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Policy Number: C9975-A

Ozurdex (dexamethasone intravitreal implant)

PRODUCTS AFFECTED

Ozurdex (dexamethasone intravitreal implant)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

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.

DIAGNOSIS:
Diabetic macular edema, Macular edema following retinal vein occlusion, Non-infectious uveitis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. DIABETIC MACULAR EDEMA OR RETINAL VEIN OCCLUSION:
1. Documented diagnosis of Diabetic macular edema or Macular edema following retinal vein occlusion AND
2. Documentation of baseline visual status with notation of eye(s) being treated [DOCUMENTATION REQUIRED]

AND

3. Documentation of an inadequate response (defined as 1-2 injections with minimal to no improvement), clinically significant adverse effects, or contraindication to bevacizumab
   AND
4. Documentation of an inadequate response to an appropriate trial of intravitreal glucocorticoids (i.e., triamcinolone)
   AND
5. Member was previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure
   AND
6. Prescriber attests or clinical reviewer has found that Ozurdex (dexamethasone intravitreal implant) is NOT intended for administration with other intravitreal implants (e.g., fluocinolone acetonide intravitreal implant [Iluvien/Retisert])
   AND
7. Prescriber attests member has been counseled 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
8. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Ozurdex (dexamethasone intravitreal implant) include: ocular or periocular infections, glaucoma, torn or ruptured posterior lens capsule, hypersensitivity.]

B. NON-INFECTIOUS UVEITIS:
   1. Documented diagnosis of non-infectious posterior segment uveitis
      NOTE: Ozurdex is not for use in *anterior* uveitis or in uveitis caused by infection
      AND
   2. Documentation of member's baseline best-corrected visual acuity (BCVA) in order to measure efficacy
      AND
   3. Documentation of an inadequate response (appropriate trial period included), serious side effects, or contraindication to formulary topical glucocorticoids OR an intravitreal steroid (e.g., triamcinolone, dexamethasone) OR a systemic corticosteroid
      AND
   4. Documented trial and failure, serious side effects, or contraindication to an anti-metabolite (e.g., methotrexate, azathioprine, mycophenolate) OR a calcineurin inhibitor (e.g., cyclosporine, tacrolimus)
      AND
   5. Member was previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure
      AND
   6. Prescriber attests member has been counseled 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
   7. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Ozurdex (dexamethasone intravitreal implant) include: ocular or periocular infections, glaucoma, torn or ruptured posterior lens capsule, hypersensitivity.]

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:

1. Reauthorization request is for the same eye(s) as initial authorization
   NOTE: *The continuation of therapy criteria is only for the same previously treated eye(s). If member has developed condition in an untreated eye, Prescriber must submit new request with Initial Coverage criteria*.
   AND
2. Documentation ONE of the following is applicable based on member's diagnosis:
   a. DME: Member had an initial positive, but subsequently has experienced decreased vision and/or an increase in retinal thickness, secondary to recurrent or worsening DME
      OR
   b. RVO: Member experienced an initial positive response to treatment, but has subsequently experienced a loss in visual acuity
      OR
   c. Non-infectious Posterior Segment Uveitis: Member experienced an initial positive response to treatment defined as the following, but has subsequently experienced a loss in visual acuity:
      i. Greater than (>) 15 letters (3 lines) in BCVA from baseline after 12 weeks following administration or the patient achieves driving visual acuity; OR
      ii. Visual acuity is maintained to at least 50% of the best recorded following diagnosis of uveitis

   NOTE: Ozurdex treatment should be discontinued (and patient monitored) in absence of macular edema or stable visual acuity. Treatment (and monitoring intervals) may be resumed at prescribing specialist's discretion and submission of authorization request with presence of macular edema or visual acuity is decreasing at any time. Retreatment is usually not necessary for patients that have maintained vision improvement. Exceptions may be reviewed on a case-by-case basis with relevant supporting documentation from Prescriber.
   AND
3. Prescriber attests member is likely to benefit from re-treatment without being exposed to significant risk, according to Prescriber's clinical judgment
   AND
4. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity (e.g., cataracts, increased intraocular pressure, hypotony, endophthalmitis)

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified ophthalmologist, ophthalmic surgeon or retinal specialist, or other specialist in uveal eye disease [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
ONE dexamethasone intravitreal implant per affected eye every 4 to 6 months

PLACE OF ADMINISTRATION:
The recommendation is that implant medications in this policy will be for pharmacy or medical benefit coverage and the intravitreal implant products be administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravitreal implant

DRUG CLASS:
Ophthalmic Steroid

FDA-APPROVED USES:
Indicated for:

- The treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)
- The treatment of non-infectious uveitis affecting the posterior segment of the eye
- The treatment of diabetic macular edema

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Dexamethasone Implant for DME

The MEAD (Macular Edema: Assessment of Implantable Dexamethasone in Diabetes) study consists of two multicenter, three-year, sham controlled, masked RCTs that assess the proportion of patients whose BCVA improved by 15 or more letters from baseline. The trial included 1,048 DME patients, with 351 receiving a 0.7-mg implant, 347 receiving a 0.35-mg implant, and 348 receiving sham treatment (350 participants). Patients with a BCVA of 34 to 68 ETDRS letters and a central subfield retinal thickness of 300 mm on OCT were randomized to therapy with dexamethasone implant 0.7 mg, dexamethasone implant 0.35 mg, or a placebo operation in a 1:1:1 ratio. Re-treatment was limited to once every six months for patients who met the re-treatment eligibility criteria. The primary endpoint in the intent-to-treat population was a 15-letter improvement in BCVA from baseline at trial conclusion, with the last observation carried forward for missing values. Adverse events and IOP were both utilized as safety measures. More patients treated with dexamethasone implant 0.7-mg experienced a statistically significant improvement in BCVA (22.4%) compared to patients in the placebo group (12.0%), as well as a statistically significant reduction in central macular thickness (112 vs. 42 µm) when compared to patients in the placebo group. Dexamethasone 0.7 mg and 0.35 mg implant had a greater mean average reduction in central retinal thickness from baseline during the study than placebo. The dexamethasone intravitreal implant of 0.7 mg and 0.35 mg met the primary efficacy endpoint for improvement in BCVA and reduction in central subfield retinal thickness with an average of four to five injections administered over three years (NCT00168337 and NCT00168389, ClinicalTrials.gov).

Dexamethasone Implant for Noninfectious Posterior Uveitis

The HURON study demonstrated the efficacy and safety of dexamethasone intravitreal implants (Ozurdex) for the treatment of noninfectious posterior segment uveitis (Lowder et al., 2011). The study (n = 229) was a 26-week multicenter, masked, randomized, sham-controlled trial of a dexamethasone intravitreal implant. Patients were randomized to 0.35-mg implants (n=76), 0.7-mg implants (n=77), or placebo (n=76) and followed up for 8 weeks with an 18-week masked extension for 26 weeks. The primary outcome measure was the proportion of eyes with a vitreous haze score of 0 (0 = no inflammation) at week 8. Other outcome measures were vitreous haze through week 26, BCVA, adverse events, IOP, and biomicroscopy/ophthalmoscopy. A single dexamethasone intravitreal implant effectively reduced vitreous haze compared to placebo. At the primary endpoint of week 8, 47% of eyes treated with the 0.7 mg dexamethasone implant had complete vitreous haze resolution, compared to 10% of eyes treated with sham. Compared to sham controls, 0.7-mg implant-treated phakic eyes had a greater rate of increased IOP (>25 mm Hg). Twenty-three percent (n=77) of Ozurdex-treated patients required IOP-lowering

medications, while 7.9% (n=76) had a pressure increase greater than 35 mm Hg. Cataract developed in 15% of phakic eyes treated with the implant compared to 7% in the control group, and only one eye required surgery. Dexamethasone intravitreal implant treatment improved BCVA by week 3 and continued through week 26. This study had limitations, such as a shorter follow-up time (6 months), which might have made it difficult to detect adverse effects such as cataract formation. Long-term efficacy and safety data for the dexamethasone 0.7 mg implant are unavailable, and the trial lacked information regarding the efficacy of recurrent 0.7 mg dexamethasone implantation.

Dexamethasone Implant for RVO

Two randomized, prospective, masked, sham-controlled studies assessed the safety and efficacy of dexamethasone implant (0.7 mg and 0.35 mg to a sham procedure) during a 6-month period followed by a 6-month open-label extension (Haller et al. 2011 & 2010; Ozurdex GENEVA Study Group). Adults with BRVO or CRVO-related macular edema were studied. Inclusion required a duration of macular edema between 6 weeks and 12 months for BRVO and 6 weeks to 9 months for CRVO (Haller et al., 2010). Three months after administration of a single dexamethasone implant, the 0.7 mg and 0.35 mg dexamethasone implants were preferable to the sham procedure in terms of reducing central retinal thickness and enhancing BCVS. At month 1 and month 3, the proportion of eyes with at least a 15-letter improvement in vision was higher in the treatment groups. The effect was no longer statistically significant by the sixth month. At month 3, the reduction in mean OCT central retinal thickness was greater in the 0.7mg and 0.35mg groups compared to the sham group, but statistically insignificant at month 6. Based on the findings of the GENEVA study, the FDA approved the 0.7 mg dexamethasone intravitreal implant for the treatment of RVO-associated macular edema. Except for cataract, the rate of adverse events was comparable in the open-label extension between patients who received their first or second DEX implant (Haller et al., 2011). Increases in intraocular pressure (IOP) were also observed in groups treated with DEX implant, which were typically transient and managed with medications or observation. Furthermore, 30% and 32% of patients improved by 15 letters 60 days after the first and second DEX implants, respectively.

Comparative Studies

The BEVORDEX study was the first head-to-head RCT comparing bevacizumab to a slow-release intravitreal dexamethasone implant (Ozurdex) for DME. At 12 months, there was no difference between groups in the proportion of eyes achieving a 10-letter improvement in visual acuity. At 12 months, the dexamethasone implant significantly reduced central macular thickness with fewer intravitreal injections compared to the bevacizumab group. However, more eyes in the dexamethasone implant group lost vision, primarily due to cataracts. Similarly, the 24-month results of the BEVORDEX study found no significant difference between bevacizumab and dexamethasone implant treatment in terms of the proportion of eyes with a 10-letter gain in visual acuity, with both agents providing acceptable improvements (Fraser-Bell et al., 2016). Significantly more infusions were required with bevacizumab (mean 9.1 versus 2.8). However, the dexamethasone implant group had a higher incidence of visual impairment, particularly in phakic eyes at baseline. In the dexamethasone implant group, elevated IOP was essentially manageable with topical therapy. The dexamethasone implant may therefore be considered a first-line treatment option for pseudophakic patients and a second-line treatment option for phakic patients with DME.

Efficacy of the Intravitreal Sustained-Release Dexamethasone Implant for DME Refractory to Anti-VEGF

Khan et al. (2017) conducted a meta-analysis to evaluate the effect of 0.7 mg dexamethasone implant (Ozurdex) on BCVA and its efficacy in 3,859 patients with refractory DME. Studies included adults undergoing treatment with Ozurdex for DME. At total of 15 studies were included in the final analysis. Dexamethasone intravitreal implant treatment in patients with DME resistant to anti-VEGF therapy is associated with a mean improvement of 20 ETDRS letters or a gain of 4 lines after a mean follow-up period of 6 months. The authors concluded that Ozurdex therapy is associated with a significant mean improvement in visual acuity. A multimodal approach is recommended for the treatment of DME, and clinicians should be aware that Ozurdex is an option for patients whose response to anti-VEGF therapy is suboptimal.

Callanan et al. (2017) in a multicenter, open-label, 12-month, randomized, parallel-group, noninferiority

study in 363 patients with DME, compared a 0.7 mg dexamethasone intravitreal implant with an anti-VEGF agent (ranibizumab). The study assessed whether dexamethasone delivered a mean change from baseline in BCVA every 5 months, like ranibizumab 0.5 mg. Patients received the dexamethasone implant at baseline, 5, and 10 months, and ranibizumab was administered every 4 weeks until maximum visual acuity was achieved and maintained stable over 3 visits.

Treatment can then be discontinued but can be resumed if the BCVA decreases. Over one year, the mean average improvement in BCVA for the dexamethasone group was 4.34 letters and for the ranibizumab group it was 7.60 letters. Both the dexamethasone implant and ranibizumab improved BCVA in patients with DME while being well tolerated. Based on these findings, the dexamethasone implant was shown to be noninferior to ranibizumab; however, the dexamethasone group had a higher risk of IOP elevation. Ocular adverse effects in the study eyes were more common in the dexamethasone implant group due to the frequency of IOP rises and cataracts. IOP increases were usually addressed with topical medication because they were transitory. Cataract surgery was performed on 7 individuals in the dexamethasone group and 1 patient in the ranibizumab group.

The Diabetic Retinopathy Clinical Research Network (DRCR Retina Network) conducted Protocol U, a phase 2, multicenter RCT comparing ranibizumab monotherapy to a combination of dexamethasone implant (Ozurdex) and ranibizumab (Lucentis) for persistent DME. To confirm DME, patients were run in. 65 eyes were treated with ranibizumab and 64 with a combination. If edema persisted or the Snellen equivalent was 20/25 or worse, ranibizumab was retreated every 4 weeks. The combination arm received a second dexamethasone implant at 3rd month and was followed to week 24. Lucentis alone and Lucentis + dexamethasone implant had similar visual acuity at 24 weeks. During the 24-week research, both groups gained three letters. Dexamethasone implants did not improve visual acuity at 24 weeks. Combination therapy with dexamethasone implant improved macular thickness but elevated IOP.

National and Specialty Organizations

The **American Academy of Ophthalmology (AAO)** published its Preferred Practice Pattern for retinal vein occlusions in 2019: ‘Macular edema may complicate both CRVOs and BRVOs. The first line of treatment for associated macular edema is anti-VEGFs. Intravitreal corticosteroids, with the associated risk of glaucoma and cataract formation, have demonstrated efficacy. Also, laser photocoagulation surgery in BRVO has a potential role in treatment.’

The **National Institute for Health and Clinical Excellence (NICE)** published the following:
Dexamethasone Intravitreal Implant for the Treatment of Macular Edema Secondary to RVO (2011; TA229)
NICE, published guidance on the use of the dexamethasone intravitreal implant for macular edema secondary to retinal vein occlusion. The dexamethasone implant is recommended as an option for the treatment of macular edema following CRVO. It is recommended as an option for the treatment of macular edema following BRVO when treatment with laser photocoagulation has not been beneficial, or if laser photocoagulation is not considered suitable because of the extent of macular hemorrhage.

Dexamethasone Intravitreal Implant for Treating DME (2022; TA824)
NICE issued recommendations for the treatment of DME with the dexamethasone intravitreal implant (Ozurdex). Ozurdex is suggested for diabetic macular edema patients “only if their condition has not responded well enough to, or if they are unable to receive, non-corticosteroid therapy.” This recommendation applies regardless of whether a patient's lens is phakic or pseudo phakic.

Adalimumab and Dexamethasone for Treating Noninfectious Uveitis (2017; TA460)
NICE, released guidance in 2017 addressing the use of dexamethasone intravitreal implant (with adalimumab) for the treatment of noninfectious uveitis. NICE recommended the dexamethasone intravitreal implant is recommended as an option for treating non-infectious uveitis in the posterior segment of the eye in adults, only if there is:

- Active disease (that is, current inflammation in the eye) and
- Worsening vision with a risk of blindness

Other information
Age-Related Macular Degeneration.
The ERIE Study Group published a single-masked, sham-controlled, multicenter trial on the use of a dexamethasone intravitreal implant as adjunctive therapy to treat age-related macular edema (Kuppermann et al. 2015). All patients (n=243) in this study received 2 ranibizumab injections, with the next injection given as needed based on established study criteria. The primary efficacy end point was the ranibizumab injection-free interval. Ozurdex increased the injection interval based on Kaplan-Meier survival analysis. A small, but statistically significant percentage of patients did not require rescue ranibizumab over the 6-month study period (8.3% vs 2.5%). There was a small reduction in the mean number of as needed ranibizumab injections over the 6 months of the study (3.15 vs. 3.37), but patients in the Ozurdex group received an additional injection of the implant. There were no significant differences between the groups in mean change from baseline BCVA. More patients in the Ozurdex group had increased IOP (13.2% vs 4.2%), however there were no differences between the groups in cataract-related events.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Ozurdex (dexamethasone intravitreal implant) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Ozurdex (dexamethasone intravitreal implant) include: ocular or periocular infections, glaucoma, torn or ruptured posterior lens capsule, hypersensitivity.

OTHER SPECIAL CONSIDERATIONS:
Corticosteroids are not recommended to be used in patients with a history of ocular herpes simplex because of the potential for reactivation of the viral infection.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J7312	Injection, dexamethasone, intravitreal implant, 0.1 mg

AVAILABLE DOSAGE FORMS:
Ozurdex IMPL 0.7MG single-use applicator

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SUMMARY OF REVIEW/REVISIONS	DATE
MCP Conversion	Q4 2023
06/14/2023	Policy reviewed and updated. No changes in coverage criteria. Updated summary of medical evidence and references. Coding updated to include 67027.
06/08/2022	Policy reviewed and updated. No changes in coverage criteria Updated references.
06/09/2021	Policy revised. Updated references. IRO (Independent Review Organization) Peer Review. 5/19/2021. Practicing Physician. Board certified in Ophthalmology. Content update includes: In the 'Initial Coverage Criteria' section: •DME and Non-infectious Posterior Segment Uveitis: the requirement for 'Triamcinolone acetonide, intravitreal injection' was removed. •Macular Edema due to BRVO and CRVO: In the criterion 'FOR CRVO ONLY (BRVO not required)'—previously 'Triamcinolone acetonide, intravitreal injection' replaced with 'Intravitreal glucocorticoids' AND removed: 'Laser Photocoagulation [AS APPLICABLE ONLY]'

	requirement. •Added criterion to #5: '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.' •Added criterion to #6 for congruency with existing continuation of treatment requirement: 'Prescriber to maintain record of administration of intravitreal therapy (recorded in the procedure or post-procedure note following the completion of treatments) with the following information: name of the medication, dose/amount of drug administered, and treated eye (right eye, left eye, or both eyes). Submit with re-authorization requests.' •Reauthorization/Continuation of Treatment section: Removed 'Member continues to meet initial coverage criteria' from criteria #1
Q3 2020 P&T	Policy reviewed and updated, no changes in coverage criteria, updated references.
Q3 2019 P&T	Policy revised. Updated references. IRO Peer Review. 7/10/2019. Practicing Physician. Board certified in Ophthalmology. Content update included: Revised authorization limit criterion from ONE dexamethasone intravitreal implant per affected eye 'every 6 months' to 'every 4 to 6 months'
12/15/2016	New policy. IRO Peer Review. 10/20/2016. Practicing Physician. Board certified in Ophthalmology, Surgery Vitreoretinal.