

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	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, 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 recommendations¹. 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 APPLICABLE HCPCS CODE J1096

- 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) OPTHALMIC 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]
H57.10 - H57.13	Ocular pain [ocular pain following ophthalmic surgery]
H10.10 - H10.13	Acute atopic conjunctivitis
H10.45	Other chronic allergic conjunctivitis