Policy Name	Clinical Policy – DEXTENZA® dexamethasone intracanalicular insert
Policy Number	1348.00
Department	Clinical Strategy
Subcategory	Medical Management
Original Approval Date	04/06/2022
Current MPC/CCO Approval Date	04/09/2025
Current Effective Date	06/01/2025

Company Entities Supported (Select All that Apply):
X Superior Vision Benefit Management
X Superior Vision Services
X Superior Vision of New Jersey, Inc.
X Block Vision of Texas, Inc. d/b/a Superior Vision of Texas
X Davis Vision
(Collectively referred to as 'Versant Health' or 'the Company')

ACRONYMS or DEFINITIONS	
n/a	

PURPOSE

To provide the medical necessity criteria to support the indication(s) for DEXTENZA®. Applicable procedure codes are also defined.

POLICY

A. Background

Ocular surgery is often associated with post operative inflammatory changes that may compromise the ultimate surgical outcome. Corticosteroids are recognized to be efficacious in controlling inflammation and are in the delivery forms of drops, pills, or intravitreal injected implants. DEXTENZA® is designed to be placed in the tear duct.

B. Medically Necessary

Dextenza® (dexamethasone 0.4mg intracanalicular insert) may be medically necessary for the control of pain and inflammation when used in conjunction with ocular surgery or for allergic conjunctivitis.

C. Not Medically Necessary

1. Dextenza is contraindicated in patients with any (bacterial, fungal, or viral) ocular infection[1]
2. Dextenza should be used cautiously, with monitoring, in patients with wide angle glaucoma.
3. The patient history should be reviewed to rule out patients with a history of increased intraocular pressure from glucocorticoids.

D. Documentation

Medical necessity must be supported by adequate and complete documentation in the patient's medical record that describes the procedure and the medical rationale for it as in requirements above. For any retrospective review, a full operative report and/ the medical plan of care is needed.

All items must be available upon request to initiate or sustain previous payments. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, date(s) of service). Services provided/ordered must be authenticated by the physician, in a handwritten or electronic signature. Stamped signatures are not acceptable.

E. Procedural Detail

CPT/HCPCS Codes	
68841	Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each
J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg (x 4 for 0.4 mg dose)
Required Modifiers	
RT LT or 50	Right side, or Left side, or Bilateral
Allowable modifiers for J Codes	
JW or JZ	Drug waste or no drug waste

[1] Lee, 2020.

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RELATED POLICIES	
1317	Intravitreal Anti-VEGF injections
1346	Corticosteroid Injections and Implants

DOCUMENT HISTORY		
Approval Date	***Revision***	***Effective Date***
04/06/2022	Initial policy; extracted from 1346.	09/01/2022
04/12/2023	Add indication of allergic conjunctivitis; add contraindications of ocular infections and intraocular pressure increase from glucocorticoid use.	10/01/2023
04/03/2024	Annual review; no criteria changes.	06/01/2024
04/09/2025	Annual review; no criteria changes.	06/01/2025

REFERENCES AND SOURCES

1. Alsudais AS, Alshehri WM, Alrehaili AM, et al. The Efficacy and Safety of Dexamethasone Intracanalicular Insert Use in Patients with Chronic Seasonal/Perennial Allergic Conjunctivitis: A Systematic Review and Meta-Analysis. Clin Ophthalmol. 2024;18:2657-2666. Published 2024 Sep 21. doi:10.2147/OPTH.S470657.
2. Blizzard C, McLaurin EB, Driscoll A, et.al. Plasma Pharmacokinetic Parameters of Dexamethasone Following Administration of a Dexamethasone Intracanalicular Insert in Healthy Adults. Clin Ophthalmol. 2021 May 18; 15:2055-2061. doi: 10.2147/OPTH.S307194. PMID: 34040341; PMCID: PMC8140928.
3. Brooks CC, Jabbehdari S, Gupta PK. Dexamethasone 0.4mg Sustained-Release Intracanalicular Insert in the Management of Ocular Inflammation and Pain Following Ophthalmic Surgery: Design, Development and Place in Therapy. Clin Ophthalmol. 2020 Jan 13; 14:89-94. doi: 10.2147/OPTH.S238756. PMID: 32021072; PMCID: PMC6968807.
4. Cheng KJ, Hsieh CM, Nepali K, et.al. Ocular Disease Therapeutics: Design and Delivery of Drugs for Diseases of the Eye. J Med Chem. 2020 Oct 8;63(19):10533-10593. doi: 10.1021/acs.jmedchem.9b01033. Epub 2020 Jun 2. PMID: 32482069.
5. Foster B. Same-Day versus Next-Day Dexamethasone Intracanalicular Insert Administration for Inflammation and Pain Control Following Cataract Surgery: A Retrospective Analysis. Clin Ophthalmol. 2021 Oct 18; 15:4091-4096. doi: 10.2147/OPTH.S335764. PMID: 34703199; PMCID: PMC8541700.
6. Greenwood MD, Gorham RA, Boever KR. A Randomized Fellow-Eye Clinical Trial to Evaluate Patient Preference for Dexamethasone Intracanalicular Insert or Topical Prednisolone Acetate for Control of Postoperative Symptoms Following Bilateral Femtosecond Laser in Site Keratomileusis (LASIK). Clin Ophthalmol. 2020 Aug 6; 14:2223-2228. doi: 10.2147/OPTH.S265311. PMID: 32821083; PMCID: PMC7418164.
7. Ibach MJ, Shafer BM, Wallin DD, et.al. The Effectiveness and Safety of Dextenza 0.4 mg for the Treatment of Postoperative Inflammation and Pain in Patients After Photorefractive Keratectomy: The RESTORE Trial. J Refract Surg. 2021 Sep;37(9):590-594. doi: 10.3928/1081597X-20210610-05. Epub 2021 Sep 1. PMID: 34506241.

8. Larsen J, Whitt T, Parker B, et.al. A Randomized, Controlled, Prospective Study of the Effectiveness and Safety of an Intracanalicular Dexamethasone Ophthalmic Insert (0.4 Mg) for the Treatment of Post-Operative Inflammation in Patients Undergoing Refractive Lens Exchange (RLE). Clin Ophthalmol. 2021 May 27; 15:2211-2217. doi: 10.2147/OPTH.S311070. PMID: 34079218; PMCID: PMC8166314.
9. Lee A, Blair HA. Correction to: Dexamethasone Intracanalicular Insert: A Review in Treating Post-Surgical Ocular Pain and Inflammation. Drugs. 2020 Aug;80(12):1265. doi: 10.1007/s40265-020-01366-0. Erratum for: Drugs. 2020 Jul;80(11):1101-1108. PMID: 32700064; PMCID: PMC7395051.
10. Lee A, Blair HA. Dexamethasone Intracanalicular Insert: A Review in Treating Post-Surgical Ocular Pain and Inflammation. Drugs. 2020 Jul;80(11):1101-1108. doi: 10.1007/s40265-020-01344-6. Erratum in: Drugs. 2020 Aug;80(12):1265. PMID: 32588339; PMCID: PMC7371664.
11. McLaurin EB, Evans D, Repke CS, et.al. Phase 3 Randomized Study of Efficacy and Safety of a Dexamethasone Intracanalicular Insert in Patients with Allergic Conjunctivitis. Am J Ophthalmol. 2021 Sep; 229:288-300. doi: 10.1016/j.ajo.2021.03.017. Epub 2021 Mar 25. PMID: 33773984.
12. Nattis AS, Rosenberg ED, Rasool F. Intracanalicular dexamethasone insert for post-corneal crosslinking inflammation and pain: the LINK study. J Cataract Refract Surg. 2023 Nov 1;49(11):1114-1119. doi: 10.1097/j.jcrs.0000000000001279. PMID: 37532250.
13. Saenz B, Ferguson TJ, Abraham N, et.al. Evaluation of Same-Day versus Next-Day Implantation of Intracanalicular Dexamethasone for the Control of Postoperative Inflammation and Pain Following Cataract Surgery. Clin Ophthalmol. 2021 Dec 7; 15:4615-4620. doi: 10.2147/OPTH.S334297. PMID: 34916773; PMCID: PMC8669496.
14. Singer MA, Boyer DS, Williams S, et.al. Phase 2 randomized study (orion-1) of a novel, biodegradable dexamethasone implant (ar-1105) for the treatment of macular edema due to central or branch retinal vein occlusion. Retina. 2023 Jan 1;43(1):25-33. doi: 10.1097/IAE.0000000000003632. Epub 2022 Oct 14. PMID: 36542081; PMCID: PMC9750099.
15. Suñer IJ, Peden MC. Dexamethasone Sustained-Release Intracanalicular Insert for Control of Postoperative Inflammation After Pars Plana Vitrectomy. Clin Ophthalmol. 2021 Sep 17; 15:3859-3864. doi: 10.2147/OPTH.S330255. PMID: 34556974; PMCID: PMC8455509.
16. Torkildsen G, Abelson MB, Gomes PJ, et.al. Vehicle-Controlled, Phase 2 Clinical Trial of a Sustained-Release Dexamethasone Intracanalicular Insert in a Chronic Allergen Challenge Model. J Ocul Pharmacol Ther. 2017 Mar;33(2):79-90. doi: 10.1089/jop.2016.0154. Epub 2017 Jan 10. PMID: 28072552
17. Trivedi RH, Wilson ME. A sustained release intracanalicular dexamethasone insert (Dextenza) for pediatric cataract surgery. J AAPOS. 2021 Feb;25(1):43-45. doi: 10.1016/j.japos.2020.10.001. Epub 2020 Dec 13. PMID: 33321213.
18. Tyson SL, Campbell P, Biggins J, et.al. Punctum and canalicular anatomy for hydrogel-based intracanalicular insert technology. Ther Deliv. 2020 Mar;11(3):173-182. doi: 10.4155/tde-2020-0010. Epub 2020 Mar 16. PMID: 32172659.
19. Tyson SL, Bafna S, Gira JP, et.al.; Dextenza Study Group. Multicenter randomized phase 3 study of a sustained release intracanalicular dexamethasone insert for treatment of ocular inflammation and pain after cataract surgery. J Cataract Refract Surg. 2019 Feb;45(2):204-212. doi: 10.1016/j.jcrs.2018.09.023. Epub 2018 Oct 24. Erratum in: J Cataract Refract Surg. 2019 Jun;45(6):895. PMID: 30367938.

20. Ueberroth JA, Oellers PR, Brown J, et.al. Intracanalicular Dexamethasome Insert after Retinal Surgery: the ADHERE Trial. Ophthalmol Retina. 2023 Sep;7(9):831-833. doi: 10.1016/j.oret.2023.06.011. Epub 2023 Jun 24. PMID: 37356492.
21. Xu J, Liu Z, Mashaghi A, et.al. Novel Therapy for Primary Canaliculitis: A Pilot Study of Intracanalicular Ophthalmic Corticosteroid/Antibiotic Combination Ointment Infiltration. Medicine (Baltimore). 2015 Sep;94(39): e1611. doi: 10.1097/MD.0000000000001611. PMID: 26426646; PMCID: PMC4616879.

SOURCES

1. CMS Billing and Coding: Dexamethasone Intracanalicular Ophthalmic Insert (Dextenza®).A58392. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58392&ver=13&. Accessed 2/2025.
2. DEXTENZA® Reimbursement Guide https://www.dextenza.com/wp-content/uploads/PP-US-DX-0091-V3-DEXTENZA-ReimbursementGuide.pdf . Accessed 2/2025.
3. FDA Drug Summary and Prescribing Information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208742s001lbl.pdf Accessed 2/2025.