Molina Clinical Policy
Dextenza: Dexamethasone Intracanalicular Insert
Policy No. 405

Last Approval: 4/10/2024
Next Review Due By: April 2025

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Dextenza (biodegradable dexamethasone intracanalicular insert) is a sustained-release formulation of the corticosteroid dexamethasone that is inserted non-invasively into the canaliculus to deliver a 30-day tapered release of 0.4 mg of dexamethasone to the ocular surface following ophthalmic surgery. The intracanalicular insert, which is administered by a physician, includes a visualization aid for retention monitoring throughout the treatment period. The insert is conjugated with fluorescein and allows visualization using blue light with a yellow filter. Dextenza resorbs and exits the nasolacrimal system without the need for removal; however, saline irrigation or manual expression may be used to remove the insert if necessary. Dextenza was first approved in November 2018 to treat ocular pain and inflammation after ophthalmic surgery (FDA 2018). The FDA approved a supplemental New Drug Application for an expanded indication to its label on October 11, 2021, to include the treatment of ocular itching caused by allergic conjunctivitis (FDA 2021).

Postoperative pain and inflammation are common following ocular surgery and are generally managed by a post-operative topical ophthalmic regimen. Prolonged inflammation increases the risk of secondary ocular complications, including increased intraocular pressure, cystoid macular edema, posterior adhesion formation, posterior capsule opacities, secondary glaucoma, delayed recovery, and decreased vision (Tyson et al. 2019). Topical treatments that are generally used for postoperative pain and/or inflammation include corticosteroids (e.g., dexamethasone, loteprednol etabonate, difluprednate, and prednisolone acetate) and nonsteroidal anti-inflammatory drugs (e.g., bromfenac, nepafenac, diclofenac, and ketorolac) (Jacobs 2024). Although topical ophthalmic corticosteroids treat pain and inflammation after ocular surgery, these agents are also associated with class-related adverse events (AE) and limited ocular bioavailability. Patients with physical or cognitive limitations may have difficulty instilling eye drops due to decreased manual dexterity, tremor, difficulty tilting the head back, and visual impairments, which usually affect older persons and further impede successful eyedrop administration (Matossian 2020).

Dextenza is an alternative treatment option to topical corticosteroid preparations (e.g., ophthalmic drops) in patients with ocular inflammation and pain following ophthalmic surgery. The best available evidence includes 3 pivotal, double-blind, randomized, vehicle-controlled phase 3 trials comparing the safety and efficacy of Dextenza with a placebo vehicle (Walters et al., 2016; Tyson et al., 2019). However, a direct comparison of the risks and benefits of Dextenza relative to standard dexamethasone is lacking. While an alternative delivery system for Dextenza may alleviate limitations associated with patient administration of post-operative eye drop regimens, no clear clinical benefit has been established to date, and there are no long-term data on potential AEs. Phase 3 trials of the intracanalicular insert versus placebo showed a statistically significant superiority in managing inflammation and pain in patients who have undergone cataract surgery.

Allergic conjunctivitis (AC) is an inflammatory disease of the conjunctiva primarily caused by an inflammatory response to an allergen that binds to immunoglobulin E on the surface of mast cells. Hallmark signs and symptoms of AC include itching, redness, swelling, tearing, and temporary acute photophobia and may range from mild to severely debilitating (Baab et al. 2024). AC occurs in a seasonal or, less frequently, perennial form. The difference between the two conditions is the periodic or chronic nature of symptoms, depending on the type of allergen to which the patient is sensitive. Seasonal AC is typically associated with allergic rhinitis and is most commonly triggered by

pollens while perennial AC is triggered by allergens (e.g., animal dander or dust mites) that are present throughout the year. Symptoms are usually less severe than with seasonal AC. Topical ophthalmic agents are generally first-line pharmacologic therapy for AC, including antihistamines, mast cell stabilizers, and topical corticosteroids with the persistence or severity of symptoms persist (Sacks et al. 2018). Topical dual-activity agents (antihistamine/mast-cell stabilizing activity) are considered first-line treatment in AC and are clinically superior due to both symptom/sign relief and tolerability (Sacks et al. 2018; Leonardi et al. 2019). Topical dexamethasone is routinely used to treat ocular inflammation and is a widely used ocular corticosteroid with extensive studies (Holland et al. 2019). The efficacy and safety of Dextenza in the treatment of AC was demonstrated in 3 trials that showed lower itching scores in the Dextenza-treated group compared to the control group. Ocular adverse reactions commonly reported with Dextenza include increased intraocular pressure (3%), increased lacrimation (1%), eye discharge (1%) and reduced visual acuity (1%). The most common nonocular adverse reaction was headache (1%).

RELATED POLICIES / PROCEDURES

MCP-342: Dexycu (dexamethasone intraocular suspension)
MCP-301: Iluvien (fluocinolone acetonide intravitreal implant)
MCP-282: Ozurdex (dexamethasone intravitreal implant)
MCP-302: Retisert, Yutiq (fluocinolone acetonide intravitreal implants)

COVERAGE POLICY

Ocular Postoperative Inflammation and Pain

Dextenza (dexamethasone 0.4 mg intracanalicular implant) for the treatment of ocular inflammation and pain following ophthalmic surgery **may be considered medically necessary** when **ALL** of the following clinical criteria are met:

1. Prescribed for the treatment of ocular inflammation and pain following cataract surgery**.**
   Informational Note: The published evidence to date supporting the approval of postoperative pain and inflammation only includes cataract patients, patients with glaucoma or increased intraocular pressure were not included in pivotal phase 3 clinical trials.
2. Confirmed date of cataract surgery**.**
3. Attestation that Dextenza will be inserted by a physician experienced in the administration of ophthalmic inserts immediately following surgery**.**
4. Member is unable to use corticosteroid eye drops due to **ONE** of the following conditions supported by clinical documentation (including chart notes, medical records, dates of therapy/adverse events, etc.):
   a. Post-operative treatment with corticosteroid ophthalmic drops has previously failed or is contraindicated**.**
   b. Cognitive (such as dementia or Alzheimer's disease) or dexterity issues prohibiting the member from using corticosteroid eye drops**.**
   c. Other medical/clinical rationale supported by documentation.
5. Documentation/attestation required for **ALL** of the following:
   a. Member has been informed about the potential adverse effects of a corticosteroid intravitreal implant, including cataracts, increased intraocular pressure, or hypotony, endophthalmitis, and risk of need for additional surgical procedures**.**
   b. Requested dexamethasone intravitreal implant (Dextenza) is NOT intended for administration with other intravitreal implants or inserts (e.g., fluocinolone acetonide intravitreal implant [Iluvien/Retisert]).

      MOLINA REVIEWER: Verify medical/pharmacy claims data and medical history/chart notes for concurrent intravitreal implants.

Ocular Itching associated with Allergic Conjunctivitis

Dextenza for the treatment of ocular inflammation and pain following ophthalmic surgery **may be considered medically necessary** when **ALL** of the following clinical criteria are met with documentation:

1. Diagnosis of allergic conjunctivitis**.**
2. Positive history of ocular allergies and a positive skin test reaction to a perennial allergen and a seasonal allergen.
3. Inadequate response to **ALL** of the following topical ophthalmic therapies unless contraindicated or clinically significant adverse effects are experienced:
    a. Antihistamines (e.g., azelastine, olopatadine, ketotifen, epinastine, etc.)**.**
    b. Mast cell stabilizers (e.g., cromolyn, nedocromil, lodoxamide, etc.)**.**
    c. Vasoconstrictors (e.g., naphazoline, etc.)**.**
    d. Nonsteroidal Anti-Inflammatory Drugs (e.g., ketorolac tromethamine).

    Refer to the 'Supplemental Information' section of policy for information on 'Ophthalmic Medications for the Treatment of AC.'
4. Lack of therapeutic response from short-term topical ophthalmic corticosteroids
5. Dextenza is not prescribed for use in combination with sustained-release intravitreal corticosteroids (e.g., fluocinolone acetonide or dexamethasone implants)**.**
6. Absence of any eye diseases / conditions or contraindication (*listed below in Limitations/Exclusions) that may cause the member to experience lack of benefit or safety from the use of Dextenza.

CONTINUATION OF THERAPY

Ocular Postoperative Inflammation and Pain: Reauthorization is not applicable for this indication

Ocular Itching associated with Allergic Conjunctivitis: Reauthorization is not applicable for this indication.

Continuation of therapy beyond 30 days as long-term steroids, especially dexamethasone, can cause irreversible cataracts and glaucoma. Safety and efficacy of repeated doses have not been evaluated (McLaurin et al. 2021).

LIMITATIONS AND EXCLUSIONS

The following are considered **contraindications/exclusions** based on insufficient evidence:

1. Hypersensitivity to dexamethasone, other corticosteroids, or any component of the formulation
2. Presence of an active ocular infection or positive history of an ocular herpetic infection: Active corneal, conjunctival, or canalicular infections, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella
3. Mycobacterial infections
4. Ophthalmic fungal disease
5. Dacryocystitis
6. History of refractive surgery (including LASIK procedures) within the past 2 years
7. History of retinal detachment, diabetic retinopathy, or active retinal disease
8. History of increased intraocular pressure as a result of steroid treatment

The following are considered **experimental, investigational, and unproven** based on insufficient evidence:

1. Any indications other than those listed above

PRESCRIBER REQUIREMENTS: Prescribed by board-certified ophthalmologists or retinal specialist, retinal surgeon experienced in the administration of intraocular injections.

AGE RESTRICTIONS: 18 years of age or older

DOSING CONSIDERATIONS: Place single 0.4 mg insert into the lower lacrimal canaliculus

DURATION OF APPROVAL: 30 days

QUANTITY LIMITATIONS: ONE intracanalicular insert (0.4 mg) per affected eye

ADMINISTRATION:

1. Dextenza is considered a provider-administered procedure performed in an office-based setting by an ophthalmologist, retinal specialist, or retinal surgeon by experienced in intracanalicular insertions.
2. Refer to MHI Policy & Procedure: *Specialty Medication Administration Site of Care Policy: MHI Pharm 11.*

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DRUG INFORMATION

ROUTE OF ADMINISTRATION: Intracanalicular insert

DRUG CLASS: Anti-inflammatory Agent, Corticosteroid, Ophthalmic

FDA-APPROVED USES:

- **Ocular Postoperative Inflammation and Pain:** Treatment of ocular inflammation and pain following ophthalmic surgery
  Dextenza was approved for marketing through the FDA's New Drug Approval (NDA) clearance pathway. In November 2018, the FDA approved it to treat ocular pain after ophthalmic surgery, and in June 2019, it received approval to treat ocular inflammation after ophthalmic surgery.

- **Ocular Itching Associated with Allergic Conjunctivitis:** Treatment of ocular itching associated with allergic conjunctivitis.
  FDA approval of Supplemental New Drug Application (sNDA) to expand the use of Dextenza with an additional indication for the treatment of ocular itching associated with allergic conjunctivitis in October 2021.

SUMMARY OF MEDICAL EVIDENCE

<u>Ocular Itching Associated with Allergic Conjunctivitis</u>

FDA approval was based on efficacy data from three randomized, multicenter, double-masked, parallel group, vehicle-controlled phase 3 studies that evaluated the efficacy and safety of Dextenza in 255 patients (n = 255) with a history of ocular allergies and a positive skin test reaction to perennial and seasonal allergens (ClinicalTrials.gov Identifier: NCT02445326, NCT02988882, NCT04050865). Dextenza treatment resulted in lower mean ocular itching scores compared to vehicle at all time points throughout the 30-day study duration, according to all three trials. In two of the three studies, a higher proportion of patients in the Dextenza arm achieved statistically significant reductions in ocular itching on day 8, at 3 minutes, 5 minutes, and 7 minutes post challenge, compared with patients in the vehicle arm. The most common ocular AEs associated with Dextenza were increased intraocular pressure (3%), increased lacrimation (1%), eye discharge (1%), and reduced visual acuity (1%). Headache was the most common non-ocular AE (1%).

McLaurin et al. (2021) assessed the efficacy and safety of the Dextenza intracanalicular ocular insert for the treatment of AC in a multicenter, randomized, double-masked, Phase 3 placebo-controlled trial. Seventy-three (n = 73) patients with a positive conjunctival allergen challenge were randomized to receive Dextenza (n = 35) or (n = 38). A modified conjunctival allergen challenge model was used to induce the underlying inflammatory component of

AC. Challenges occurred over the next 30 days following in-office insert placement, and primary efficacy was assessed at Week 1 conjunctival allergen challenge Day 8 (primary endpoint visit). Dextenza-treated patients reported a significant decrease in ocular itching at each time point across all visits, continuing through 4 weeks after insertion, showing both the early onset of response (3 minutes after allergen exposure) and the durability of this response (to 30 days after insert placement). Study limitations are noted for the trial design using the conjunctival allergen challenge model. While this trial design is favorable for ocular allergy studies in providing a strictly controlled environments of allergen exposures, therapeutic outcomes from real-world, uncontrolled environment of allergen exposures are not permitted. The authors advised re-evaluation by the clinician if retreatment is required. The outcomes of repeated doses were not evaluated.

Meyer et al. (2021) completed a pooled post-hoc analysis of four prospective, randomized, double-masked, vehicle-controlled, parallel-group studies concluded that Dextenza is safe and well-tolerated for the treatment of AC. The analysis assessed the safety of Dextenza for the treatment of signs and symptoms of chronic AC in 315 subjects across the trials (Dextenza n = 154, placebo n = 161). Patients with a history of ocular allergies were randomly assigned to receive a dexamethasone insert or a placebo insert in both eyes on the same day. Each of the four studies had a safety assessment, which included AEs, visual acuity, and intraocular pressure. Mild to moderately serious ocular AEs were reported in 12.3% and 14.3% of Dextenza-treated and placebo-treated subjects, respectively. There were no reports of serious ocular-related AEs and one non-ocular serious AE that was unrelated to the study.

Ocular Inflammation and Pain Following Ophthalmic Surgery

FDA approval of Dextenza was based on results from 3 prospective, randomized, double-masked, vehicle-controlled trials that evaluated the safety and efficacy of Dextenza for the treatment of ocular pain and inflammation following cataract surgery [Walters et al.: Study 1 (NCT02034019), Study 2 (NCT02089113); Tyson et al. 2019 (NCT02736175)] A total of 926 individuals were enrolled in the studies and randomized to Dextenza or placebo intracanalicular inserts immediately following cataract surgery (n = 541 for Dextenza and n = 385 for placebo). The duration of clinic follow-up was 120, 90, and 45 days, respectively. The co-primary outcomes were the absence of ocular pain on day 8 (7 days after surgery) and the absence of cells in the anterior chamber cells of the eye on day 14 (indicating inflammation). In the three pivotal phase 3 trials, a considerably greater proportion of patients treated with the dexamethasone intracanalicular insert reported no discomfort on day 8 (the co-primary outcome, 7 days post-operation). Two of three trials met the inflammation co-primary endpoint (absence of anterior chamber cells) at day 14 (13 days post-operation). The Dextenza insert was well-tolerated, with no serious ocular AEs reported across the phase 3 studies

Walters et al. (2016) published the results of two phase 3 double-blind pivotal trials, Study 1 (n = 247) and Study 2 (n = 241). Participants undergoing cataract surgery were randomly assigned to receive Dextenza or a vehicle in these studies.

- Study 1 enrolled 164 patients in the dexamethasone arm and 83 in the vehicle-treated arm;
- Study 2 enrolled 161 patients in the dexamethasone arm and 60 in the vehicle-treated arm.

The coprimary efficacy endpoints were the percentages of patients in each group with an absence of ocular pain in the study eye at day 8 and an absence of anterior chamber cells in the study eye at day 14 (inflammation endpoint). (Note: Day 1 is the day of surgery and the insertion of dexamethasone or a placebo). Both studies met the primary endpoint for ocular pain. At day 8, the dexamethasone groups had statistically higher proportions of patients without ocular pain:

- In study 1, 80% of dexamethasone-treated patients were pain-free on day 8, compared to 43% of vehicle-treated patients.
- In study 2, 77% of dexamethasone-treated patients were pain-free after 8 days, compared to 59% of vehicle-treated patients.

The inflammation endpoint was met only in Study 1. According to the researchers, Study 2 failed to establish statistical significance for the inflammatory endpoint because a significantly larger proportion of patients in the control group lacked anterior chamber cells on day 14. Significantly fewer Dextenza-treated patients than vehicle-treated patients required anti-inflammatory rescue medication on trial days 8 and 14 (no statistical difference on study days 1, 2, and 4). No treatment-related AEs were observed.

Tyson et al. (2019) published the findings of a prospective multicenter randomized parallel-arm, double-masked vehicle-controlled phase 3 study that evaluated the efficacy and safety of Dextenza for the treatment of postoperative ocular inflammation and pain in 438 adult cataract surgery patients. Patients were randomized to receive a dexamethasone insert (n = 216) or vehicle (n = 222) after completion of cataract surgery (day 1). The coprimary efficacy endpoint was similar to the two previous phase 3 trials reported by Walters et al. (2016): 1) complete absence of anterior chamber cells at day 14, and 2) complete absence of pain at day 8. On day 14, the dexamethasone-injected arm had significantly more anterior chamber cell loss (52.3%) than the placebo group (31.1%). On day 8, the dexamethasone-injected arm had significantly more patients with no eye pain (79.5%) than the control group (61.3%). There was no increase in the incidence of AEs or ocular AEs in the dexamethasone-inserted group compared to the placebo group. Rescue treatment was required by twice as many placebo patients on day 14. The lack of a direct comparison of the dexamethasone insert with an active control (e.g., standard dexamethasone eye drops) to determine clinical utility and benefit of the dexamethasone insert is a limitation of this trial. There were no serious AEs associated with the treatment. The dexamethasone insert was reported to be well tolerated, with AEs similar to a placebo.

National and Specialty Organizations

Corticosteroids and nonsteroidal anti-inflammatory drugs have traditionally been used to treat inflammation, both prophylactically and post-operatively; however, currently there are no established guidelines or consensus for the treatment of inflammation induced by cataract surgery.

A preferred postoperative regimen for control of inflammation and pain after cataract surgery and other intraocular surgeries has not been established due to a lack of sufficient evidence from randomized controlled studies (Aptel et al. 2017).

American Academy of Ophthalmology (AAO)

Ocular Postoperative Inflammation and Pain
The Cataract in the Adult Eye Preferred Practice Pattern guidelines suggest that postoperative management after cataract surgery may include topical corticosteroids and nonsteroidal anti-inflammatory drugs. Due to a lack of high-level evidence comparing these interventions, no optimal postoperative medication regimens have been established. The guidelines state that complications of postoperative medications include elevated intraocular pressure with corticosteroids and allergic reactions to antibiotics, but they do not mention the use of dexamethasone intracanalicular ocular insert (Miller et al. 2021).

Allergic Conjunctivitis
The Conjunctivitis Preferred Practice Pattern (Cheung et al. 2024) does not address the use of a dexamethasone intracanalicular ocular insert for the treatment of AC. The report recommends adding a brief course (1 to 2 weeks) of topical corticosteroids with a minimal side effect profile if the symptoms are not adequately controlled and includes a list of topical medications for seasonal AC.

The **National Institute for Health and Clinical Excellence (NICE)** is developing guidance on dexamethasone intracanalicular inserts for treating inflammation and pain after cataract surgery. The expected publication date for the proposed guidance [GID-TA10198] is to be confirmed (as of the review of this policy in March 2024).

SUPPLEMENTAL INFORMATION

Ophthalmic Medications for Treatment of Allergic Conjunctivitis
References: American Academy of 0phthalmology (Sacks et al. 2018); UpToDate (Hamrah and Dana 2023)

Antihistamines with Mast Cell-Stabilizing Properties	Usual Adult Dosing
Olopatadine 0.1% (Patanol OTC), 0.2% (Pataday OTC), 0.7% (Pazeo), 0.1% and 0.2% (generics)	1 drop per eye twice daily (Patanol); 1 drop per eye once daily (Pataday and Pazeo)
Alcaftadine 0.25% (Lastacaft)	1 drop per eye once daily
Bepotastine 1.5% (Bepreve)	1 drop per eye twice daily

Cetirizine 0.24% (Zerviate)	1 drop per eye twice daily
Epinastine 0.05% (generics)	1 drop per eye twice daily
Ketotifen 0.025% (multiple OTC products)	1 drop per eye twice daily
Azelastine 0.05% (generics)	1 drop per eye twice daily
Emedastine 0.05% (generics)	1 drop per eye up to four times daily
Mast cell stabilizers	**Usual Adult Dosing**
Cromolyn sodium 4% (generics)	1 to 2 drops per eye up to six times daily
Nedocromil 2% (Alocril)	1 to 2 drops per eye twice daily
Lodoxamide 0.1% (Alomide)	1 to 2 drops per eye four times daily for up to three months
Pemirolast 0.1% (Alamast)	One to two drops per eye up to four times daily
Corticosteroids	**Usual Adult Dosing**
Loteprednol etabonate 0.2% or 0.5% (Alrex, Lotemax)	1 drop per eye four times daily
Prednisolone acetate 0.12% [Pred Mild] or 1% [generics])	1 to 2 drops per eye two to four times daily
Fluorometholone 0.1% (generics)	1 to 2 drops per eye two to four times daily

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Code

Code	Description
68841	Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each

HCPCS (Healthcare Common Procedure Coding System) Code

Code	Description
J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg

AVAILABLE DOSAGE FORMS: Biodegradable intravitreal implant containing dexamethasone 0.7 mg

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

04/10/2024 Policy reviewed, no changes to criteria.
04/13/2023 Policy reviewed and updated. No changes to coverage criteria. Updated references.
04/13/2022 Policy reviewed and updated. Added clinical summary and coverage criteria for the indication of Ocular Itching associated Allergic Conjunctivitis in relevant sections of policy. Added a table of 'Ophthalmic Medications for Treatment of Allergic Conjunctivitis in the Supplemental Information section. Updated references. IRO Peer Review. 4/8/2022. Practicing Physician. Board certified in Ophthalmology.
10/13/2021 New policy. IRO Peer Review. 9/28/2021. Practicing Physician. Board certified in Ophthalmology.

REFERENCES

1. Aptel F, Colin C, Kaderli S, et al. Management of postoperative inflammation after cataract and complex ocular surgeries: A systematic review and Delphi survey. Br J Ophthalmol. 2017 Nov;101(11):1-10. doi: 10.1136/bjophthalmol-2017-310324. Epub 2017 Aug 3. PMID: 28774934.
2. Baab S, Le PH, Gurnani B, et al. Allergic conjunctivitis. In: StatPearls [Internet]. Treasure Island (FL). Updated January 26, 2024. Accessed March 12, 2024. https://www.ncbi.nlm.nih.gov/books/NBK448118/.
3. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database: Dexamethasone intracanalicular ophthalmic insert (Dextenza®) (L38792). Revised May 26, 2022. Accessed March 12, 2024. https://www.cms.gov/medicare-coverage-database/search.aspx.

4. Cheung AY, Choi DS, Ahmad S, et al. Conjunctivitis preferred practice pattern. Ophthalmology. 2024 Feb 12:S0161-6420(24)00009-5. doi: 10.1016/j.ophtha.2023.12.037. Epub ahead of print. PMID: 38349304.
5. Clinical Pharmacology powered by ClinicalKey. Tampa (FL): Elsevier. 2024. Accessed March 12, 2024. http://www.clinicalkey.com.
6. ClinicalTrials.gov. NCT04050865, NCT02445326, NCT02988882, NCT02034019, NCT02089113, NCT02736175. National Library of Medicine. Accessed March 12, 2024. www.clinicaltrials.gov.
7. Dextenza (dexamethasone ophthalmic insert) 0.4mg [prescribing information]. Bedford, MA: Ocular Therapeutix. Revised October 2021. Accessed March 12, 2024. https://www.dextenza.com/wp-content/uploads/DEXTENZA-Full-Prescribing-Information-1.pdf.
8. Hamrah P, Dana R. Allergic conjunctivitis: Management. Updated January 21, 2023. Accessed March 12, 2024. www.uptodate.com.
9. Holland EJ, Fingeret M, Mah FS. Use of topical steroids in conjunctivitis: A review of the evidence. Cornea. 2019 Aug;38(8):1062-1067. doi: 10.1097/ICO.0000000000001982. PMID: 31276464.
10. Jacobs DS. Cataract in adults. Updated February 29, 2024. Accessed March 12, 2024. www.uptodate.com.
11. Leonardi A, Silva D, Perez Formigo D, et al. Management of ocular allergy. Allergy. 2019 Sep;74(9):1611-1630. doi: 10.1111/all.13786. Epub 2019 Jun 24. PMID: 30887530.
12. Matossian C. Noncompliance with prescribed eyedrop regimens among patients undergoing cataract surgery – Prevalence, consequences, and solutions. US Ophthalmic Rev. 2020;13(1):18-22. doi:10.17925/USOR.2020.13.1.18.
13. 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.
14. Meyer J, Kenyon K, Sato M, et al. Safety of an intracanalicular Dexamethasone insert for the treatment of allergic conjunctivitis: Pooled post-hoc analysis of four studies. Invest Ophthalmol Vis Sci. 2021;62(8):731.
15. Miller KM, Oetting TA, Tweeten JP, et al. Cataract in the adult eye preferred practice pattern. Ophthalmology. 2022 Jan;129(1):P1-P126. doi: 10.1016/j.ophtha.2021.10.006. Epub 2021 Nov 12. PMID: 34780842.
16. National Institute for Health and Care Excellence (NICE). Dexamethasone intracanalicular insert for treating inflammation and pain after cataract surgery [GID-TA10198]. Accessed March 12, 2024. https://www.nice.org.uk/guidance/awaiting-development/gid-ta10198/.
17. Sacks D, Baxter B, Campbell BCV, et al. Multisociety consensus quality improvement revised consensus statement for endovascular therapy of acute ischemic stroke. Int J Stroke. 2018 Aug;13(6):612-632. doi: 10.1177/1747493018778713. Epub 2018 May 22. PMID: 29786478.
18. 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. 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.
19. United States Food and Drug Administration (FDA) Center for Drug Evaluation and Research. Supplemental approval: NDA 208742/S-007. Published October 7, 2021. Accessed March 13, 2024. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208742Orig1s000SumR.pdf.
20. United States Food and Drug Administration (FDA) Center for Drug Evaluation and Research. Summary review: NDA 208742 Dextenza (dexamethasone insert) 0.4mg. Published November 30, 2018. Accessed March 13, 2024. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208742Orig1s000SumR.pdf.
21. 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. 7:1000572. doi:10.4172/2155-9570.1000572.