CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Ozurdex (dexamethasone)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Ozurdex is an intravitreal implant containing dexamethasone 0.7 mg. It is indicated for the treatment of retinal vein occlusion (RVO), posterior segment uveitis, and diabetic macular edema (DME).
RVO occurs when there is a partial or complete obstruction of a retinal vein. Macular edema is a complication of RVO and can lead to vision loss. First-line treatment is with anti-vascular endothelial growth factor (anti-VEGF) drugs.
DME is a common consequence of diabetic retinopathy. It is caused by leakage from retinal capillaries and leads to fluid build-up in the macula part of the retina. This can result in loss of central vision. The importance of maintaining glucose control cannot be understated.
Uveitis is an inflammation of the uvea (middle layer of the eye). It can be infectious or non-infectious. Non-infectious uveitis (NIU) is often associated with inflammatory conditions such as rheumatoid arthritis. If the anterior segment of the uvea is affected, it can be treated with topical glucocorticoids. If resistant or affecting the intermediate or posterior segments, more invasive or systemic treatment is needed.

Ozurdex (dexamethasone) will be considered for coverage when the following criteria are met:

Retinal Vein Occlusion (RVO)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an ophthalmologist; AND
3. Member has a documented diagnosis of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO); AND
4. Trial and failure of or contraindication to an anti-VEGF drug; bevacizumab is the preferred product; AND
5. Member does NOT have any of the following:
   a) Active or suspected ocular or periocular infections
   b) Glaucoma with a cup to disc ratio of greater than 0.8
   c) Torn or ruptured posterior lens capsule
6. **Dosage allowed/Quantity limit:** One implant (0.7 mg) per eye
   Limit: 2 implants (1 per eye) per 4 months

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Chart notes must include documentation of improved or stabilized visual acuity; AND
2. At least 4 months have elapsed since the prior treatment (of the same eye).

If all the above requirements are met, the medication will be approved for an additional 3 months.

Uveitis

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an ophthalmologist; AND
3. Member has a documented diagnosis of non-infectious uveitis affecting the posterior segment of the eye; AND
4. Member has tried and failed at least one of the following for at least 3 months:
   a) Systemic corticosteroid (e.g., prednisone)
   b) Non-biologic immunosuppressive (e.g., mycophenolate mofetil, methotrexate, cyclosporine, tacrolimus); AND
5. Member does NOT have any of the following:
   a) Active or suspected ocular or periocular infections
   b) Glaucoma with a cup to disc ratio of greater than 0.8
   c) Torn or ruptured posterior lens capsule.
6. **Dosage allowed/Quantity limit:** One implant (0.7 mg) per eye
   Limit: 2 implants (1 per eye) per 6 months

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Chart notes must show improved or stabilized visual acuity following treatment and/or an improved vitreous haze score; AND
2. At least 6 months have elapsed since the prior treatment (of the same eye); AND
3. Member has recurrent symptoms.

If all the above requirements are met, the medication will be approved for an additional 3 months.

Diabetic Macular Edema (DME)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an ophthalmologist; AND
3. Member has a documented diagnosis of diabetic macular edema; AND
4. Member does NOT have any of the following:
   a) Active or suspected ocular or periocular infections
   b) Glaucoma with a cup to disc ratio of greater than 0.8
   c) Torn or ruptured posterior lens capsule.
5. **Dosage allowed/Quantity limit:** One implant (0.7 mg) per eye
   Limit: 2 implants (1 per eye) per 6 months

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Chart notes must show improved or stabilized visual acuity following treatment; AND
2. At least 6 months have elapsed since the prior treatment (of the same eye).

If all the above requirements are met, the medication will be approved for an additional 3 months.

CareSource considers Ozurdex (dexamethasone) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
11/03/2021	New policy created for Ozurdex.
10/23/2023	Updated references. Changed treatment interval from 6 months to 4 months for RVO.

References:

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11. Schmidt-Erfurth U, Garcia-Arumi J, Gerendas BS, et al. Guidelines for the Management of Retinal Vein Occlusion by the European Society of Retina Specialists (EURETINA). *Ophthalmologica*. 2019;242(3):123-162. doi:10.1159/000502041

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