Policy Title:	Policy - Dexamethasone INTRACANALICULAR Ophthalmic Insert (Dextenza®)	Number & Version:	UM-EYERX.v.1
Functional Unit:	Utilization Management	Effective Date:	05/19/2022
Policy Owner (Title):	Director, Utilization Management	Page Number:	1 of 5

I. POLICY STATEMENT and PURPOSE

The purpose of this policy is to describe the circumstances under which Dexamethasone INTRACANALICULAR Ophthalmic Insert (Dextenza®) would or would not be considered medically necessary for members under the guidelines used for clinical review of organizational determinations.

II. BACKGROUND

Unique anatomical and physiological protective barriers in the eye can impede the administration of topically administered ocular drugs to target tissue. Barriers to absorption include tear dilution, lymphatic drainage, and the layers of eye structures themselves, to name a few. Eye drops have typically low bioavailability (approximately 5%) (Gaudana, 2009).

A frequent occurrence following ophthalmic surgery is postoperative inflammation. This is usually addressed by the prescribing of corticosteroid eye drops to reduce pain and inflammation. Cataract surgery is the most commonly performed ophthalmic surgery in the United States. More than 1 million cataract surgeries are performed in the U.S. each year, according to the Centers for Disease Control and Prevention (CDC) (VEHSS/CDC, 2021). The American Academy of Ophthalmology (AAO) notes that approximately 24.5 million in America have cataracts. Cataracts are a leading cause of blindness in the United States. Cataract surgery remains the most effective way to help restore vision for those with cataracts. (Dang, 2014).

Patient compliance with postoperative eye drop regimens is lacking due to complexity of regimens, side effects, forgetfulness, and lack of manual dexterity required for accurate self-instillation of drops. Alternatives to standard eye drops for drug administration to increase bioavailability of prescribed medications and improve patient compliance/adherence with medication regimens were needed. (Hayes, 2021).

III. SCOPE

This Policy applies to the procedures described by the following codes:

CPT® Code	Description
68841	Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each
J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg

(Optum, 2022)

IV. DEFINITIONS

Dexamethasone INTRACANALICULAR Ophthalmic Insert (Dextenza®) is an intracanalicular insert that that allows for the sustained release of 0.4mg/day dexamethasone over the course of 30 days. The device is resorbable, but can be manually removed if required (FDA, 2019)

Medically Necessary – Covered Services rendered by a Health Care Provider that the Plan determines are:

1) Safe and effective
2) Not experimental or investigational
3) Appropriate for patients,
   a) including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is—
      i) furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member,
      ii) furnished in a setting appropriate to the patient's medical needs and condition,
      iii) ordered and furnished by qualified personnel,
      iv) one that meets, but does not exceed, the patient's medical need; and
      v) is at least as beneficial as existing and available medically appropriate alternatives.

V. OWNERSHIP & TRAINING

The Director of Utilization Management is responsible for administration, oversight, and training regarding performance under this Policy.

VI. PROTOCOLS / COVERAGE POLICY

Dexamethasone INTRACANALICULAR Ophthalmic Insert (Dextenza®) insert is considered reasonable and necessary for the treatment of ocular inflammation and pain following ophthalmic surgery when the following conditions are met:

- the patient demonstrates forgetfulness or the inability to understand the instructions for administering corticosteroid eye drops; and / or
- the patient lacks the manual dexterity to administer corticosteroid eye drops safely and effectively.

Dexamethasone INTRACANALICULAR Ophthalmic Insert (Dextenza®) is contraindicated in patients with the following conditions:

- active corneal, conjunctival or canalicular infections, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella
- mycobacterial infections of the eye
- fungal diseases of the eye
- dacryocystitis
- any allergy or history of adverse reactions to dexamethasone or corticosteroids.

VII. REGULATORY REFERENCES / CITATIONS

CMS National Coverage Determinations (NCDs)	None
CMS Local Coverage Determinations (LCDs)	L38792 see table next
CMS Articles	A58392, A58548 see table next

ID	Title	Type	Contractor
Title Results (3)			
A58392	Billing and Coding: Dexamethasone Intracanalicular Ophthalmic Insert (Dextenza®)	Article	Palmetto GBA
L38792	Dexamethasone Intracanalicular Ophthalmic Insert (Dextenza®)	LCD	Palmetto GBA
A58548	Response to Comments: Dexamethasone Intracanalicular Ophthalmic Insert (Dextenza®)	Article	Palmetto GBA

(CMS, Dexamethasone **INTRACANALICULAR** Ophthalmic Insert (Dextenza®), 2022)

VIII. PROFESSIONAL REFERENCES / CITATIONS

1. Centers for Disease Control (CDC). Vision and Eye Health Surveillance System (VEHSS). August 10, 2021. Accessed at: https://www.cdc.gov/visionhealth/vehss/data/studies/cataract.html on February 8, 2022.

2. Centers for Medicare and Medicaid Services (CMS). Medicare Coverage Database. Search Results. Posterior Tibial Nerve Stimulation (PTNS) for Urinary Control. Accessed at: https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=intracanalicular&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance on February 8, 2022.

3. Dang, Shirley. American Academy of Ophthalmology (AAOC). "Cataract Surgery Infographic." June 10, 2014. Accessed at: https://www.aao.org/eye-health/news/cataract-surgery-infographic on February 8, 2022.

4. Food and Drug Administration (FDA). Highlights of Prescribing Information. Dextenza®. Reference ID: 4451660. June 2019. Accessed at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208742s001lbl.pdf on February 8, 2022.

5. Gaudana, Ripal et al. "Recent perspectives in ocular drug delivery." *Pharmaceutical research* vol. 26,5 (2009): 1197-216. doi:10.1007/s11095-008-9694-0. Accessed at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4516219/ on February 8, 2022.

6. Hayes. Evidence Analysis Research Brief. "Dexamethasone Ophthalmic Insert (Dextenza) for Treatment of Postoperative Ocular Pain and Inflammation." Sep 30, 2021. Accessed at: https://evidence.hayesinc.com/report/earb.dexamethasone5231 on February 8, 2022.

7. Optum 360⁰. EncoderPro.com. 2022. Accessed at: https://www.encoderpro.com/epro/cptHandler.do?_k=101*68841&_a=view&searchTerms=68841&_mrad=true&#selected on February 8, 2022.

IX. RELATED POLICIES / PROCEDURES

None

X. ATTACHMENTS

- L38792 Local Coverage Determination: Dexamethasone **INTRACANALICULAR** Ophthalmic Insert (Dextenza®)
- A58392 Billing and Coding: Dexamethasone **INTRACANALICULAR** Ophthalmic Insert (Dextenza®)
- A58548 Response to Comments: Dexamethasone **INTRACANALICULAR** Ophthalmic Insert (Dextenza®)

APPROVALS:

	Printed Name	Signature
Senior Medical Director, UM:	Michael Fusco, MD	
Corporate Chief Medical Officer (QMMC Chair):	Debbie Zimmerman, MD	

VERSION HISTORY:

Version #	Date	Author	Purpose/Summary of Major Changes
01	03/01/2022	Gina Vehige	Original; Approve by QMMC on 5/13/2022