
- 6.2 Consent to perform
- 6.3 Consent to waive
- 6.4 Patient or Representative Signature
- 6.5 Surgeon/Physician Signature
- 6.6 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
E08.311	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema

ICD-10 Code	Description
E08.3211 – E08.3213	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema
E08.3311 – E08.3313	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema
E08.3411 – E08.3413	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema
E08.3511 – E08.3513	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema
E09.311	E09.311 Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with macular edema
E09.3211 – E09.3213	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E09.3311 – E09.3313	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E09.3411 – E09.3413	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E08.3511 – E08.3513	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.3211 – E10.3213	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E10.3311 – E10.3313	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E10.3411 – E10.3413	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E10.3511 – E10.3513	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E11.3211 – E11.3213	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E11.3311 – E11.3313	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E11.3411 – E11.3413	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E11.3511 – E11.3513	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema
E13.311	Other specified diabetes mellitus with unspecified diabetic retinopathy with macular edema
E13.3211 – E13.3213	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E13.3311 – E13.3313	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E13.3411 – E13.3413	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E13.3411 – E13.3413	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E13.3511 – E13.3513	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY					
BENEFIT	**EYE CARE**	**POLICY SECTION**	**600 INJECTIONS, INSERTS & IMPLANTS**	**POLICY NO**	**600.07**
POLICY TITLE	**LUCENTIS® (ranibizumab) INTRAVITREAL INJECTION**				
POLICY DATE	**01/01/2020**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**
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 for the state(s) of Louisiana as Lucentis® is not a covered benefit.** - **This policy is not applicable to Medicaid in the state(s) of North Carolina, as LUCENTIS® does not require a prior authorization, however, must be billed appropriately with applicable diagnosis code located in Section V.**				

I. POLICY STATEMENT

Coverage of Lucentis® (ranibizumab) intravitreal injection will be provided 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)
- 2.3 Macular edema associated with retinal vein occlusion.

3.0 Lucentis® (ranibizumab)will not be covered at a frequency that exceeds what is medically reasonable and necessary.

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

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

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

III. TREATMENT RECOMMENDATIONS

1.0 The recommended dose for Lucentis® (ranibizumab) is:

- 1.1 3 mg or 5 mg intravitreal injection once every 4 weeks (monthly) for the first 12 weeks (3 months)
- 1.2 Although Lucentis® may be dosed as frequently as 2 mg every 4 weeks (monthly), minimal efficacy (1-2 letter gain) was demonstrated when Lucentis® (ranibizumab) was dosed every 4 weeks as compared to every 8-12 weeks.

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 Lucentis® (ranibizumab) preoperatively, and when it may reasonably be restarted after surgery.

IV. MEDICAL NECESSITY IS ESTABLISHED for <u>APPLICABLE CODE J2778</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 Lucentis® (ranibizumab) 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 Lucentis® (ranibizumab) 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 In accordance with the prescribing information for Lucentis® (ranibizumab), 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 Lucentis® (ranibizumab), 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.

Code	Description
B39.4 – B39.9	Histoplasmosis capsulati, unspecified – Histoplasmosis, unspecified
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.3211 – E10.3219	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E10.3311 – E10.3319	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E10.3411 – E10.3419	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E10.3511 – E10.3519	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema
E10.37X1 – E10.37X9	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E11.3211 – E11.3219	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E11.3311 – E11.3319	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E11.3411 – E11.3419	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E11.3511 – E11.3519	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema
E11.37X1 – E11.37X9	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment
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
H35.351 – H35.359	Cystoid macular degeneration
H35.81	Retinal edema

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY					
BENEFIT	**EYE CARE**	**POLICY SECTION**	**600 INJECTIONS, INSERTS & IMPLANTS**	**POLICY NO**	**600.08**
POLICY TITLE	**SUSVIMO® (Ranibizumab) INSERT or INJECTION**				
POLICY DATE	**01/01/2024**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**
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 SUSVIMO® does not require a prior authorization, however, must be billed appropriately with applicable diagnosis code located in Section V.**				

I. POLICY STATEMENT

Coverage of SUSVIMO® (ranibizumab) pars plana insert or injection will be provided 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*:

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

3.0 SUSVIMO® (Ranibizumab) will not be covered at a frequency that exceeds what is medically reasonable and necessary.

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

- 4.1 Decrease in best corrected acuity; or
- 4.2 No decrease in macula changes as evidence by OCT or clinical exam and
- 4.3 Have had previously responded to at least 2 anti-vascular endothelial growth factor injections

5.0 Authorizations will be given for the time period of 6 months and will cover up to one implant during that time period.

- 5.1 Additional injections requested will be subject to review and determinations will be made on a case-by-case basis and subject to medical necessity.
- 5.2 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 SUSVIMO® is 2 mg (0.02 mL of 100 mg/mL solution) continuously delivered via the SUSVIMO® ocular implant with refills administered every 24 weeks (approximately 6 months)

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

**Note, refer to Section V for additional required detail*

2.0 Supplemental treatment with 0.5 mg (0.05 mL of 10 mg/mL) intravitreal ranibizumab injection may be administered in the affected eye while the SUSVIMO® implant is in place and if clinically necessary

IV. MEDICAL NECESSITY REQUIREMENTS for APPLICABLE HCPCS CODE J3590

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.

4.0 Medical documentation must clearly state the clinical indication/medical necessity for the SUSVIMO® (ranibizumab) 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 SUSVIMO® (ranibizumab) 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 provide evidence along with full informed consent, outlining all pertinent risks, inclusive of the following:
- 6.1 Date
- 6.2 Consent to perform
- 6.3 Consent to waive
- 6.4 Patient or Representative Signature
- 6.5 Surgeon/Physician Signature
- 6.6 Witness Signature

V. HCPCS/ICD-10 CODES SUPPORTING MEDICAL NECESSITY

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.

Table 1: HCPCS/ICD-10 CODES

***SUSVIMO® (Ranibizumab) INSERT or INJECTION*:**	
HCPCS codes covered if selection criteria are met:	
J2779	*SUSVIMO® (Ranibizumab)*, pars plana insert or injection, 2 mg
ICD-10 codes covered if selection criteria are met:	
H35.3210	Exudative age-related macular degeneration, right eye, stage unspecified
H35.3211	Exudative age-related macular degeneration, right eye, with active choroidal neovascularization
H35.3212	Exudative age-related macular degeneration, right eye, with inactive choroidal neovascularization

H35.3213	Exudative age-related macular degeneration, right eye, with inactive scar
H35.3220	Exudative age-related macular degeneration, left eye, stage unspecified
H35.3221	Exudative age-related macular degeneration, left eye, with active choroidal neovascularization
H35.3222	Exudative age-related macular degeneration, left eye, with inactive choroidal neovascularization
H35.3223	Exudative age-related macular degeneration, left eye, with inactive scar
H35.3230	Exudative age-related macular degeneration, bilateral, stage unspecified
H35.3231	Exudative age-related macular degeneration, bilateral, with active choroidal neovascularization
H35.3232	Exudative age-related macular degeneration, bilateral, with inactive choroidal neovascularization
H35.3233	Exudative age-related macular degeneration, bilateral, with inactive scar
H35.3290	Exudative age-related macular degeneration, unspecified eye, stage unspecified
H35.3291	Exudative age-related macular degeneration, unspecified eye, with active choroidal neovascularization
H35.3292	Exudative age-related macular degeneration, unspecified eye, with inactive choroidal neovascularization
H35.3293	Exudative age-related macular degeneration, unspecified eye, with inactive scar

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY					
BENEFIT	**EYE CARE**	**POLICY SECTION**	**600 INJECTIONS, INSERTS & IMPLANTS**	**POLICY NO**	**600.09**
POLICY TITLE	**YUTIQ® (fluocinolone acetonide) INTRAVITREAL IMPLANT**				
POLICY DATE	**01/01/2022**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**
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 YUTIQ® 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 YUTIQ® (fluocinolone acetonide) intravitreal implant when medically necessary and in accordance with nationally accepted clinical guidelines[1]. To establish medical necessity 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. Specific to Medicare Advantage membership, National and Local Coverage Determinations are also reviewed. Avēsis Medical Directors are licensed medical professionals and review criteria and documentation submitted by requesting providers against Avēsis criteria 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.

1.1 New enrollee ninety (90) day continuity applies

2.0 Coverage is indicated for treatment when enrollees have the following condition*:

2.1 Chronic non-infectious uveitis affecting the posterior segment of the eye (including birdshot chorioretinopathy)

3.0 YUTIQ® intravitreal implant contains a steroid and is indicated for treatment of posterior uveitis affecting the back of the eye in patients who have been previously treated with a course of corticosteroids and have not had a clinically significant rise in intraocular pressure.

4.0 YUTIQ® is a sterile non-bioerodable intravitreal implant containing fluocinolone acetonide 0.18 mg in a 36-month sustained-release drug delivery system. It is designed to release fluocinolone acetonide, a corticosteroid, at an initial rate of 0.25 mcg/day.

5.0 Diagnosis and disease progression (history of progressive visual loss or worsening of anatomic appearance) as confirmed/determined by fluorescein angiography, Optical Coherence Tomography (OCT) or Scanning Computerized Ophthalmic Diagnostic Imaging (SCODI).

6.0 YUTIQ® will be considered medically necessary only:

6.1 When there is an inadequate response to injectable or systemic steroids OR

6.2 when there is an inadequate response to at least two administrations of intraocular steroids for the management of uveitis.

7.0 YUTIQ® is contraindicated, and the service will NOT be authorized if ANY of the following conditions apply:

7.1 Hypersensitivity to fluocinolone, or other corticosteroids

7.2 Ocular or periocular infections (viral, bacterial, or fungal): Active or suspected ocular or periocular infections including most viral diseases of the cornea and conjunctiva, including active epithelial

herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, or fungal infections of the eye

7.3 Advanced glaucoma

7.4 Concurrent treatment with other intravitreal implants

III. TREATMENT RECOMMENDATIONS

1.0 Patient post-injection assessment & monitoring for endophthalmitis & IOP may consist of:

1.1 Monitoring intraocular pressure (IOP) for minimum thirty (30) minutes post injection

1.2 Optic nerve perfusion notation

1.3 Bio-microscopy 2-7 days post injection

1.4 Provision of patient counseling specific to risk for endophthalmitis and 'red flag' symptoms

IV. MEDICAL NECESSITY REQUIREMENTS for <u>APPLICABLE HCPCS CODE J7314</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.

4.0 Medical documentation must clearly state the clinical indication/medical necessity for YUTIQ® (fluocinolone acetonide) Intravitreal Implant.

5.0 Procedure note must include:

5.1 Actual administered dosage of YUTIQ® (fluocinolone acetonide) Intravitreal Implant given

5.2 Site of injection

5.3 Route of administration

5.4 Injection Lot #

5.5 Injection expiration date

5.6 Post-injection vision ≥ CF

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

6.1 Date

6.2 Consent to perform

6.3 Consent to waive

6.4 Patient or Representative Signature

6.5 Surgeon/Physician Signature

6.6 Witness Signature

V. HCPCS/ICD-10 CODES SUPPORTING MEDICAL NECESSITY

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.

See Table 1 on page 3

Table 1: HCPCS/ICD-10 CODES

***YUTIQ® (fluocinolone acetonide) INTRAVITREAL IMPLANT*:**	
HCPCS codes covered if selection criteria are met:	
J7314	Dexamethasone, lacrimal ophthalmic insert, 0.01 mg
ICD-10 codes covered if selection criteria are met:	
H30.001 - H30.049	Focal chorioretinal inflammation
H30.101 - H30.149	Disseminated chorioretinal inflammation
H30.90 - H30.93	Unspecified chorioretinal inflammation [birdshot chorioretinopathy]

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY									
BENEFIT	**EYE CARE**	**POLICY SECTION**	**600 INJECTIONS, INSERTS & IMPLANTS**			**POLICY NO**	**600.10**		
POLICY TITLE	**VABYSMO® (faricimab-svoa) INTRAVITREAL INJECTION**								
POLICY DATE	**01/01/2022**	**REVISION DATE**	**12/01/2023**	**APPROVAL DATE**	**01/18/2024**				
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 VABYSMO® 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 VABYSMO® (faricimab-svoa) intravitreal injection when medically necessary and in accordance with nationally accepted clinical guidelines[1]. To establish medical necessity 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. Specific to Medicare Advantage membership, National and Local Coverage Determinations are also reviewed. Avēsis Medical Directors are licensed medical professionals and review criteria and documentation submitted by requesting providers against Avēsis criteria using sound medical judgment.

II. DESCRIPTION

1.0 VABYSMO® (faricimab-svoa) is a vascular endothelial growth factor (VEGF) and angiopoietin -2(Ang-2) inhibitor.

III. 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.
- 1.1 New enrollee ninety (90) day continuity applies

2.0 Coverage is indicated for treatment when enrollees have the following condition(s)*:
- 2.1 Neovascular (Wet) age-related macular degeneration (AMD)
- 2.2 Diabetic macular edema (DME)
- 2.3 Macular Edema Following Retinal Vein Occlusion (RVO)

3.0 Coverage will be considered only for enrollees who have completed a minimum of three (3) months of Avastin® (bevacizumab) with unsatisfactory outcome, defined as:
- 3.1 Minimum 3-month treatment trial
- 3.2 Fewer than four lines of improvement on visual acuity testing

4.0 VABYSMO® (faricimab-svoa) will not be covered at a frequency that exceeds what is medically reasonable and necessary.

5.0 Authorizations will be given for the time period of 6 months and will cover up to 8 injections during that time period.
- 5.1 Additional injections requested will be subject to review and determinations will be made on a case by-case basis and subject to medical necessity.
- 5.2 When services are performed more than established parameters, they may be subject to utilization, peer quality review.

IV. TREATMENT RECOMMENDATIONS

1.0 The recommended dose for VABYSMO® (faricimab-svoa):

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

1.1.1 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days) for the first 4 doses.

1.2 It is recommended that an 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:

1.2.1 Weeks 28 and 44 (q 16 weeks)

1.2.2 Weeks 24, 36 and 48 (q 12 weeks)

1.2.3 Weeks 20, 28, 36 and 44 (q 8 weeks)

1.3 Although additional efficacy was not demonstrated in most patients when VABYSMO® (faricimab-svoa) was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4-week (monthly) dosing after the first four doses. Patients should be assessed regularly.

2.0 The recommended dose for VABYSMO® (faricimab-svoa):

2.1 Diabetic Macular Edema (DME)

2.1.1 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (every 28 days) for at least 4 doses. 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:

2.1.2 6 mg dose of VABYSMO® can be administered every 4 weeks for the first six doses, followed by 6 mg dose via intravitreal injection at intervals of every 8 weeks (2 months).

3.0 The recommended dose for VABYSMO® (faricimab):

3.1 Macular Edema Following Retinal Vein Occlusion (RVO)

3.1.1 The recommended dose for VABYSMO® is 6 mg (0.05 mL of 120 mg/mL) administered by intravitreal injection every 4 weeks (approximately every 28 days) for 6 months.

3.1.2 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 four doses. Patients should be assessed regularly.

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

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

4.0 Continued Therapy

4.1 Avēsis considers continuation of therapy medically necessary for an indication listed in below section:

4.1.1 Currently receiving medication such as a vascular endothelial growth factor (VEGF) and angiopoietin -2(Ang-2) inhibitor and member has previously met initial approval criteria. Member is responding positively to therapy as evidenced by one of the following:

a. Detained neovascularization
b. Improvement in visual acuity
c. Maintenance of corrected visual acuity from prior treatment
d. Supportive findings from optical coherence tomography or fluorescein angiography

V. MEDICAL NECESSITY REQUIREMENTS for APPLICABLE HCPCS CODE J2777

1.0 Documentation Requirements

- 1.1 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.
- 1.2 Areas where 'white out' is used are not accepted.
- 1.3 Areas with 'black out' or 'scribble' will not be accepted.
  - 1.3.1 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 VABYSMO® (faricimab-svoa)

4.0 Medical documentation must clearly state the clinical indication/medical necessity for the VABYSMO® (faricimab-svoa) 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 VABYSMO® (faricimab-svoa) 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 VABYSMO® (faricimab-svoa) 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 contain evidence from 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

VI. HCPCS/ICD-10 CODES SUPPORTING MEDICAL NECESSITY

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.

See Table 1 on page 4

Table 1: HCPCS/ICD-10 CODES

***YUTIQ® (fluocinolone acetonide) INTRAVITREAL IMPLANT*:**	
HCPCS codes covered if selection criteria are met:	
J2777	VABYSMO® (Faricimab-svoa) injection, 0.1 mg
ICD-10 codes covered if selection criteria are met:	
E08.311	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema
E08.3211 – E08.3213	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema
E08.3311 – E08.3313	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema
E08.3411 – E08.3413	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema
E08.3511 – E08.3513	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema
E09.311	Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with macular edema
E09.3211 – E09.3213	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E09.3311 – E09.3313	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E09.3411 – E09.3413	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E09.3511 – E09.3513	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.3211 – E10.3213	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E10.3311 – E10.3313	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E10.3411 – E10.3413	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E10.3511 – E10.3513	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E11.3211 – E11.3213	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E11.3311 – E11.3313	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E11.3411 – E11.3413	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E11.3511 – E11.3513	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema
E13.311	Other specified diabetes mellitus with unspecified diabetic retinopathy with macular edema

E13.3211 – E13.3213	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E13.3311 – E13.3313	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E13.3411 – E13.3413	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E13.3511 – E13.3513	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema
H34.8110	Central retinal vein occlusion, right eye, with macular edema
H34.8120	Central retinal vein occlusion, left eye, with macular edema
H34.8130	Central retinal vein occlusion, bilateral, with macular edema
H34.8190	Central retinal vein occlusion, unspecified eye, with macular edema
H34.8310	Tributary (branch) retinal vein occlusion, right eye, with macular edema
H34.8320	Tributary (branch) retinal vein occlusion, left eye, with macular edema
H34.8330	Tributary (branch) retinal vein occlusion, bilateral, with macular edema
H34.8390	Tributary (branch) retinal vein occlusion, unspecified eye, with macular edema
H35.3210 – H35.3293	Exudative age-related macular degeneration

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY					
BENEFIT	**EYE CARE**	**POLICY SECTION**	**600 INJECTIONS, INSERTS & IMPLANTS**	**POLICY NO**	**600.11**
POLICY TITLE	**SYFOVRE® (pegcetacoplan) INTRAVITREAL INJECTION**				
POLICY DATE	**01/01/2024**	**REVISION DATE**	**03/06/2024**	**APPROVAL DATE**	**01/02/2025**
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 SYFOVRE® does not require a prior authorization, however, must be billed appropriately with applicable diagnosis code located in Section V.**				

I. POLICY STATEMENT

Avēsis offers coverage for SYFOVRE® (pegcetacoplan) intravitreal injection when it is deemed medically necessary and in accordance with nationally accepted clinical guidelines. To establish medical necessity, Avēsis follows the criteria recommended by the American Academy of Ophthalmology (AAO), which incorporates evidence-based best practices and FDA approval and recommendations. For Medicare Advantage membership, Avēsis also reviews National and Local Coverage Determinations. The criteria and documentation submitted by providers requesting coverage are reviewed by Avēsis Medical Directors, who are licensed medical professionals using sound medical judgment.

II. DESCRIPTION

1.0 SYFOVRE® (pegcetacoplan) injection is used for treating geographic atrophy, a condition caused by dry advanced age-related macular degeneration.

III. 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.
  1.1 New enrollee ninety (90) day continuity applies.
2.0 Coverage is indicated for treatment when enrollees have the following condition(s)*:
  2.1 Geographic Atrophy
    2.1.1 Advanced atrophic with and without subfoveal involvement.
      a. The patient has a diagnosis of Geographic Atrophy as defined by a phenotype of central geographic atrophy having 1 or more zones of well-demarcated retinal pigmented epithelium (RPE) and/or choriocapillaris atrophy; AND
      b. Disease is secondary to age-related macular degeneration (AMD); AND
      c. Conditions other than AMD have been ruled out (e.g., Stargardt disease, cone-rod dystrophy, toxic maculopathies, etc.)
3.0 SYFOVRE® (pegcetacoplan) will not be covered at a frequency that exceeds what is medically reasonable and necessary.
4.0 Authorizations will be granted for a period of 6 months.
  4.1 Additional injections requested will be subject to review, and determinations will be made on a case-by-case basis and subject to medical necessity.
  4.2 When services are performed more than established parameters, they may be subject to utilization and peer quality review.

IV. TREATMENT RECOMMENDATIONS

1.0 The recommended dose for SYFOVRE® (pegcetacoplan)
- 1.1 Advanced atrophic with or without subfoveal involvement:
  - 1.1.1 The recommended dose for SYFOVRE® (pegcetacoplan) is 15 mg (0.1 mL of 150 mg/mL solution) administered by intravitreal injection to each affected eye once every 25 to 60 days.
  - 1.1.2 Max units 30 billable units (30 mg) every 25 days

2.0 The patient's disease progression was stabilized or slowed through therapy compared to the pre-treatment baseline, as measured by any of the following:
- 2.1 Best corrected visual acuity (BCVA)
- 2.2 Fundus Autofluorescence (FAF)
- 2.3 Optical Coherence Tomography (OCT)

3.0 Continued administration is necessary for the maintenance treatment of the condition, and the patient and provider have discussed a potential decrease in the frequency of administrations.

4.0 A medical screening and clearance should be considered for enrollees with medical comorbidities.
- 4.1 Medical clearance should also be obtained when the enrollee is scheduled for any major surgery and should include when to stop the use of SYFOVRE® (pegcetacoplan) preoperatively and when it may reasonably be restarted after surgery.

5.0 Continued Therapy
- 5.1 Continued treatment may be authorized for those who have shown a positive clinical response to therapy.

V. SIDE EFFECTS

1.0 Based on the medication's prescribing information, SYFOVRE® (pegcetacoplan) has certain risks that need to be considered. These risks are listed under the below section:
- 1.1 Endophthalmitis and retinal detachments
- 1.2 Neovascular ARMD
  - 1.2.1 In clinical trials, use of SYFOVRE® (pegcetacoplan) was associated with increased rates of neovascular (wet) AMD or choroidal neovascularization.
- 1.3 Intraocular inflammation
- 1.4 Increased intraocular pressure

VI. CONTRAINDICATIONS

1.0 Based on the guidelines for prescribing SYFOVRE® (pegcetacoplan) there are certain situations where the use of this medication is not recommended. These are known as contraindications and include the following:
- 1.1 Ocular or periocular infections
- 1.2 Active intraocular inflammation

VI. MEDICAL NECESSITY REQUIREMENTS for APPLICABLE HCPCS CODE J2781

1.0 Documentation Requirements
- 1.1 To establish medical necessity, all criterion points referenced below must be clearly and legibly documented in the medical record and made available to Avēsis upon submission of the request.
- 1.2 Areas where ‘white out’ is used are not accepted.
- 1.3 Areas with ‘blackout’ or ‘scribble’ will not be accepted.
  - 1.3.1 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 the chart and procedural notes, orders, and testing interpretations.

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

4.0 Ocular Coherence Tomography (OCT), Fluorescein angiography (FA), or Fundus Autofluorescence (FAF) test results must be interpreted and firmly established/supported diagnosis.

5.0 Procedure note must include:
- 5.1 The actual dosage of SYFOVRE® (pegcetacoplan) was given.
- 5.2 Site of injection
- 5.3 Route of Administration
- 5.4 Injection Lot #
- 5.5 Injection expiration date
- 5.6 Post-injection vision ≥ CF

6.0 Medical documentation must display that the enrollee has been queried/screened for contraindications and/or co-morbidities.

7.0 Medical documentation must contain evidence from number 6.0 above, along with full informed consent, outlining all pertinent risks, inclusive of the following:
- 7.1 Date
- 7.2 Consent to perform.
- 7.3 Consent to waive.
- 7.4 Patient or Representative Signature
- 7.5 Surgeon/Physician Signature
- 7.6 Witness Signature

VII. HCPCS/ICD-10 CODES SUPPORTING MEDICAL NECESSITY

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.

Table 1: HCPCS/ICD-10 CODES

SYFOVRE® (pegcetacoplan) INTRAVITREAL Injection:	
HCPCS codes covered if selection criteria are met:	
J2718	SYFOVRE® is 15 mg (0.1 mL of 150 mg/mL solution)
ICD-10 codes covered if selection criteria are met:	
H35.3113	Nonexudative age-related macular degeneration, right eye advanced atrophic without subfoveal involvement
H35.3114	Nonexudative age-related macular degeneration, right eye advanced atrophic with subfoveal involvement
H35.3123	Nonexudative age-related macular degeneration left eye advanced atrophic without subfoveal involvement
H35.3124	Nonexudative age-related macular degeneration left eye advanced atrophic with subfoveal involvement
H35.3133	Nonexudative age-related macular degeneration, bilateral eye advanced atrophic without subfoveal involvement
H35.3134	Nonexudative age-related macular degeneration, bilateral eye advanced atrophic with subfoveal involvement
H35.3193	Nonexudative age-related macular degeneration, unspecified eye advanced atrophic without subfoveal involvement
H35.3194	Nonexudative age-related macular degeneration, unspecified eye advanced atrophic with subfoveal involvement

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY					
BENEFIT	**EYE CARE**	**POLICY SECTION**	**600 INJECTIONS, INSERTS & IMPLANTS**	**POLICY NO**	**600.12**
POLICY TITLE	**CIMERLI® (ranibizumab-eqrn) INTRAVITREAL INJECTION**				
POLICY DATE	**01/01/2024**	**REVISION DATE**	**12/05/2024**	**APPROVAL DATE**	**01/02/2025**
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 CIMERLI® does not require a prior authorization, however, must be billed appropriately with applicable diagnosis code located in Section V.**				

I. POLICY STATEMENT

Coverage of CIMERLI® (ranibizumab-eqrn) intravitreal injection will be provided 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 (RVO)
- 2.4 Myopic Choroidal Neovascularization (nCNV)

3.0 CIMERLI® (ranibizumab-eqrn) will not be covered at a frequency that exceeds what is medically reasonable and necessary.

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 Authorizations will be given for the time period of 12 months and will cover up to 26 injections during that time period.

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

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

III. TREATMENT RECOMMENDATIONS

1.0 The recommended dose for CIMERLI® (ranibizumab-eqrn) is:

- 1.1 0.3 mg or 0.5 mg intravitreal injection once every 4 weeks (monthly) for the first 12 weeks (3 months)
- 1.2 Although CIMERLI® (ranibizumab-eqrn) may be dosed as frequently as 0.3 mg or 0.5 mg every 4 weeks (monthly), minimal efficacy (1-2 letter gain) was demonstrated when CIMERLI® (ranibizumab-eqrn) was dosed every 4 weeks as compared to every 8-12 weeks.

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 CIMERLI® (ranibizumab-eqrn) preoperatively, and when it may reasonably be restarted after surgery.

IV. MEDICAL NECESSITY IS ESTABLISHED for <u>APPLICABLE CODE Q5128</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 CIMERLI® (ranibizumab-eqrn) 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 CIMERLI® (ranibizumab-eqrn) 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 In accordance with the prescribing information for CIMERLI® (ranibizumab-eqrn) 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 CIMERLI® (ranibizumab-eqrn), 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
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.3211 – E10.3219	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E10.3311 – E10.3319	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E10.3411 – E10.3419	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E10.3511 – E10.3519	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema
E10.37X1 – E10.37X9	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E11.3211 – E11.3219	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E11.3311 – E11.3319	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E11.3411 – E11.3419	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E11.3511 – E11.3519	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema
E11.37X1 – E11.37X9	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment
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
H35.351 – H35.359	Cystoid macular degeneration
H35.81	Retinal edema

CLINICAL CRITERIA POLICY

CLINICAL CRITERIA POLICY TO ESTABLISH MEDICAL NECESSITY									
BENEFIT	**EYE CARE**	**POLICY SECTION**	**600 INJECTIONS, INSERTS & IMPLANTS**			**POLICY NO**	**600.13**		
POLICY TITLE	**IZERVAY™ (avacincaptad pegol) INTRAVITREAL INJECTION**								
POLICY DATE	**01/01/2024**	**REVISION DATE**	**03/06/2024**	**APPROVAL DATE**	**01/02/2025**				
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 IZERVAY™ does not require a prior authorization, however, must be billed appropriately with applicable diagnosis code located in Section V.**								

I. POLICY STATEMENT

Avēsis offers coverage for IZERVAY™ (avacincaptad pegol) intravitreal injection when it is deemed medically necessary and in accordance with nationally accepted clinical guidelines. To establish medical necessity, Avēsis follows the criteria recommended by the American Academy of Ophthalmology (AAO), which incorporates evidence-based best practices and FDA approval and recommendations. For Medicare Advantage membership, Avēsis also reviews National and Local Coverage Determinations. The criteria and documentation submitted by providers requesting coverage are reviewed by Avēsis Medical Directors, who are licensed medical professionals using sound medical judgment.

II. DESCRIPTION

1.0 IZERVAY™ (avacincaptad pegol) injection is used for treating geographic atrophy, a condition caused by dry advanced age-related macular degeneration.

III. 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.
  1.1 New enrollee ninety (90) day continuity applies.
2.0 Coverage is indicated for treatment when enrollees have the following condition(s)*:
  2.1 Geographic Atrophy
    2.1.1 Advanced atrophic with and without subfoveal involvement.
      a. The patient has a diagnosis of Geographic Atrophy as defined by a phenotype of central geographic atrophy having 1 or more zones of well-demarcated retinal pigmented epithelium (RPE) and/or choriocapillaris atrophy; AND
      b. Disease is secondary to age-related macular degeneration (AMD); AND
      c. Conditions other than AMD have been ruled out (e.g., Stargardt disease, cone-rod dystrophy, toxic maculopathies, etc.)
3.0 IZERVAY™ (avacincaptad pegol) will not be covered at a frequency that exceeds what is medically reasonable and necessary.
4.0 Authorizations will be granted for a period of 6 months.
  4.1 Additional injections requested will be subject to review, and determinations will be made on a case-by-case basis and subject to medical necessity.
  4.2 When services are performed more than established parameters, they may be subject to utilization and peer quality review.

IV. TREATMENT RECOMMENDATIONS

1.0 The recommended dose for IZERVAY™ (avacincaptad pegol)
  1.1 Advanced atrophic with or without subfoveal involvement:
    1.1.1 The recommended dose for IZERVAY™ (avacincaptad pegol) is 2 mg (0.1 mL of 20 mg/mL solution) administered by intravitreal injection to each affected eye once monthly for up to 12 months.
    1.1.2 Max units: 2 billable units (2 mg) every 28 days (single dose vial)
2.0 The patient's disease progression was stabilized or slowed through therapy compared to the pre-treatment baseline, as measured by any of the following:
  2.1 Best corrected visual acuity (BCVA)
  2.2 Fundus Autofluorescence (FAF)
  2.3 Optical Coherence Tomography (OCT)
3.0 Continued administration is necessary for the maintenance treatment of the condition, and the patient and provider have discussed a potential decrease in the frequency of administrations.
4.0 A medical screening and clearance should be considered for enrollees with medical comorbidities.
  4.1 Medical clearance should also be obtained when the enrollee is scheduled for any major surgery and should include when to stop the use of IZERVAY™ (avacincaptad pegol) preoperatively and when it may reasonably be restarted after surgery.
5.0 Continued Therapy
  5.1 Continued treatment may be authorized for those who have shown a positive clinical response to therapy.

V. SIDE EFFECTS

1.0 Based on the medication's prescribing information, IZERVAY™ (avacincaptad pegol) has certain risks that need to be considered. These risks are listed under the below section:
  1.1 Endophthalmitis and retinal detachments
  1.2 Neovascular ARMD
    1.2.1 In clinical trials, use of IZERVAY™ (avacincaptad pegol) was associated with increased rates of neovascular (wet) AMD or choroidal neovascularization.
  1.3 Increased intraocular pressure

VI. CONTRAINDICATIONS

1.0 Based on the guidelines for prescribing IZERVAY™ (avacincaptad pegol) there are certain situations where the use of this medication is not recommended. These are known as contraindications and include the following:
  1.1 Ocular or periocular infections
  1.2 Active intraocular inflammation

VI. MEDICAL NECESSITY REQUIREMENTS for APPLICABLE HCPCS CODE J3490

1.0 Documentation Requirements
  1.1 To establish medical necessity, all criterion points referenced below must be clearly and legibly documented in the medical record and made available to Avēsis upon submission of the request.
  1.2 Areas where ‘white out’ is used are not accepted.
  1.3 Areas with ‘blackout’ or ‘scribble’ will not be accepted.
    1.3.1 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 the chart and procedural notes, orders, and testing interpretations.
3.0 The submitted documentation must support medical necessity as outlined in Section III, Indications and Limitations of Coverage.

4.0 Ocular Coherence Tomography (OCT), Fluorescein angiography (FA), or Fundus Autofluorescence (FAF) test results must be interpreted and firmly established/supported diagnosis.

5.0 Procedure note must include:
- 5.1 The actual dosage of IZERVAY™ (avacincaptad pegol) was given.
- 5.2 Site of injection
- 5.3 Route of Administration
- 5.4 Injection Lot #
- 5.5 Injection expiration date
- 5.6 Post-injection vision ≥ CF

6.0 Medical documentation must display that the enrollee has been queried/screened for contraindications and/or co-morbidities.

7.0 Medical documentation must contain evidence from number 6.0 above, along with full informed consent, outlining all pertinent risks, inclusive of the following:
- 7.1 Date
- 7.2 Consent to perform.
- 7.3 Consent to waive.
- 7.4 Patient or Representative Signature
- 7.5 Surgeon/Physician Signature
- 7.6 Witness Signature

VII. HCPCS/ICD-10 CODES SUPPORTING MEDICAL NECESSITY

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.

Table 1: HCPCS/ICD-10 CODES

IZERVAY™ (avacincaptad pegol) INTRAVITREAL Injection:	
HCPCS codes covered if selection criteria are met:	
J3490	IZERVAY™ (avacincaptad pegol) is 15 mg (0.1 mL of 150 mg/mL solution)
ICD-10 codes covered if selection criteria are met:	
H35.3113	Nonexudative age-related macular degeneration, right eye advanced atrophic without subfoveal involvement
H35.3114	Nonexudative age-related macular degeneration, right eye advanced atrophic with subfoveal involvement
H35.3123	Nonexudative age-related macular degeneration left eye advanced atrophic without subfoveal involvement
H35.3124	Nonexudative age-related macular degeneration left eye advanced atrophic with subfoveal involvement
H35.3133	Nonexudative age-related macular degeneration, bilateral eye advanced atrophic without subfoveal involvement
H35.3134	Nonexudative age-related macular degeneration, bilateral eye advanced atrophic with subfoveal involvement