Medical Necessity Guidelines

Medical Benefit Drugs

Intravitreal Implants and Corticosteroid Inserts for Ophthalmic Conditions

Effective: September 1, 2025

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☐ No ☒

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☒ Tufts Health Plan Commercial products; Fax 617-673-0988
CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
☒ Tufts Health One Care-- A dual-eligible product; Fax 617-673-0956

Senior Products

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Diabetic macular edema (DME), a manifestation of diabetic retinopathy and is characterized by increased vascular permeability and a breakdown of the blood–retina barrier. This results in the leakage of fluid into or surrounding the macula, causing retinal thickening in the macular area.

Food and Drug Administration (FDA) Approved Indications:

- Iluvien fluocinolone acetonide intravitreal implant is a sterile, nonbiodegradable, intravitreal implant in a polyimide tube that is injected into the eye through a 25-gauge needle. The implant contains 0.19 milligrams of fluocinolone acetonide (FA), a potent glucocorticoid receptor agonist. The FA is released at an initial rate of 0.25 micrograms per day (µg/day). It is intended for use for up to 3 years for the treatment of diabetic macula edema (ME).
- Retisert fluocinolone acetonide intravitreal implant is surgically implanted into the posterior segment of the affected eye through a pars plana incision. The implant contains 0.59 mg of FA and is released at an initial rate of 0.6 mcg/day, decreasing over the first month to a rate of 0.3-0.4 mcg/day over the course of approximately 30 months. It is intended for the treatment of chronic noninfectious uveitis affecting the posterior segment of the eye
- Yutiq fluocinolone acetonide intravitreal implant is surgically implanted and contains 0.18 mg of fluocinolone acetonide which is intended for the treatment of chronic noninfectious uveitis affecting the posterior segment of the eye. The implant releases FA at a rate of 0.25 mcg/day over a period of 36 months.
- Ozurdex dexamethasone intravitreal implant is composed of a biodegradable copolymer made of lactic acid and glycolic acid with micronized dexamethasone. The implant contains 0.7 mg of dexamethasone which is a steroid used to treat inflammation. Ozurdex is used to treat macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO), noninfectious uveitis affecting the posterior segment of the eye and diabetic macular edema
- Dextenza is a dexamethasone ophthalmic insert used to treat inflammation and pain following ophthalmic surgery. The insert

contains 0.4 mg of dexamethasone which is released for up to 30 days following insertion.

Clinical Guideline Coverage Criteria

The Plan may cover ILUVIEN when all the following clinical criteria is met:

1. Member has confirmed diagnosis of chronic diabetic macular edema

AND

2. Member is refractory to first-line treatment of diabetic macular edema, including anti-vascular endothelial growth factor (VEGF) injections and/or laser photocoagulation.

AND

3. Member has been previously treated with a course of corticosteroids and documentation supports there was not a change from baseline intraocular pressure suggestive of a hypertensive response.

The Plan may cover RETISERT (fluocinolone acetonide intravitreal implant 0.59 mg) when the following clinical criteria is met:

1. Member has a diagnosis of chronic noninfectious uveitis affecting the posterior segment of the eye

The Plan may cover YUTIQ (fluocinolone acetonide intravitreal implant 0.18 mg) when the following clinical criteria is met:

1. Member has a diagnosis of chronic noninfectious uveitis affecting the posterior segment of the eye

The Plan may cover OZURDEX (dexamethasone intravitreal implant 0.7 mg) when one of the following clinical criteria is met:

1. Member has a diagnosis of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)

OR

2. Member has a diagnosis of noninfectious uveitis affecting the posterior segment of the eye

OR

3. Member has a diagnosis of diabetic macular edema

The Plan may cover DEXTENZA (dexamethasone insert 0.4 mg) when the following clinical criteria is met:

1. Member has ocular inflammation and pain following ophthalmic surgery

Limitations

Illuvien is considered not medically necessary:

- When used as a first-line treatment of diabetic macular edema
- For treatment of conditions other than diabetic macular edema

Retisert, Yutiq and Dextenza are considered experimental for the following:

- When there is presence of active viral, bacterial, mycobacterial or fungal infections of the ocular structures
- Member experiences hypersensitivity of the eyes

Ozurdex is considered experimental for the following:

- When there is presence of active viral, bacterial, mycobacterial, or fungal infection of the ocular structures
- Member experiences hypersensitivity of the eyes
- Member has a diagnosis of glaucoma
- Member has a torn or ruptured posterior lens capsule

Codes

Table 1: The following code(s) are associated with this service:

CPT Codes	Description
67027	Implantation of intravitreal drug delivery system (eg, ganciclovir implant), includes concomitant removal of

CPT Codes	Description
	vitreous
67028	Intravitreal injection of a pharmacologic agent (separate procedure)
J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg

Table 2: HCPCS Codes: The following code(s) are considered medically necessary when submitted with a covered ICD-10 code:

HCPCS Codes	Description
J7313	Injection, fluocinolone acetonide, intravitreal implant, 0.01 mg
J7311	Injection, fluocinolone acetonide, intravitreal implant (Retisert), 0.01 mg
J7312	Injection, dexamethasone, intravitreal implant, 0.1 mg
J7314	Injection, fluocinolone acetonide, intravitreal implant (Yutiq), 0.01 mg

List of Medically Necessary ICD-10 Codes

References:

1. Hayes, Inc. Health Technology Brief. Iluvien (Fluocinolone Acetonide Intravitreal Implant; Alimera Sciences) for Treatment of Diabetic Macular Edema. May 26, 2016. Available at www.hayesinc.com.
2. Hayes, Inc. Health Technology Brief. Iluvien (Fluocinolone Acetonide Intravitreal Implant; Alimera Sciences) for Treatment of Diabetic Macular Edema. December 10, 2018. Available at www.hayesinc.com.
3. Fraser C.E, MD, PhD, D'Amico DJ, MD. Diabetic Retinopathy: Prevention and Treatment. UpToDate®, Waltham, MA: Available at http:www.uptodate.com
4. National Institute for Health Care and Excellence. Technology Appraisal Guidance: Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema after an inadequate response to prior therapy. November 27, 2013. Available at nice.org.uk/guidance/ta301 April 10. Last accessed April 12, 2021.
5. Massa H, Nagar AM, et. al. Intravitreal fluocinolone acetonide implant (ILUVIENVR) for diabetic macular oedema: a literature review. Journal of International Medical Research 2019, Vol. 47(1) 31–43. Available at journals.sagepub.com/doi/10.1177/0300060518816884
6. United States Food and Drug Administration. Package Insert- ILUVIEN® (fluocinolone acetonide intravitreal implant) 0.19 mg. Available accessdata.fda.gov/drugsatfda_docs/label/2014/201923s000lbl.pdf. Accessed April 12, 2021.
7. United States Food and Drug Administration. Package Insert – RETISERT ® (fluocinolone acetonide intravitreal implant) 0.59 mg. Available https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021737s007lbl.pdf
8. United States Food and Drug Administration. Package Insert – YUTIQ ® (fluocinolone acetonide intravitreal implant) 0.18 mg. Available https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210331Orig1s000SumR.pdf
9. United States Food and Drug Administration. OZURDEX® (dexamethasone intravitreal implant) .7mg. Available https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022315s009lbl.pdf
10. United States Food and Drug Administration. Dextenza ® (dexamethasone intravitreal implant) .4mg. Available https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208742s001lbl.pdf
11. Hayes, Inc. Health Technology Brief. Dexamethasone Intravitreal Implant (Ozurdex; Allergan Inc.) for Treatment of Diabetic Macular Edema. December 10, 2018. Available at www.hayesinc.com. Last accessed April 12, 2021.
12. Estebainha R, Goldhardt R, Falcão M. A New Approach for Diabetic Macular Edema Treatment: review of clinical practice results with 0.19 mg fluocinolone acetonide intravitreal implant including vitrectomized eyes. Curr Ophthalmol Rep. 2020;8(1):1-10. doi:10.1007/s40135-020-00225-1

Approval And Revision History

May 21, 2025: Reviewed by MPAC as a new Medical Necessity Guideline effective September 1, 2025

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the

individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.