CareSource

PHARMACY POLICY STATEMENT
Nevada Medicaid

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

Iluvien, approved by the FDA in 2014, 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 is also indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. Uveitis is an inflammation of the uvea (middle layer of the eye). It can be infectious or non-infectious. Noninfectious uveitis (NIU) is often associated with inflammatory conditions such as rheumatoid arthritis. If the anterior segment of the uvea is affected, it can be treated with topical glucocorticoids. If resistant or affecting the intermediate or posterior segments, more invasive or systemic treatment is needed.

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.

Uveitis

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 diagnosis of chronic (1 year or more) non-infectious uveitis affecting the posterior segment of the eye; AND
4. Member has tried and failed at least one of the following for at least 3 months:
   a) Systemic corticosteroid (e.g., prednisone)
   b) Non-biologic immunosuppressive (e.g., mycophenolate mofetil, methotrexate, cyclosporine, tacrolimus); AND
5. Member does not have active or suspected ocular or periocular infection; AND
6. **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/or an improved vitreous haze score; AND
2. At least 36 months have elapsed since the prior treatment (of the same eye); AND
3. Member has recurrent symptoms.

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.
04/02/2025	Added criteria for new indication: Uveitis.

References:

1. Iluvien [prescribing information]. Alimera Sciences, Inc.; 2025.
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
9. Jaffe GJ, Pavesio CE; Study Investigators. Effect of a Fluocinolone Acetonide Insert on Recurrence Rates in Noninfectious Intermediate, Posterior, or Panuveitis: Three-Year Results. *Ophthalmology*. 2020;127(10):1395-1404. doi:10.1016/j.ophtha.2020.04.001
10. Reddy A, Liu SH, Brady CJ, Sieving PC, Palestine AG. Corticosteroid implants for chronic non-infectious uveitis. *Cochrane Database Syst Rev*. 2023;1(1):CD010469. Published 2023 Jan 16. doi:10.1002/14651858.CD010469.pub3
11. Tan HY, Agarwal A, Lee CS, et al. Management of noninfectious posterior uveitis with intravitreal drug therapy. *Clin Ophthalmol*. 2016;10:1983-2020. Published 2016 Oct 13. doi:10.2147/OPTH.S89341
12. Wu X, Tao M, Zhu L, Zhang T, Zhang M. Pathogenesis and current therapies for non-infectious uveitis. *Clin Exp Med*. 2023;23(4):1089-1106. doi:10.1007/s10238-022-00954-6
13. Abdulla D, Ali Y, Menezo V, Taylor SRJ. The Use of Sustained Release Intravitreal Steroid Implants in Non-Infectious Uveitis Affecting the Posterior Segment of the Eye. *Ophthalmol Ther*. 2022;11(2):479-487. doi:10.1007/s40123-022-00456-4

Effective date: 01/01/2026
Revised date: 04/02/2025