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® (dexamethasone), Iluvien® (fluocinolone), and Yutiq (fluocinolone).

Ozurdex® (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® (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® (dexamethasone), Iluvien® (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. <u>Yutiq (fluocinolone)</u>

- 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

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.
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. Opththalmology. 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. Opththalmology. 2012; 119:2125-2132.
8. Product Information: Yutiq. Eyepoint Pharmaceuticals; Watertown, MA. October 2018.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/2023*
Selected Revision *Addition of MPC vs Non-MPC Renewal Criteria*	*08/2022*
Annual review	*02/2022*
Addition of dosing requirements and off-label restrictions	*12/2021*
P&T Review	*11/2021*