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

Last Approval: 4/13/2022
Next Review Due By: April 2023

Ohio MEDICAID: No age restrictions to be applied. Must consider ESPDT.

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 physician-administered intracanalicular insert contains 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 need for removal; however, saline irrigation or manual expression may be performed to remove the insert if necessary. Dextenza was originally approved to treat ocular pain and inflammation following ophthalmic surgery in November 2018. On October 11, 2021, the FDA approved a supplemental New Drug Application for an expanded indication to its label to including the treatment of ocular itching caused by allergic conjunctivitis.

Postoperative pain and inflammation are common following ocular surgery and generally managed by a post-operative topical ophthalmic regimen. Prolonged inflammation increases the risk of secondary ocular complications, including increased intraocular pressure (IOP), 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 2021). 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 manual dexterity, tremor, difficulty tilting the head back, and visual impairments, which usually affects older persons and further impedes 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. 2021). 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 (AAO 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 (AAO 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

Dexycu (dexamethasone intraocular suspension) Policy No. 342
Iluvien (fluocinolone acetonide intravitreal implant) Policy No. 301
Ozurdex (dexamethasone intravitreal implant) Policy No. 282
Retisert, Yutiq (fluocinolone acetonide intravitreal implants) Policy No. 302

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; **AND**
   Informational Note: The published evidence to date supporting the approval of postoperative pain and inflammation only includes cataract patients, patients with glaucoma or increased IOP were not included in pivotal phase 3 clinical trials.
2. Confirmed date of cataract surgery; **AND**
3. Attestation that Dextenza will be inserted by a physician experienced in the administration of ophthalmic inserts immediately following surgery; **AND**
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/AEs, etc.):
   a. Post-operative treatment with corticosteroid ophthalmic drops has previously failed or is contraindicated; **OR**
   b. Cognitive (such as dementia or Alzheimer's disease) or dexterity issues prohibiting the member from using corticosteroid eye drops; **OR**
   c. Other medical/clinical rationale supported by documentation.

AND

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; **AND**
   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; **AND**
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 topic ophthalmic therapies unless contraindicated or clinically significant adverse effects are experienced:
   a. Antihistamines (e.g., azelastine, olopatadine, ketotifen, epinastine, etc.); **AND**
   b. Mast cell stabilizers (e.g., cromolyn, nedocromil, lodoxamide, etc.); **AND**
   c. Vasoconstrictors (e.g., naphazoline, etc.); **AND**
   d. NSAID (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); **AND**
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 (ophthalmologist peer review, 2022). 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 IOP increase 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 (P&P) *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 received clearance for marketing (NDA 208742) via the FDA New Drug Approval (NDA) clearance pathway. FDA approved in November 2018 to treat ocular pain after ophthalmic surgery and received indication for treatment of ocular inflammation after ophthalmic surgery in June 2019.
- **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 on Oct 2021.

COMPENDIAL APPROVED OFF-LABELED USES: None

SUMMARY OF MEDICAL EVIDENCE

Ocular Itching Associated with Allergic Conjunctivitis

FDA approval was based on efficacy data from 3 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 positive skin test reaction to perennial and seasonal allergens (ClinicalTrials.gov Identifier: NCT02445326, NCT02988882, NCT04050865). All 3 trials reported that treatment with Dextenza resulted in lower mean ocular itching scores compared with vehicle at all time points throughout the 30-day study duration. In 2 of the 3 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 adverse reactions reported with Dextenza included increased IOP (3%), increased lacrimation (1%), eye discharge (1%) and reduced visual acuity (1%). The most common non-ocular adverse reaction was headache (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 (CAC) were randomized to receive Dextenza (n = 35) or (n = 38). A modified CAC model (Ora-CAC model) was used to induce the underlying inflammatory component of AC. Challenges occurred over 30 days following in-office insert placement, and primary efficacy was assessed at Week 1 CAC Day 8 (primary endpoint visit). Dextenza-treated patients reported 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 noted is the trial design using the CAC model. While this trial design is favorable for ocular allergy studies in providing a strictly controlled environment of allergen exposures, therapeutic outcomes from real-world, uncontrolled environment of allergen exposures is not permitted. The authors advised re-evaluation by the clinician if retreatment is required. Outcomes of repeated doses were not evaluated.

A pooled post hoc analysis of 4 prospective, randomized, double-masked, vehicle-controlled, parallel-group studies concluded that Dextenza is safe and well-tolerated for the treatment of AC. The analysis evaluated 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) (Meyer et al. 2021). Patients with a history of ocular allergies were randomized to receive a dexamethasone insert or a placebo insert in both eyes on the same day. Safety assessments including AEs, visual acuity and IOP were performed in each of the 4 studies. Mild or moderately serious ocular AEs were reported in 12.3% and 14.3% of Dextenza-treated and placebo 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 patients (n=541, Dextenza; n=385, placebo insert) were enrolled across the trials and randomized to either Dextenza or placebo intracanalicular inserts (i.e., an insert without dexamethasone) immediately following cataract surgery (day 1 of the study). Clinic follow-up continued up to day 120, day 90, and day 45, respectively. The co-primary endpoints were similar across all trials: absence of ocular pain on day 8 (7 days post-operation), and the absence of cells in the anterior chamber cells of the eye (indicating inflammation) on day 14. A significantly higher proportion of patients treated with the dexamethasone intracanalicular insert experienced no pain at day 8 (co-primary endpoint, 7 days post-operation) across the 3 pivotal phase 3 trials. The inflammation co-primary endpoint (absence of anterior chamber cells) at day 14 (13 days post-operation) was met in 2 of 3 trials. The Dextenza insert was well-tolerated with no treatment-related serious ocular AEs reported across the phase 3 studies.

Walters et al. (2016) reported on the two phase 3 double-blind pivotal trials, Study 1 (n=247) and Study 2 (n=241). These studies randomly assigned adults undergoing cataract surgery to receive Dextenza or a vehicle.

- Study 1 included 164 patients in the dexamethasone arm and 83 patients in the vehicle-treated arm.
- Study 2 included 161 patients in the dexamethasone arm and 60 in the vehicle-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: The day of surgery and insertion of dexamethasone or the placebo is considered to be day 1). Both studies met the primary endpoint for ocular pain. The dexamethasone groups had statistically higher proportions of patients with no ocular pain at day 8:

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

The inflammation endpoint was met only in Study 1. According to the researchers, Study 2 failed to achieve statistical significance for the inflammation endpoint because of the much higher proportion of patients in the vehicle group

without anterior chamber cells at day 14. Anti-inflammatory rescue medications on study days 8 and 14 were required by significantly fewer Dextenza-treated patients than vehicle-treated patients (no statistical difference on study days 1, 2, and 4). No treatment-related AEs were observed.

Tyson et al. (2019) reported the results of a prospective multicenter randomized parallel-arm double-masked vehicle-controlled phase 3 study that assessed the efficacy and safety of Dextenza for the treatment of postoperative ocular inflammation and pain in 438 adult patients having cataract surgery. Patients were randomized to receive dexamethasone insert (n=216) or vehicle (n=222) after completion of cataract surgery (day 1). The coprimary efficacy endpoint was similar to the 2 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, significantly more patients had anterior chamber cell loss in the dexamethasone-inserted arm (52.3%) compared to the placebo group (31.1%). On day 8, significantly more patients had no eye pain in the dexamethasone-inserted arm (79.6%) compared to the control group (61.3%). There was no increase in the incidence of AEs or ocular AEs in the dexamethasone-inserted group compared with placebo. Rescue treatment was required by twice as many placebo patients on day 14. A limitation of this trial is the lack of a direct comparison of the dexamethasone insert with an active control (e.g., standard dexamethasone eye drops) to determine the clinical utility and benefit of the dexamethasone insert. No treatment-related serious AEs were observed. It was reported that the dexamethasone insert was well-tolerated, and the AEs profile was similar to placebo.

National and Specialty Organizations

Corticosteroids and NSAIDs have traditionally been used to treat inflammation, prophylactically as well as 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 lack of sufficient evidence from randomized controlled studies (Aptel et al. 2017; Olson et al. 2017).

American Academy of Ophthalmology (AAO)

Ocular Postoperative Inflammation and Pain
The Cataract in the Adult Eye Preferred Practice Pattern (PPP) guidelines advise that postoperative management after cataract surgery may include topical corticosteroids and nonsteroidal anti-inflammatory drugs (NSAIDs). There are no optimal postoperative medication regimens established due to a lack of high-level evidence comparing these interventions. The guidelines note that complications of postoperative medications include elevated IOP with corticosteroids and allergic reactions to antibiotics but do not mention the use of dexamethasone intracanalicular ocular insert (AAO 2021).

Allergic Conjunctivitis
The Conjunctivitis PPP (2018) does not address the use of dexamethasone intracanalicular ocular insert for the treatment of AC due to the more recent approval of this indication in October 2021.

The report advises that a brief course (1 to 2 weeks) of topical corticosteroids with a low side effect profile can be added to a treatment regimen if the symptoms are not adequately controlled and provides a list of topical medications that can be used 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 the policy in Feb 2022).

SUPPLEMENTAL INFORMATION

Ophthalmic Medications for Treatment of Allergic Conjunctivitis *Reference: AA0 2018 (Varu et al. 2019); UpToDate (Hamrah and Dana, 2022)*	
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 Code

CPT	Description
68841	Insertion of drug-eluting implant, include. punctal dilation when performed, into lacrimal canaliculus, each

HCPCS Code

HCPCS	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

4/13/2022 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

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database: National coverage determination (NCD) - Dexamethasone Intracanalicular Ophthalmic Insert (DEXTENZA®) (L38792). Available from CMS. Effective Date February 7, 2021. Accessed February 2022.
2. ClinicalTrials.gov. National Library of Medicine; 2000 Feb 29 - [cited February 2019]. Accessed February 2022.
   - A study evaluating the safety and efficacy of OTX-DP for the treatment of allergic conjunctivitis. ClinicalTrials.gov Identifier: NCT04050865). Posted August 8, 2019. Updated October 7, 2021. Available from ClinicalTrials.gov.
   - Phase 3 study evaluating safety and efficacy of OTX-DP for treatment of ocular inflammation and pain after cataract surgery. ClinicalTrials.gov Identifier: NCT02034019. Posted January 13, 2014. Updated January 31, 2020. Available from ClinicalTrials.gov.
   - Second phase 3 study evaluating safety and efficacy of OTX-DP for treatment of ocular inflammation and pain after cataract surgery. ClinicalTrials.gov Identifier: NCT02089113. Posted March 17, 2014. Updated September 26, 2019. Available from ClinicalTrials.gov.
   - Phase 3 study evaluating safety and efficacy of OTX-DP for treatment of ocular inflammation and pain after cataract surgery. ClinicalTrials.gov Identifier: NCT02736175. Posted April 13, 2016. Updated November 13, 2017. Available from ClinicalTrials.gov.
3. United States Food and Drug Administration (FDA). CDER. Summary Review: NDA 208742 Dextenza (dexamethasone insert) 0.4 mg Available from FDA. Accessed February 2022.

Prescribing Information and Drug Compendia

1. Dextenza (dexamethasone) [prescribing information]. Bedford, MA: Ocular Therapeutix Inc; October 2021.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available from ClinicalPharmacology. Registration and login required. Accessed February 2022.
3. Drug Facts and Comparisons. Facts and comparisons eAnswers [online]. Clinical Drug Information LLC, 2021. Available from Wolters Kluwer Health, Inc. Accessed February 2022. Registration and login required.

Peer Reviewed Publications

Allergic Conjunctivitis

1. Baab S, Le PH, Kinzer EE. Allergic Conjunctivitis. [Updated 2021 Jul 25]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available here.
2. Holland EJ, Fingeret M, Mah FS. Use of topical steroids in conjunctivitis: A review of the evidence, cornea: 2019; 38(8): 1062-1067. doi: 10.1097/ICO.0000000000001982.
3. Leonardi A, Silva D, Formigo D, et al. Management of ocular allergy. Allergy. 2019 Sep;74(9):1611-1630. doi: 10.1111/all.13786.
4. 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;229:288-300.
5. 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.

Ocular Postoperative Inflammation and Pain

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;101(11):1-10. doi: 10.1136/bjophthalmol-2017-310324.
2. Matossian C. Noncompliance with prescribed eyedrop regimens among patients undergoing cataract surgery – prevalence, consequences, and solutions. US Ophthalmic Review. 2020;13(1):18-22. doi:10.17925/USOR.2020.13.1.18.
3. 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; 45(2):204-212. doi: 10.1016/j.jcrs.2018.09.023.
4. 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.
5. Walters T, Endl M, Elmer TR, et al. Sustained-release dexamethasone for the treatment of ocular inflammation and pain after cataract surgery. J Cataract Refract Surg. 2015 Oct;41(10):2049-59.

National and Specialty Organizations

American Academy of Ophthalmology (AAO)

1. Miller KM, Oetting TA, et al. Cataract in the adult eye preferred practice pattern. Ophthalmology. 2021 Nov doi: https://doi.org/10.1016/j.ophtha.2021.10.006. Accessed February 2022.
2. Varu DM, Rhee MK, et al. Conjunctivitis Preferred Practice Pattern. 2018 Oct. doi: https://doi.org/10.1016/j.ophtha.2018.10.020

National Institute for Health and Clinical Excellence (NICE)

1. Dexamethasone intravitreal implant for the treatment of macular edema secondary to retinal vein occlusion. NICE Technology Appraisal guidance 229 [TA229]. 27 July 2011. Available here. Accessed February 2022.

Other Peer Reviewed Publications

1. Jacobs, DS. Cataract in adults. Available from UpToDate. Updated April 12, 2022. Accessed February 2022. Registration and log in required.
2. Hamrah P, Dana R. Allergic conjunctivitis: Management. Available from UpToDate. Updated January 28, 2022. Accessed February 2022. Registration and log in required.
3. DynaMed. Management of cataracts in adults. Available from DynaMed. Accessed February 2022. Registration and login required.
4. DynaMed. Allergic conjunctivitis. Available from DynaMed. Updated Nov. 30, 2018. Accessed Feb. 2022. Registration and login required.

APPENDIX

Reserved for State specific information *(to be provided by the individual States, not Corporate). Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

Ohio MEDICAID: No age restrictions to be applied. Must consider ESPDT.