RX.PA.057.CCH INTRAVITREAL CORTICOSTEROID IMPLANTS (OZURDEX®, ILUVIEN®, RETISERT®, YUTIQ®)

The purpose of this policy is to define the prior authorization process for Ozurdex® (dexamethasone), Iluvien® (fluocinolone), Retisert® (flucinolone), 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

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

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

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

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

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity and approval by the Medical Policy Committee.

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

PROCEDURE

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
- Must have previously tried and failed intravitreal steroid injections unless contraindicated or intolerant

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 diabetic macular edema
- Must have previously received a treatment course with corticosteroids and did not have a clinically significant rise in intraocular pressure

3. Retisert® (fluocinolone)

- Must be prescribed by an ophthalmologist
- Must be age 12 years or older
- Must not have active infection of the ocular structures
- Must have a diagnosis of chronic non-infectious uveitis affecting the posterior segment of the eye
- Must have previously tried and failed intravitreal steroid injections unless contraindicated or intolerant
- For ages 18 years or older, must have previously tried and failed Yutiq®

4. 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 chronic non-infectious uveitis affecting the posterior segment of the eye
- Must have previously tried and failed intravitreal steroid injections unless contraindicated or intolerant

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 chart documentation from the prescriber that the member's condition has improved or stabilized based upon the prescriber's assessment while on therapy.

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	Brand	Description
J7311	**RETISERT**	INJECTION, FLUOCINOLONE ACETONIDE, INTRAVITREAL IMPLANT, 0.01 MG
J7312	**OZURDEX**	INJECTION, DEXAMETHASONE, INTRAVITREAL IMPLANT, 0.1 MG
J7313	**ILUVIEN**	INJECTION, FLUOCINOLONE ACETONIDE, INTRAVITREAL IMPLANT, 0.01 MG
J7314	**YUTIQ**	INJECTION, FLUOCINOLONE ACETONIDE, INTRAVITREAL IMPLANT, 0.01 MG

REFERENCES

1. Iluvien [prescribing information]. Alpharetta, GA: Alimera Sciences, Inc.; November 2016.
2. Ozurdex [prescribing information]. Irvine, CA: Allergan, INC.; October 2020.
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. Yutiq [prescribing information]. Watertown, MA: Eyepoint Pharmaceuticals; January 2021.
9. Retisert [prescribing information]. Bridgewater, NJ: Bausch + Lomb; January 2021.
10. Bakri SJ, Wolfe JD, Regillo CD, et al. Evidence-Based Guidelines for Management of Diabetic Macular Edema. *Journal of VitreoRetinal Diseases.* 2019; 1-8.

RECORD RETENTION
Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Initial Review	3/22