

## **RX.PA.018.MPC Intravitreal Corticosteroid Implants: Ozurdex, Iluvien, and Yutiq**

The purpose of this policy is to define the prior authorization process for Ozurdex<sup>®</sup> (dexamethasone), Iluvien<sup>®</sup> (fluocinolone), and Yutiq (fluocinolone).

Ozurdex<sup>®</sup> (dexamethasone) is indicated for the treatment of patients with:

- Macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)
- Non-infectious uveitis affecting the posterior segment of the eye
- Diabetic macular edema (DME)

Iluvien<sup>®</sup> (fluocinolone) is indicated for the treatment of patients with:

- Diabetic macular edema who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure

Yutiq (fluocinolone) is indicated for the treatment of patients with:

- Chronic non-infectious uveitis affecting the posterior segment of the eye

The drugs, Ozurdex<sup>®</sup> (dexamethasone), Iluvien<sup>®</sup> (fluocinolone), and Yutiq (fluocinolone), are subject to the prior authorization process.

## **PROCEDURE**

### **A. Initial Authorization Criteria:**

*Must meet all of the criteria listed under the respective product:*

#### **1. Ozurdex (dexamethasone)**

- Must be prescribed by an ophthalmologist
- Must be age 18 years or older
- Must not have active ocular or periocular infection
- Must not have a torn or ruptured posterior lens capsule
- Must not have glaucoma
- Must have a diagnosis of one of the following:
  - macular edema following branch retinal vein occlusion or central retinal vein occlusion
  - non-infectious uveitis affecting the posterior segment of the eye
  - diabetic macular edema
- For treatment of macular edema: must have previously tried and failed ALL of the following for at least 3 months, unless contraindicated or intolerant:
  - Intravitreal corticosteroid injections
  - Anti-vascular endothelial growth factor (VEGF) injections

- For treatment of non-infectious uveitis: must have previously tried and failed ALL of the following for at least 3 months, unless contraindicated or intolerant:
  - A systemic corticosteroid (e.g., prednisone)
  - Two non-biologic immunosuppressive treatments
    - Azathioprine
    - Mycophenolate
    - Calcineurin inhibitor (cyclosporine, tacrolimus)
    - Methotrexate
  - Humira (adalimumab)

## 2. Iluvien (fluocinolone)

- Must be prescribed by an ophthalmologist
- Must be age 18 years or older
- Must not have active ocular or periocular infection
- Must not have glaucoma
- Must have a diagnosis of macular edema
- For the treatment of macular edema: must have previously tried and failed ALL of the following for at least 3 months, unless contraindicated or intolerant:
  - Intravitreal corticosteroid injections
  - Anti-vascular endothelial growth factor (VEGF) injections

## 3. Yutiq (fluocinolone)

- Must be prescribed by an ophthalmologist
- Must be age 18 years or older
- Must not have active ocular or periocular infection
- Must have a diagnosis of non-infectious uveitis affecting the posterior segment of the eye
- For the treatment of non-infectious uveitis: must have previously tried and failed ALL of the following for at least 3 months, unless contraindicated or intolerant:
  - A systemic corticosteroid (e.g., prednisone)
  - Two non-biologic immunosuppressive treatments
    - Azathioprine
    - Mycophenolate
    - Calcineurin inhibitor (cyclosporine, tacrolimus)
    - Methotrexate
  - Humira (adalimumab)

**B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.**

**C. Intravitreal corticosteroid implants will be considered investigational or experimental for any other use and will not be covered.**

**D. Reauthorization Criteria:**

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon:

**MPC Renewal:**

- Chart documentation from the prescriber that the member's condition has improved or stabilized based upon the prescriber's assessment while on therapy.
- Must be for the same eye previously treated

**Non-MPC Renewal:**

- Members who have previously been taking Ozurdex, Iluvien, or Yutiq and are requesting a non-MPC renewal should be considered under criterion A (Initial Authorization Criteria)
- Member has not been receiving medication samples for Ozurdex, Iluvien, or Yutiq; AND
- Provider has documented clinical response of the member's condition which has stabilized or improved based upon the prescriber's assessment

**Limitations:**

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

**HCPCS Code(s):**

Code	Description
J7312	Injection, dexamethasone, intravitreal implant, 0.1 mg

**Ozurdex (Dexamethasone) and Iluvien (Fluocinolone)**

**POLICY NUMBER: RX.PA.018.MPC**

**REVISION DATE: 08/2022**

**PAGE NUMBER: 4 of 4**

**REFERENCES**

1. Iluvien [prescribing information]. Alpharetta, GA: Alimera Sciences, Inc.; September 2014.
2. Ozurdex [prescribing information]. Irvine, CA: Allergan, INC.; September 2014.
3. American Academy of Ophthalmology Retina Panel. Preferred Pattern1 Guidelines diabetic retinopathy. San Fransico, CA: American Academy of Ophthalmology; 2014. Accessed January 6, 2015. Available at: [www.aao.org/ppp](http://www.aao.org/ppp).
4. Mitchell P and Wong TY. Management paradigms for diabetic macular edema. AJO. 2013; 157(3):505-513e8
5. American Optometric Association. Eye care of patient with diabetes mellitus. 2014.
6. Campochiaro PA, Brown DM, Pearson A, et al. Long-term benefit of sustained-delivery fluocinolone acetonide vitreous inserts for diabetic macular edema. Ophthalmology. 2011; 118:626-635.
7. Campochiaro PA, Brown DM, Pearson A, et al. Sustained delivery fluocinolone acetonide vitreous inserts provide benefit for at least 3 years in patients with diabetic macular edema. Ophthalmology. 2012; 119:2125-2132.
8. Product Information: Yutiq. Eyepoint Pharmaceuticals; Watertown, MA. October 2018.

**REVIEW HISTORY**

<b>DESCRIPTION OF REVIEW / REVISION</b>	<b>DATE APPROVED</b>
<i>Selected Revision Addition of MPC vs Non-MPC Renewal Criteria</i>	<i>08/2022</i>
<i>Annual review</i>	<i>02/2022</i>
<i>Addition of dosing requirements and off-label restrictions</i>	<i>12/2021</i>
<i>P&amp;T Review</i>	<i>11/2021</i>