

PHARMACY POLICY STATEMENT

Arkansas PASSE

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| DRUG NAME | Ozurdex (dexamethasone) |
| BILLING CODE | J7312 |
| BENEFIT TYPE | Medical |
| SITE OF SERVICE ALLOWED | Office |
| 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 6 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 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.

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. |

References:

1. Ozurdex [prescribing information]. Allergan USA, Inc.; 2020.
2. Tan HY, Agarwal A, Lee CS, et al. Management of noninfectious posterior uveitis with intravitreal drug therapy. *Clin Ophthalmol*. 2016;10:1983-2020. Published 2016 Oct 13. doi:10.2147/OPTH.S89341
3. Flaxel CJ, Adelman RA, Bailey ST, et al. Diabetic Retinopathy Preferred Practice Pattern® [published correction appears in *Ophthalmology*. 2020 Sep;127(9):1279]. *Ophthalmology*. 2020;127(1):P66-P145. doi:10.1016/j.ophtha.2019.09.025
4. Grover D, Li TJ, Chong CC. Intravitreal steroids for macular edema in diabetes. *Cochrane Database Syst Rev*. 2008;(1):CD005656. Published 2008 Jan 23. doi:10.1002/14651858.CD005656.pub2
5. Rittiphairoj T, Mir TA, Li T, Virgili G. Intravitreal steroids for macular edema in diabetes. *Cochrane Database Syst Rev*. 2020;11(11):CD005656. Published 2020 Nov 17. doi:10.1002/14651858.CD005656.pub3
6. Zur D, Iglicki M, Loewenstein A. The Role of Steroids in the Management of Diabetic Macular Edema. *Ophthalmic Res*. 2019;62(4):231-236. doi:10.1159/000499540
7. Schmidt-Erfurth U, Garcia-Arumi J, Bandello F, et al. Guidelines for the Management of Diabetic Macular Edema by the European Society of Retina Specialists (EURETINA). *Ophthalmologica*. 2017;237(4):185-222. doi:10.1159/000458539
8. Flaxel CJ, Adelman RA, Bailey ST, et al. Retinal Vein Occlusions Preferred Practice Pattern® [published correction appears in *Ophthalmology*. 2020 Sep;127(9):1279]. *Ophthalmology*. 2020;127(2):P288-P320. doi:10.1016/j.ophtha.2019.09.029

Effective date: 07/01/2022

Revised date: 11/03/2021