

# Fluocinolone acetonide intravitreal implant (Iluvien®) J7313 (0.01mg)

## Covered with prior authorization

**Iluvien® (fluocinolone acetonide intravitreal implant) may be authorized when the following criteria are met:**

- Individual has a diagnosis of diabetic macular edema; **AND**
- Individual has previously been treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure; **AND**
- 18 years of age and older.

### Exclusion criteria:

Requests may not be approved for the following:

- Individual has active or suspected ocular or periocular infections including most viral disease of the cornea and conjunctiva (such as epithelial herpes simplex keratitis [dendritic keratitis], vaccinia, varicella), mycobacterial infections and fungal diseases.
- Concurrent treatment with other intravitreal implants such as Retisert (Fluocinolone acetonide intravitreal implant) or Ozurdex (dexamethasone intravitreal implant).
- Individual has glaucoma with a cup to disc ratio of greater than 0.8.
- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

**Initial authorization approval is for 12 months.**

### Reauthorization Criteria:

Iluvien® is considered medically necessary for continued use when initial criteria are met.

**Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.**

### U.S. Food and Drug Administration:

This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

**Iluvien® (fluocinolone acetonide intravitreal implant)** contains a corticosteroid and is indicated for the treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure cell support.

**References:**

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.
2. Iluvien [Prescribing Information]. Alpharetta, GA: Alimera Sciences Inc; 2022.

**Criteria History/ Revision Information:**

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call [833-980-2352](tel:833-980-2352) to speak to a member of the Ascension Rx prior authorization team

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