Policy Title:	Policy - Dexamethasone INTRACANALICULAR Ophthalmic Insert (Dextenza®)	Number & Version:	UM-EYERX.v.4
Functional Unit:	Utilization Management	Effective Date:	6/7/2024
Policy Owner (Title):	Senior Director, Utilization Management	Page Number:	1 of 5

I. POLICY STATEMENT and PURPOSE

In its administration of Medicare Advantage plans (Health Plans), the Company shall determine benefits in accordance with the requirements of the Centers for Medicare & Medicaid Services (CMS). Where CMS has established a national coverage policy on an item or service or a local Medicare contractor has done so as authorized by CMS, the Company follows the Medicare coverage policy. In the absence of fully established Medicare coverage criteria, the Company may develop and implement internal criteria based on current evidence in widely used treatment guidelines or clinical literature. Internal criteria are reviewed and approved by the Medical Management Committee and are made publicly accessible.

CMS has not established coverage criteria for Dexamethasone INTRACANALICULAR Ophthalmic Insert (Dextenza®), therefore the Company has developed and implemented this coverage policy to ensure that patients receive clinically appropriate, medically necessary care at the appropriate level, which allows for the best clinical outcome and prevents harm. The purpose of this policy is to describe the circumstances under which Dexamethasone INTRACANALICULAR Ophthalmic Insert (Dextenza®) would be considered medically necessary. (CMS, 2024)

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.

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 Dexamethasone INTRACANALICULAR Ophthalmic Inserts.

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

VI. PROTOCOLS / COVERAGE POLICY

The protocols / coverage policy that follow pertain only to the following states: AR, KY, IN, MO, IL, OH, MI

The following states are covered by the Local Coverage Determination(s), as described in section VIII: AL, GA, NC, SC, TN, VA, WV

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. SUMMARY of EVIDENCE

Published evidence evaluating the use of Dexamethasone INTRACANALICULAR Ophthalmic Insert (Dextenza®) exhibit positive outcomes for patients requiring this treatment for ocular inflammation and pain when the aforementioned conditions are met. Efficacy was noted across 3 Phase 3 trials that included a total of 926 subjects (n=541, Dextenza®, n=385, placebo insert). It was demonstrated that patients receiving Dextenza® achieved statistically, significantly superior outcomes compared to patients receiving placebo. Patients were observed to have absence of ocular pain and less adverse ocular events. (Tyson, 2019) (Walters, 2016)

VIII. REGULATORY REFERENCES / CITATIONS

CMS National Coverage Determinations (NCDs) None
CMS Local Coverage Determinations (LCDs) L38792 see table next.

ID	Title	Type	Service Area	Contractor
L38792	Dexamethasone Intracanalicular Ophthalmic Insert (Dextenza®)	LCD	AL, GA, NC, SC, TN, VA, WV	Palmetto GBA

(CMS, 2024)

IX. PROFESSIONAL REFERENCES / CITATIONS

1. Centers for Medicare and Medicaid Services (CMS). Medicare Coverage Database. Search Results. Dexamethasone Intracanalicular Ophthalmic Insert. Accessed at: https://www.cms.gov/medicare-coverage-database/search-

results.aspx?keyword=Dexamethasone%20INTRACANALICULAR%20Ophthalmic%20Insert&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance l on April 3, 2024.

2. 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 April 3, 2024.

3. 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 April 3, 2024.

4. Hayes. Evidence Analysis Research Brief. "Dexamethasone Ophthalmic Insert (Dextenza) for Treatment of Postoperative Ocular Pain and Inflammation." Sep 30, 2021. Archived October 30, 2022. Accessed at: https://evidence.hayesinc.com/report/earb.dexamethasone5231 on April 3, 2024.

5. Tyson, Syd L et al. "Multicenter randomized phase 3 study of a sustained-release intracanalicular dexamethasone insert for treatment of ocular inflammation and pain after cataract surgery." Journal of cataract and refractive surgery vol. 45,2 (2019): 204-212. doi:10.1016/j.jcrs.2018.09.023. Accessed at: https://journals.lww.com/jcrs/fulltext/2019/02000/multicenter_randomized_phase_3_study_of_a.14.aspx on April 3, 2024.

6. Walters T, et al. Efficacy and safety of sustained release dexamethasone for the treatment of ocular pain and inflammation after cataract surgery: results from two phase 3 studies. J Clin Exp Ophthalmol. 2016;7(4):1-11. 1. Accessed at: https://www.longdom.org/open-access/efficacy-and-safety-of-sustained-release-dexamethasone-for-the-treatment-of-ocular-pain-and-inflammation-after-cataract--51147.html on April 3, 2024.

X. RELATED POLICIES / PROCEDURES

None

XI. ATTACHMENTS

See Section VIII.

APPROVALS:

Printed Name **Signature**

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Senior Medical Officer (MMC Chair): Michael Fusco, MD

Corporate Chief Medical Officer: 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
02	05/10/2023	Gina Vehige	Updated references, added MAC Coverage Table, No changes to conclusions
03	04/03/2024	Gina Vehige	Updated references; Added Summary of Evidence, No changes to conclusions
04	04/10/2024	Gina Vehige	Updated section numbering and format; updated signatories' titles. Approved by MMC 6/7/2024.