CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Arkansas PASSE

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.

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
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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

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