



## PHARMACY POLICY STATEMENT

### HAP CareSource™ Marketplace

DRUG NAME	Iluvien (fluocinolone acetonide)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Iluvien is an intravitreal implant containing 0.19 mg (190 mcg) fluocinolone acetonide in a 36-month sustained-release drug delivery system. It 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. DME is a common complication of diabetic retinopathy.

Iluvien (fluocinolone acetonide) will be considered for coverage when the following criteria are met:

#### Diabetic Macular Edema (DME)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an ophthalmologist; AND
3. Member has a confirmed diagnosis of diabetic macular edema; AND
4. Member has been previously treated with a course of corticosteroids and did not have a clinically significant increase in intraocular pressure; AND
5. Member has tried and failed Ozurdex or an anti-VEGF drug (bevacizumab preferred); AND
6. Member does not have active or suspected ocular or periocular infection; AND
7. Member does not have glaucoma with a cup to disc ratio greater than 0.8.
8. **Dosage allowed/Quantity limit:** One implant (0.19 mg) per eye  
Limit: 2 implants (1 per eye) per 36 months.

***If all the above requirements are met, the medication will be approved for 3 months.***

For **reauthorization**:

1. Chart notes must show improved or stabilized visual acuity following treatment; AND
2. At least 36 months have elapsed since the prior treatment (of the same eye).

***If all the above requirements are met, the medication will be approved for an additional 3 months.***

**HAP CareSource considers Iluvien (fluocinolone acetonide) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
10/27/2021	New policy created for Iluvien.

**10/16/2023**    References updated. Added anti-VEGF as trial option.

References:

1. Iluvien [prescribing information]. Alimera Sciences, Inc.; 2016.
2. Flaxel CJ, Adelman RA, Bailey ST, et al. Diabetic Retinopathy Preferred Practice Pattern® [published correction appears in *Ophthalmology*. 2020 Sep;127(9):1279]. *Ophthalmology*. 2020;127(1):P66-P145. doi:10.1016/j.ophtha.2019.09.025
3. Virgili G, Parravano M, Evans JR, Gordon I, Lucenteforte E. Anti-vascular endothelial growth factor for diabetic macular oedema: a network meta-analysis. *Cochrane Database Syst Rev*. 2018;10(10):CD007419. Published 2018 Oct 16. doi:10.1002/14651858.CD007419.pub6
4. Rittiphairoj T, Mir TA, Li T, Virgili G. Intravitreal steroids for macular edema in diabetes. *Cochrane Database Syst Rev*. 2020;11(11):CD005656. Published 2020 Nov 17. doi:10.1002/14651858.CD005656.pub3
5. Zur D, Iglicki M, Loewenstein A. The Role of Steroids in the Management of Diabetic Macular Edema. *Ophthalmic Res*. 2019;62(4):231-236. doi:10.1159/000499540
6. Schmidt-Erfurth U, Garcia-Arumi J, Bandello F, et al. Guidelines for the Management of Diabetic Macular Edema by the European Society of Retina Specialists (EURETINA). *Ophthalmologica*. 2017;237(4):185-222. doi:10.1159/000458539
7. Bailey C, Chakravarthy U, Lotery A, Menon G, Talks J; Medisoft Audit Group. Extended real-world experience with the ILUVIEN® (fluocinolone acetonide) implant in the United Kingdom: 3-year results from the Medisoft® audit study [published online ahead of print, 2021 May 10]. *Eye (Lond)*. 2021;1-7. doi:10.1038/s41433-021-01542-w
8. Yuen YS, Gilhotra JS, Dalton M, et al. Diabetic Macular Oedema Guidelines: An Australian Perspective. *J Ophthalmol*. 2023;2023:6329819. Published 2023 Feb 14. doi:10.1155/2023/6329819

Effective date: 01/01/2025

Revised date: 10/16/2023