

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	08/08/2022	APPROVAL DATE	08/10/2022
DISCLAIMER LANGUAGE	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - This policy is not applicable to Medicaid in the state(s) of Delaware, Kentucky and Texas, as YUTIQ® is not a covered benefit. - 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 guidelines¹. 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 APPLICABLE HCPCS CODE J7314

- 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

<i>YUTIQ® (fluocinolone acetonide) INTRAVITREAL IMPLANT:</i>	
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]