I. Medication Description

An intravitreal implant is a drug delivery system, injected, or surgically implanted in the vitreous of the eye, for sustained release of drug to the posterior and intermediate segments of the eye. Intravitreal implants deliver a continuous concentration of drug over a prolonged period. They are being studied for a variety of eye conditions that lead to macular edema, including uveitis, diabetic retinopathy and retinal venous occlusions. The goal of therapy is to reduce inflammation in the eye while minimizing the adverse effects of the therapeutic regimen.

Corticosteroids inhibit inflammatory responses to a variety of inciting agents including multiple inflammatory cytokines. They inhibit edema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation. Corticosteroids are thought to act by inhibition of phospholipase A2 via induction of inhibitory proteins collectively called lipocortins. It is postulated that these proteins control biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting release of the common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage is available when the medication is requested by or in consultation with an ophthalmologist as follows:

- **Iluvien**
  - Medication is requested for the treatment of diabetic macular edema (DME) **AND**
  - Member has previously been treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure.

- **Ozurdex**
  - Medication is requested for the treatment of one of the following:
    - Macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) **OR**
    - Non-infectious uveitis affecting the posterior segment of the eye **OR**
    - Diabetic macular edema.
• Retisert
  o Medication is requested for the treatment of chronic noninfectious uveitis affecting the posterior segment of the eye.

IV. Quantity Limitations

Initial coverage is available as follows:
• Iluvien: One implant per eye per 36 months
• Ozurdex: One implant per eye per 1 month
• Retisert: One implant per eye per 30 months

V. Coverage Duration

Coverage will be allowed for an appropriate duration per type of implant as follows:
• Iluvien: One implant per eye per 36 months
• Ozurdex: One implant per eye per 1 month
• Retisert: One implant per eye per 30 months

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:
• Stabilization of disease or in absence of disease progression AND
• Absence of unacceptable toxicity from the drug AND
• For Iluvien and Retisert only, member meets one of the following:
  o For Iluvien: At least 36 months have passed since last Iluvien administration
  o For Retisert: At least 30 months have passed since last Retisert administration

VII. Billing/Coding Information

Intravitreal implants covered in this policy are available as follows:
• Iluvien: 0.19 mg fluocinolone acetonide
  o J7313: 1 implant = 19 billable units; 1 billable unit = 0.01 mg
• Ozurdex: 0.7 mg dexamethasone
  o J7312: 1 implant = 7 billable units; 1 billable unit = 0.1 mg
• Retisert: 0.59 mg fluocinolone acetonide
  o J7311: 1 billable unit = 1 implant (0.59 mg)

VIII. Summary of Policy Changes

• 7/15/19: new policy
• 11/5/20: updated minimal interval required between Ozurdex implants
Intravitreal Corticosteroid Implants:
Iluvien® (fluocinolone acetonide),
Ozurdex® (dexamethasone), Retisert®
(fluocinolone acetonide)

- 1/1/21: no policy changes

IX. References


*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.