Molina Clinical Policy
Iluvien (fluocinolone acetonide intravitreal implant): Policy No. 301

Last Approval: 10/12/2022
Next Review Due By: October 2023

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Diabetic macular edema (DME) is a vision-threatening complication of diabetes that can manifest at any stage or severity of diabetic retinopathy. DME is the presence of retinal edema and thickening in the macula, the portion of the retina responsible for central vision. DME is caused by retinal microvascular changes that compromise the blood-retinal barrier, resulting in plasma constituent leakage into the surrounding retina and retinal edema. High plasma glucose levels result in the breakdown of the blood-retinal barrier due to the loss of pericytes. This results in endothelial cell dysfunction and the release of vascular endothelial growth factor (VEGF). This growth factor causes capillary leakage, resulting in an accumulation of extracellular fluid in the macula. Edema in the macula can cause significant decreases in visual acuity. DME is diagnosed using an optical coherence tomograph (OCT), which has greatly improved DME detection (Fraser et al. 2019). The following studies can also provide information for treatment and follow-up:

- *Fluorescein angiography* differentiates and localizes areas of focal versus diffuse leakage, guiding laser photocoagulation placement.
- *Color stereofundus photographs* are used to assess long-term retinal changes.
- *Visual acuity measurements* do not aid in the diagnosis of clinically significant macular edema (CSME) initially because patients may have a visual acuity of 20/20; however, it is an indicator in monitoring the progression of macular edema.

The goal of DME therapy is to maintain retinal function by reducing vascular leakage that causes edema. Photocoagulation (laser therapy), intravitreal corticosteroid injections, intravitreal anti-VEGF and intravitreal corticosteroid implants are among the current treatment options for DME (Apte 2016).

- Anti-VEGF injections, with or without laser photocoagulation, have become the first-line treatment for DME(AAO 2019). However, the limitations of anti-VEGF injections include frequent injections, resistance induction, and tachyphylaxis due to the long-term nature of the treatment. Cases of DME that do not respond well to regular anti-VEGF injections may be caused by pro-inflammatory cytokines other than VEGF (Abcouwer 2013).
- Focal laser photocoagulation is an option for either initial therapy in non-compliant DME patients who may skip follow-up appointments or for adjunctive therapy in patients who do not respond to or have a partial response to anti-VEGF medication (Fraser et al. 2019).
- In patients who are intolerant or refractory to other therapies, or who are likely to experience severe adverse events from systemic corticosteroids, an intravitreal implant may be an appropriate treatment option. The route of corticosteroid administration (topical, systemic, periocular, or intraocular injection) is determined by the cause, location, and severity of the disease. Because the benefits and risks of each therapeutic approach differ, patients should be informed about the potential side effects of a corticosteroid intravitreal implant, such as cataracts, increased intraocular pressure (IOP) or hypotony, endophthalmitis, and the risk of requiring additional surgical procedures.

Iluvien (fluocinolone acetonide intravitreal) implant is a small, non-biodegradable cylindrical tube with a central drug-polymer matrix that releases 0.19 mg of fluocinolone acetonide into the vitreous cavity. It is placed intravitreally with a 25-gauge needle in the same manner as intravitreal injections and can be administered in the office. Fluocinolone acetonide is released in minute amounts for at least three years. Iluvien was FDA approved in September 2014 to treat DME in individuals who received previous treatment with a course of corticosteroids and did not have a clinically significant rise in IOP.

COVERAGE POLICY

Iluvien (fluocinolone acetonide intravitreal implant) for the treatment of adult patients with treatment of DME **may be considered medically necessary** when **ALL** of the following clinical criteria are met:

1. Diagnosis of Diabetic Macular Edema (DME)

AND

2. Disease progression (*history of progressive visual loss or worsening of anatomic appearance*) as confirmed/determined by fluorescein angiography, Optical Coherence Tomography (OCT) or Scanning Computerized Ophthalmic Diagnostic Imaging (SCODI)

   MOLINA REVIEWER: Baseline labs (prior to treatment with requested implant) submitted and noted in member's profile to review for re-authorization of treatment

AND

3. Inadequate response, clinically significant adverse effects, labeled contraindication, or clinical rationale supporting the inappropriateness of **ALL** of the following. Documentation required, include date(s) of failed therapy or clinical event.
   a. Triamcinolone acetonide, intravitreal injection OR a previous course of corticosteroid; **AND**
   b. VEGF) Inhibitor: bevacizumab (Avastin): PREFERRED/NO PA REQUIRED; ranibizumab (Lucentis); pegaptanib (Macugen); aflibercept (Eylea); **AND**
   c. Laser Photocoagulation

AND

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

AND

5. Requested intravitreal implant will **NOT** be administered simultaneously (bilateral implantation) OR with other intravitreal implants at the same time [i.e., Ozurdex (dexamethasone intravitreal implant); Retisert (fluocinolone acetonide intravitreal Implant)]
   Informational Note: Simultaneous bilateral implantation should not be performed to limit the potential for bilateral post-operative infection (due to the risk of, and resistance to infections reduced by corticosteroids)

AND

6. Other documentation/attestation required:
   a. Member has been informed about the potential adverse effects of a corticosteroid intravitreal implant, including cataracts, increased IOP, or hypotony, endophthalmitis, and risk of need for additional surgical procedures; **AND**
   b. Requested intravitreal implant for use in affected eye: Right eye OR Left eye

CONTINUATION OF THERAPY

1. Reauthorization request is for the same eye as initial authorization AND at least 36 months have passed since last Iluvien administration

   NOTE: The continuation of therapy criteria applies only to the same previously treated eye. If member has developed condition in an untreated eye, a new request should be submitted and meet all initial coverage criteria.

   EXCEPTION: For requests more frequently than 36 months, clinical rationale and relevant supporting documentation must be submitted to Molina Medical Director for review and may require a peer-to-peer.

AND

2. Member continues to meet coverage criteria AND continued need for treatment has been formally assessed and documentation submitted for review; **AND**

3. Documentation required for continuation of therapy:
   a. Positive clinical response to Iluvien as evidenced by at least **ONE** of the following: fluorescein angiography, OCT or SCODI

   EXCEPTION: May be reviewed on a case-by-case basis with relevant, supporting documentation from Prescriber.

   Informational Note: At the end of the first 36-month treatment course, patients in the intervention arm are separated into two groups: those who are retreated with the FA implant and those who are not. In order to qualify for retreatment, patients must have gained ≥5 ETDRS letters of VA compared to baseline within the initial 36 months of treatment (FAME Study).

   AND

   b. Member is likely to benefit from re-treatment without being exposed to significant risk according to Prescriber

LIMITATIONS AND EXCLUSIONS

The following are considered **contraindications/exclusions** based on insufficient evidence:

1. Hypersensitivity to fluocinolone, other corticosteroids, or any component of the formulation.
   Informational Note: Documentation of allergenic cross-reactivity for corticosteroids is limited. However, due to similarities in chemical structure and/or pharmacologic actions, the possibility of cross-sensitivity cannot be ruled out with certainty.
2. Ocular or periocular infections (viral, bacterial, or fungal): Active or suspected ocular or periocular infections including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, or fungal infections of the eye.
   Informational Note: Corticosteroids are not recommended to be used in patients with a history of ocular herpes simplex because of the potential for reactivation of the viral infection.
3. Advanced glaucoma: Stage 3 or higher.
4. Concurrent treatment with other intravitreal implants [i.e., Retisert (Fluocinolone acetonide intravitreal implant); Ozurdex (dexamethasone intravitreal implant)].
   Informational Note: The safety and efficacy of Iluvien administered to both eyes concurrently have not been studied.

The following are considered conditions for **discontinuation of treatment** and re-treatment may not be authorized:

1. Loss of visual acuity from baseline (pre-treatment values).
2. Severely increased IOP, or moderately raised IOP, in treated eye.
3. Limited clinically meaningful benefit of treatment (i.e., maximal gain in visual acuity is less than five letters on a standard sight chart in the presence of limited anti-inflammatory effect).
   Informational Note: At the end of the first 36-month treatment course, patients in the intervention arm are separated into two groups: those who are retreated with the FA implant and those who are not. In order to qualify for retreatment, patients must have gained ≥ 5 ETDRS letters of VA compared to baseline within the initial 36 months of treatment.
4. Absence of macular edema or stable visual acuity.
   Informational Note: If absence of macular edema or stable visual acuity, treatment may be discontinued, and patient monitored. Treatment and monitoring intervals may be resumed at the Prescriber's discretion and submission of authorization request if there is presence of macular edema or visual acuity is decreasing.

The following are considered **experimental, investigational and unproven** based on insufficient evidence:

1. Any indications other than those listed above

DURATION OF APPROVAL: 36 months

PRESCRIBER REQUIREMENTS: Prescribed by board-certified ophthalmologists or retinal specialist experienced in the administration of intravitreal implants. Treatment and monitoring must be retained by the specialist.

AGE RESTRICTIONS: 18 years of age or older
Safety and efficacy not established in pediatric patients 18 years of age and younger for the indication of DME

DOSING CONSIDERATIONS: Adults: One implant (0.19 mg) in the affected eye by intravitreal injection. The implant is designed to release fluocinolone at an initial rate of 0.25 mcg/day lasting 36 months.

QUANTITY LIMITATIONS: ONE implant per eye per 36 months

EXCEPTION: For requests more frequent than 36 months, clinical rationale and relevant supporting documentation must be submitted to Molina Medical Director for review and may require a peer-to-peer.

Informational Note: From the two primary 36-month trials, subjects were eligible for retreatment no earlier than 12 months after study entry. Over the three-year follow up period, approximately 75% of the Iluvien treated subjects received only one Iluvien implant.

ADMINISTRATION:

1. Iluvien intravitreal implant is considered a **provider-administered** procedure to be performed by an ophthalmologist, retinal specialist, or retinal surgeon experienced in ophthalmic intravitreal injections; **AND**
2. Documentation of the following information required for review and submission of requests for subsequent treatment(s): Name of the intravitreal therapy; Dose and frequency; AND Treated eye (right or left eye); **AND**
   Informational Note: Simultaneous bilateral implantation should not be performed to limit the potential for bilateral post-operative infection (due to the risk of, and resistance to infections reduced by corticosteroids)
3. Refer to MHI Policy & Procedure (P&P): *Specialty Medication Administration Site of Care Policy: MHI Pharm 11.*

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DRUG INFORMATION

ROUTE OF ADMINISTRATION: Ophthalmic intravitreal injection

DRUG CLASS: Anti-inflammatory Agent, Corticosteroid, Ophthalmic

FDA-APPROVED USES: Diabetic Macular Edema (Iluvien)
Treatment of diabetic macular edema in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in IOP.

COMPENDIAL APPROVED OFF-LABELED USES: None

NOTE: Iluvien is not FDA approved for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye at this time; however, Retisert is approved for this indication. ***Retisert (Fluocinolone Acetonide Intravitreal Implant) is addressed in MCP-302***

*Significant differences between Retisert and Iluvien include different dosages of the drug being delivered to different areas of the eye. Retisert is a 0.59 mg sterile implant designed to release FA to the posterior segment of the eye over approximately 30 months, while Iluvien is a 0.19 mg sterile implant in a 36-month drug delivery system injected directly into the vitreous.

SUMMARY OF MEDICAL EVIDENCE

Fluocinolone Acetonide for Diabetic Macular Edema (FAME) A and B (Campochiaro, 2011; Campochiaro, 2012)

Fluocinolone acetonide (FA) received FDA approval based on two Phase 3 trials conducted under a single protocol. FAME-A and FAME-B were 36-month randomized controlled trials in adult patients with DME who had previously received laser therapy. They were identically designed, multi-center, double-masked, parallel-group, sham-controlled RCTs. The two parallel studies assessed the long-term safety and efficacy of intravitreal inserts releasing 0.2 g/day (low-dose) or 0.5 g/day (high-dose) FA in DME patients. A total of 956 patients with persistent DME despite 1 or more macular laser treatments were randomized 1:2:2 to receive either sham injection or intravitreal injection of 0.2 g/day or 0.5 g/day FA implants: low-dose insert (n=375) or high-dose insert (n=393) or a sham group (n=185). Randomization was based on baseline best-corrected visual acuity (BCVA) letter scores of ≤40 and >40.

- Demographic and mean baseline information for the FAME trial was age 62.5 years, 59.4% males, time to diagnosis of DME 3.6 years, A1C (7.8%), pseudophakic (34.8%), BCVA 53.4 letters, center point thickness 469m, IOP 15.2mmHg, cataract at baseline 47.1% (16.5% had no cataract and 36.4% cannot grade or not applicable). Patients with glaucoma, ocular hypertension, IOP more than 21 mm Hg, or concurrent IOP-lowering medications in the study eye were excluded from the trials. Patients were also excluded from the trials if they had: 1) laser treatment for DME or any ocular surgery in the study eye within 12 weeks of screening; 2) intravitreal, sub-Tenon, or periocular steroid therapy within 3 months of enrollment; 3) uncontrolled IOP elevation with steroid use that did not respond to topical therapy. Patients with a resting systolic blood pressure greater than 180 mm Hg or diastolic blood pressure greater than 105 mm Hg at the screening visit were excluded from the trials.
- After 6 weeks, patients were eligible for rescue laser, which could be repeated every 3 months. After 1 year, re-treatment criteria could allow for more masked study drug. After month 12, retreatment with originally assigned medicine was authorized if there was a loss of ≥ 5 letters in BCVA or increase in foveal thickness ≥ 50 µm compared to patient's best status during previous 12 months. In both trials, the primary efficacy endpoint was the percentage of patients with a 15-letter improvement in BCVA after 24 months. Iluvien met its primary endpoint in each of these trials. There were 74.4% of subjects who had one implant, 21.6% who had two implants, 3.5% who had three implants, 0.5% who had four implants, and 0% who had more than four implants. At 3 years, 28.7% of implant patients gained 15 letters or more versus 18.9% in the sham group. Subgroup analysis revealed that patients who were pseudophakic improved their visual acuity more than those who were phakic (difference in mean change in number of letters at 2 years from baseline was 5.6 letters in pseudophakic patients vs 1 letter in phakic patients). A significant limitation of these implants is that nearly 80% of all phakic patients develop cataracts and require cataract surgery. IOP was higher in 34% of patients who received this implant compared to 10% of controls. Patients in both studies were treated for 36 months and followed in a safety extension study for a further 12 months.

Rittiphairoj et al. (2020), in a Cochrane review, compared intravitreal steroid therapy to other treatments for DME. The systematic review included 10 RCTs (4348 participants, 4505 eyes) that compared any type of intravitreal steroids as monotherapy to any other intervention (e.g., observation, laser photocoagulation, anti-VEGF for DME. These trials compared intravitreal steroid therapies to other treatments such as intravitreal anti-VEGF therapy, laser photocoagulation, and sham injection. One study (560 eyes) compared intravitreal fluocinolone implant 0.19mg to sham. At 12 months, there was moderate certainty that fluocinolone improved visual acuity slightly more. Fluocinolone was more likely than placebo to increase visual acuity by three or more lines at 12 months, according to evidence of moderate certainty. Fluocinolone also increased the risk of cataract progression (participants = 335; moderate-certainty evidence), which occurred in approximately 8 out of 10 participants, and the use of IOP-lowering medications (participants = 558; moderate-certainty evidence), which was required in 2 to 3 out of 10 participants. The authors concluded that intravitreal steroids may improve vision in patients with DME compared to placebo or control. In the majority of comparisons, the effects were negligible, approximately one line of vision or less. More evidence is available when comparing dexamethasone or fluocinolone implants to placebo, however evidence comparing dexamethasone with anti-VEGF therapy is limited and inconsistent. Any benefits should be evaluated against IOP rise, usage of IOP-lowering medication, and cataract advancement in phakic patients. Glaucoma surgery is also increasing but remains rare.

National and Specialty Organizations

The **National Institute for Health and Clinical Excellence (NICE)** (2019) issued guidance on the use of FA intravitreal implant 0.19 mg (Iluvien) for treating chronic DME that is insufficiently responsive to available therapies in an eye with a natural lens (phakic eye) [TA613]. According to the recommendations, "*Fluocinolone acetonide intravitreal implant is not recommended as an option for treating chronic diabetic macular edema that is insufficiently responsive to available therapies in an eye with a natural lens (phakic eye)*." This conclusion was based on the interpretation that "*results from [Fluocinolone Acetonide in Diabetic Macular Edema] FAME may not be generalizable to people with chronic diabetic macular oedema in phakic eyes with symptomatic cataract seen in the NHS*" because "*in FAME, very few people had symptomatic cataract at baseline*" and that the type of rescue therapy used in FAME is not used in NHS clinical practice.

NICE replaced the January 2013 technology appraisal (TA) guidance 271 with TA 301 in November 2013. The change in guidance was the result of a review of the FA intravitreal implant for the treatment of chronic DME after an inadequate response to prior therapy. The guidance concluded that the FA intravitreal implant (Iluvien) is only recommended as a treatment option for chronic DME that is insufficiently responsive to available therapies when used in an eye with an intraocular (pseudophakic) lens.

SUPPLEMENTAL INFORMATION

Diabetic Macular Edema (DME): Leakage of fluid from retinal blood vessels which cause the macula to swell

Diabetic Retinopathy (DR): The progressive damage to the blood vessels in the back of the eye

Intravitreal: refers to that which is injected into the eye's vitreous humor between the lens and the retina. Intravitreal implants deliver a continuous concentration of drug over a prolonged period of time. Intravitreal corticosteroid implants are being studied for a variety of eye conditions leading to macular edema, including uveitis, diabetic retinopathy, and retinal venous occlusions. The goal of therapy is to reduce the inflammatory process in the eye while minimizing the adverse effects of the therapeutic regimen.

Phakic: An eye containing the natural lens

Pseudophakic: An eye in which a natural lens is replaced with an artificial lens implant

Retinopathy: Damage to the retina

Vascular Endothelial Growth Factor (VEGF): A chemical signal produced by the body's cells that stimulates growth of new blood vessels.

Uveitis: An inflammation of part or all of the uvea, the middle (vascular) tunic of the eye and commonly involving the other tunics (the sclera and cornea and the retina)

CODING & BILLING INFORMATION

CPT	Description
67027	Implantation of intravitreal drug delivery system (e.g., ganciclovir implant), includes concomitant removal of vitreous
67028	Intravitreal injection of a pharmacologic agent (separate procedure)

HCPCS	Description
J7313	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg [Iluvien]

AVAILABLE DOSAGE FORMS: 0.19-mg intravitreal implant release FA at an initial rate of 0.25mcg/day and lasting 36 months

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CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/12/2022 MCPC	Policy reviewed. References updated. Revision of criteria #3a broadened to 'a previous course of corticosteroid.' Previously 3a. Triamcinolone acetonide, intravitreal injection; Revised to: Triamcinolone acetonide, intravitreal injection OR a previous course of corticosteroid. Reference: Fraser et al. (2020).
10/13/2021 MCPC	Policy reviewed and updated, no changes in coverage criteria, updated references. IRO Peer Review. 9/1/2021. Practicing Physician. Board certified in Ophthalmology.
Q4 2020 P&T	Policy reviewed and updated, no changes in coverage criteria, updated references.
Q4 2019	Policy reviewed and updated, no changes in coverage criteria, updated references.
12/19/2018 MCPC	Policy reviewed and updated, no changes in coverage criteria, updated references.
12/13/2017 MCPC	New policy. IRO Peer Review. 10/4/2017. Practicing Physician. Board certified in Ophthalmology, Surgery Vitreoretinal

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (no National Coverage Determination identified – search: fluocinolone acetonide intravitreal implant). Available from CMS.
2. ClinicalTrials.gov. [Internet]. Bethesda (MD): National Library of Medicine; 2000 Feb 29 - [cited Dec 2017]. Available from ClinicalTrials.
3. United States Food and Drug Administration (FDA).

Prescribing Information and Drug Compendia

1. Clinical Pharmacology powered by ClinicalKey. Tampa (FL): Elsevier. Available from ClinicalKey. Published 2022. Accessed April 2022. Registration and login required.
2. Drug Facts and Comparisons. Facts and comparisons eAnswers [online]. Available from Wolters Kluwer Health, Inc. Accessed Aug 2022. Registration and login required.
3. Iluvien (fluocinolone) [prescribing information]. Alpharetta, GA: Alimera Sciences Inc; January 2022.

Peer Reviewed Publications

1. Abcouwer SF. Angiogenic factors and cytokines in diabetic retinopathy. J Clin Cell Immunol 2013; Suppl 1(11).doi:10.4172/2155-9899.
2. Apte RS. What is chronic or persistent diabetic macular edema and how should it be treated? JAMA ophthalmol. 2016;134(3):285-6.
3. Campochiaro PA, Brown DM, Pearson A, FAME Study Group, et al. Sustained delivery fluocinolone acetonide vitreous inserts provide benefit for at least 3 years in patients with diabetic macular edema. Ophthalmology. 2012; 119(10):2125-2132.
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5. Grover DA, Li T, Chong CCW. Intravitreal steroids for macular edema in diabetes. Cochrane Database of Systematic Reviews 2008, Issue 1. Art. No.: CD005656. DOI: 10.1002/14651858.CD005656.pub2. Accessed September 2019.
6. Rittiphairoj T, Mir TA, Li T, Virgili G. Intravitreal steroids for macular edema in diabetes. Cochrane Database Syst Rev. 2020 Nov 17;11(11):CD005656. doi: 10.1002/14651858.CD005656.pub3. PMID: 33206392; PMCID: PMC8095060.
7. Massa H, Nagar AM, et. al. Intravitreal fluocinolone acetonide implant (ILUVIEN) for diabetic macular edema: a literature review. Journal of International Medical Research 2019, Vol. 47(1) 31–43. Available here.

National and Specialty Organizations

1. American Academy of Ophthalmology (AAO) Retina Panel. Diabetic retinopathy preferred practice pattern. Published October 2019. Available from AAO. Accessed August 2021.
2. American Optometric Association (AOA). Guideline on eye care of patient with diabetes mellitus. Available from AOA.
3. Wong TY, Sun J, Kawasaki R, et. al. Guidelines on diabetic eye care: The International Council of Ophthalmology recommendations for screening, follow-up, referral, and treatment based on resource settings. Ophthalmology. 2018 Oct;125(10):1608-1622. Available from AAO. Accessed August 2021.
4. National Institute for Health and Care Excellence (NICE). Technology appraisal guidance: Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular edema in phakic eyes after an inadequate response to previous therapy [TA613]. Available from NICE. Published November 20, 2019. Accessed August 2022.
5. National Institute for Health and Care Excellence (NICE). Technology appraisal guidance: Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular edema after an inadequate response to prior therapy [TA301]. Available from NICE. Published November 27, 2013. Accessed August 2022.

Evidence Based Reviews and Publications

1. Fraser CE, D'Amico DJ, Shah AR. Diabetic retinopathy: Prevention and treatment. Available from UpToDate. Updated September 15, 2022. Accessed August 2022. Registration and login required.

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*