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**	**08/08/2022**	**APPROVAL DATE**	**08/10/2022**
DISCLAIMER LANGUAGE	- **Policy content and application may have state specific variance and considerations** - **Health Plan specific 'Indications and Limitations of Coverage' may apply as specified** - **Line of Business considerations (i.e., Medicaid, Medicare, Commercial) may apply as specified**				
EXCLUSIONS	- **This policy is not applicable to Medicaid in the state(s) of 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