Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Intravitreal Corticosteroid Implants: Ozurdex (dexamethasone) and Iluvien (fluocinolone)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***January 2015 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Ozurdex (dexamethasone) and Iluvien (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

DEFINITIONS

N/A

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 Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drugs, Ozurdex (dexamethasone) and Iluvien (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 macular edema following branch retinal vein occlusion or central retinal vein occlusion, non-infectious uveitis affecting the posterior segment of the eye, or diabetic macular edema

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

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.

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.

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
Annual review	*02/17, 02/18*