LCD - Dexamethasone Intracanalicular Ophthalmic Insert (Dextenza®) (L38792)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Palmetto GBA	A and B MAC	10111 - MAC A	J - J	Alabama
Palmetto GBA	A and B MAC	10112 - MAC B	J - J	Alabama
Palmetto GBA	A and B MAC	10211 - MAC A	J - J	Georgia
Palmetto GBA	A and B MAC	10212 - MAC B	J - J	Georgia
Palmetto GBA	A and B MAC	10311 - MAC A	J - J	Tennessee
Palmetto GBA	A and B MAC	10312 - MAC B	J - J	Tennessee
Palmetto GBA	A and B and HHH MAC	11201 - MAC A	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11202 - MAC B	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11301 - MAC A	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11302 - MAC B	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11401 - MAC A	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11402 - MAC B	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11501 - MAC A	J - M	North Carolina
Palmetto GBA	A and B and HHH MAC	11502 - MAC B	J - M	North Carolina

LCD Information

Document Information

LCD ID
L38792

LCD Title
Dexamethasone Intracanalicular Ophthalmic Insert (Dextenza®)

Proposed LCD in Comment Period
N/A

Source Proposed LCD
DL38792

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Original Effective Date
For services performed on or after 02/07/2021

Revision Effective Date
For services performed on or after 05/26/2022

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
12/24/2020

Notice Period End Date
02/06/2021

Issue

Issue Description

This LCD outlines coverage for this service with specific details under **Coverage Indications, Limitations and/or Medical Necessity**.

CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862(a)(1)(A) allows coverage and payment for only those services that are considered to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act, §1862(a)(1)(D) indicates no payment may be made in the case of clinical care where items and services provided are in research and experimentation.

CMS Internet-Only Manual, Pub 100-02, Medicare Benefit Policy Manual, Chapter 14, §10 Coverage of Medical Devices

CMS Internet-Only Manual, Pub 100-04, Medicare Claims Processing Manual, Chapter 23, §30 Services Paid Under the Medicare Physician's Fee Schedule

CMS Internet-Only Manual, Pub 100-08, Medicare Program Integrity Manual, Chapter 13, §13.5.4 Reasonable and Necessary Provisions in LCDs

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Background:

Dextenza® (Ocular Therapeutix, Inc., Bedford, MA, USA) is a resorbable hydrogel corticosteroid implant indicated for treating ocular inflammation and pain after ophthalmic surgery. After surgery, the insert is placed in the lower lacrimal punctum and into the canaliculus. The insert releases 0.4 mg of dexamethasone over 30 days onto the eye surface. It is made from a polyethylene glycol-based hydrogel conjugated with fluorescein, which is resorbable and does not require removal. Anterior chamber inflammation (10%) and elevated intraocular pressure (IOP) (6%) were the most common adverse reactions. IOP should be monitored during treatment. Dextenza® should not be used in patients with active corneal, conjunctival, or canalicular infections, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, fungal eye diseases, and dacryocystitis.

Dextenza® is an alternative to topical corticosteroid preparations (e.g., eye drops) used to reduce pain and inflammation after cataract surgery. Persistent inflammation may lead to complications, such as increased IOP, cystoid macular edema, secondary glaucoma, delayed recovery, ocular pain, and reduced vision. However, patients may have difficulty delivering the correct dose when using topical eye drop preparations; eye drops may need to be tapered over time and are associated with poor patient adherence.[1] The elderly population, in particular, typically has more difficulty using eye drops to deliver topical corticosteroids after eye surgery.

Coverage Indications and limitations:

Palmetto GBA considers the use of the Dextenza® dexamethasone insert reasonable and necessary for the treatment of ocular inflammation and pain following ophthalmic surgery.

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.

Summary of Evidence

An integrated assessment of Dextenza's® efficacy in ophthalmic surgery was demonstrated across 3 Phase 3 trials that included a total of 926 subjects (n=541, Dextenza®, n=385, placebo insert).[1-3] An ad hoc pooled analysis of the 3 Phase 3 studies demonstrated patients receiving Dextenza® achieved statistically, significantly superior outcomes compared to patients receiving placebo vehicle in both primary efficacy endpoints, with 42.7% of Dextenza®-treated patients observed to have absence of anterior chamber cells (score of 0) at Day 14 (placebo: 27.5%; $P < 0.0001$), and 79.2% of Dextenza®-treated patients observed to have absence of ocular pain (score of 0) at Day 8 (placebo: 56.9%; $P < 0.0001$) with a favorable safety profile. Across all 3 studies, a greater proportion of subjects in the placebo group experienced at least 1 ocular adverse event in the study eye, as compared to patients

receiving the Dextenza® insert. The most common Dextenza® ocular adverse events (>1%) were increased (IOP), anterior chamber inflammation including iritis and iridocyclitis, eye inflammation, reduced visual acuity, corneal edema, and cystoid macular edema. There were no treatment-related serious adverse events.[1-3]

Physician-administered Dextenza® delivers a 30-day tapered dose of dexamethasone to the eye (consistent with current standard of care tapered dosing regimen of patient-administered topical steroid drops).[1,2] Physician administration of Dextenza® avoids risk of improper patient installation techniques with post-op topical eye drop therapy, complicated steroid tapering dosing regimens for patient administration, manual dexterity challenges associated with older age,[5] and may reduce the potential for ophthalmic sequelae typically associated with poor patient adherence during the critical post-operative care period. Persistent ocular inflammation can potentially increase the risk for secondary ocular complications, such as increased IOP, cystoid macular edema (CME), posterior synechiae formation, posterior capsule opacification, secondary glaucoma, delayed recovery, ocular pain, and reduced visual outcomes, whereas untreated pain can affect overall patient surgical satisfaction.[6-8]

Dexamethasone is a potent corticosteroid, and the Dextenza® Phase 3 data support the utility of a sustained-release intracanalicular insert delivery approach of dexamethasone to the ocular surface following ocular surgery.[1,2] Relevant to IOP increases associated with ophthalmic surgery, the overall safety outcomes of an ad hoc pooled analysis of the Phase 3 Dextenza® studies showed IOP elevation with Dextenza® (6.3%) compared to placebo (3.4%);[3] of all events, only 1 IOP increase in the dexamethasone insert arm (0.2%) out of 538 patients across 3 studies was considered by the investigator to be related to treatment.[1-3] It is hypothesized the observed rates of IOP increase demonstrated with Dextenza® compared to placebo in the Phase 3 studies may potentially be associated with the reduced Cmax of sustained release preparations (e.g., Dextenza®), as compared to topical steroid therapy.[1]

Additionally, the benefits of consistent tapered dosing with a dexamethasone-eluting intracanalicular insert is potentially clinically meaningful in the context of the demonstrated poor bioavailability of topical steroid eye drop preparations.[9] The pharmacokinetic properties of the drug-eluting intracanalicular insert, in preclinical animal models, suggests sustained and tapered drug release into the tear film may minimize the potential of ocular rebound inflammation and demonstrate dexamethasone is eluted directionally and unilaterally towards the ocular surface, indicating limited systemic exposure and reduced wasted drug product.[10]

By being physician-administered, Dextenza® eliminates the potential for improper drop installation techniques, including missing the eye, instilling an incorrect number of drops, bottle tip contamination with ocular surface contact, and failure to wash hands prior to patient-administered topical therapy;[11] these challenges may be common amongst Medicare-aged patients. Researchers observed in an elderly ($\geq$80 years) population with chronic ophthalmic pathologies, 61% scratched the eyedrop container along the conjunctiva or cornea upon administration, and 11% of patients in this cohort failed to successfully apply a drop to the ocular surface.[2,13]

Finally, placement of Dextenza® into the intracanalicular space may afford the additional benefit of punctal occlusion. Available data indicate punctal occlusion following ophthalmic surgery is associated with improvement in postoperative healing and may prevent post-operative dry eye complications. In a study of refractive ocular surgery patients who received unilateral punctal occlusion following LASIK surgery, statistically significant ocular surface index score improvement was demonstrated, suggesting a decrease in dry eye disease severity.[14]

Overall, results of the Phase 3 Dextenza® pooled studies support a greater proportion of patients treated with Dextenza® demonstrated an absence of ocular pain as early as the day after surgery (Day 2), and absence of inflammation as early as 3 days after surgery (Day 4). Additionally, there were consistently similar results with Dextenza® across all the evaluated time points compared to placebo.[3] Treatment with Dextenza® in the Phase 3 Clinical Trials demonstrated tolerability and efficacy during the post-operative period.[1-3]

Analysis of Evidence (Rationale for Determination)

There have been 4 high quality, multicenter, double-blind random control trials (RCTs) all conducted within the United States. The trials were industry supported and lacked a comparison with the standard of care, dexamethasone eye drops. A limitation in the available studies is the lack of a comparison study between dexamethasone eye drops and Dextenza®. Studies reported outcomes up to 120 days after implant use with an excellent safety profile; however, no long-term data exists for potential adverse events.

Despite these limitations, given the availability of sufficient safety and efficacy data and the studies referenced above, the use of the dexamethasone insert to treat ocular inflammation and pain following ophthalmic surgery is reasonable and necessary. Off-label use of the dexamethasone insert for treatment of non-surgical conditions lacks evidentiary support and is considered investigational and will not be covered by Medicare outside of otherwise covered clinical trials.

General Information

Associated Information

N/A

Sources of Information

N/A

Bibliography

1. Walters T, Bafna S, Vold S, 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.
2. Tyson SL, Bafna S, Gira JP, et al. Multicenter randomized phase 3 study of a sustained-release intracanalicular dexamethasone insert for treatment of ocular inflammation and pain after cataract surgery. [published correction appears *in J Cataract Refract Surg*. 2019;45(6):895]. *J Cataract Refract Surg*. 2019;45(2):204-212.
3. Tyson S, Bafna S, Berdahl J, Walters T, Metzinger JL, Goldstein MH. Management of ocular inflammation and pain following cataract surgery with Dextenza®, dexamethasone insert (0.4 mg). Paper presented at the American Society of Cataract and Refractive Surgery Annual Meeting; San Diego, CA, May 3-7, 2019.
4. Dextenza® [package insert]. Bedford, MA: Ocular Therapeutix, Inc; 2019.
5. An JA, Kasner O, Samek DA, Lévesque V. Evaluation of eyedrop administration by inexperienced patients after cataract surgery. *J Cataract Refract Surg*. 2014;40(11):1857-1861.
6. Chang DT, Herceg MC, Bilonick RA, Camejo L, Schuman JS, Noecker RJ. Intracameral dexamethasone reduces inflammation on the first postoperative day after cataract surgery in eyes with and without glaucoma. *Clin Ophthalmol.* 2009;3:345-355.
7. Dua HS, Attre R. Treatment of post-operative inflammation following cataract surgery – a review. *Eur Ophthalmic Rev.* 2012;6(2):98-103.
8. Porela-Tiihonen S, Kokki H, Kaarniranta K, Kokki M. Recovery after cataract surgery. *Acta Ophthalmol.* 2016;94(A2):1-34.

9. Aldrich DS, Bach CM, Brown W, et al. Ophthalmic preparations. *US Pharmacopeia.* 2013;39(5): 1-21.
10. Blizzard C, Desai A, Driscoll A. Pharmacokinetic studies of sustained-release depot of dexamethasone in beagle dogs. *J Ocul Pharmacol Ther*. 2016;32(9):595-600.
11. Baudouin C, Labbé A, Liang H, Pauly A, Brignole-Baudouin F. Preservatives in eyedrops: the good, the bad and the ugly. *Prog Retin Eye Res*. 2010;29(4):312-334.
12. Aguayo Bonniard A, Yeung JY, Chan CC, Birt CM. Ocular surface toxicity from glaucoma topical medications and associated preservatives such as benzalkonium chloride (BAK). *Expert Opin Drug Metab Toxicol.* 2016;12(11):1279-1289.
13. Dietlein TS, Jordan JF, Lüke C, Schild A, Dinslage S, Krieglstein GK. Self-application of single-use eyedrop containers in an elderly population: comparisons with standard eyedrop bottle and with younger patients. *Acta Ophthalmol.* 2008;86(8):856-859.
14. Alfawaz AM, Algehedan S, Jastaneiah SS, Al-Mansouri S, Mousa A, Al-Assiri A. Efficacy of punctal occlusion in management of dry eyes after laser in situ keratomileusis for myopia. *Curr Eye Res.* 2014;39(3):257-262.

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
05/26/2022	R1	Under **CMS National Coverage Policy** revised the last regulation to read, CMS Internet-Only Manual, Pub 100-08, Medicare Program Integrity Manual, Chapter 13, §13.5.4 Reasonable and Necessary Provisions in LCDs. Under **Bibliography** changes were made to citations to reflect AMA citation guidelines.	• Provider Education/Guidance

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A58392 - Billing and Coding: Dexamethasone Intracanalicular Ophthalmic Insert (Dextenza®)

A58548 - Response to Comments: Dexamethasone Intracanalicular Ophthalmic Insert (Dextenza®)

LCDs

DL38792 - (MCD Archive Site)

Related National Coverage Documents

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
05/16/2022	05/26/2022 - N/A	Currently in Effect (This Version)
12/15/2020	02/07/2021 - 05/25/2022	Superseded

Keywords

- Dextenza
- Insert
- Dexamethasone