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

Last Approval: 10/12/2023
Next Review Due By: October 2024

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. High plasma glucose levels result in the breakdown of the blood-retinal barrier due to the loss of pericytes. This breakdown results in endothelial cell dysfunction and the release of vascular endothelial growth factor (VEGF) which causes capillary leakage, resulting in an accumulation of extracellular fluid in the macula that puts the patient at risk for significant decreased visual acuity. DME is diagnosed using an optical coherence tomograph (OCT). 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.

Iluvien (fluocinolone acetonide intravitreal) implant is a small, non-biodegradable cylindrical tube with a central drug-polymer matrix, placed intravitreally with a 25-gauge needle, that releases 0.19 mg of fluocinolone acetonide into the vitreous cavity slowly over approximately 36 months.

Regulatory Status
Iluvien (fluocinolone acetonide) 0.19 mg intravitreal implant was FDA approved in September 2014 for the indication of the 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 intraocular pressure.

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 letter scores of ≤40 and >40. In both trials, the primary efficacy endpoint was the percentage of patients with a 15-letter improvement in best-corrected visual acuity after 24 months. Iluvien met its primary endpoint in each of these trials (Campochiaro, 2011; Campochiaro, 2012).

There is currently an active Phase 4 clinical trial studying Iluvien as baseline therapy in early DME patients [ID: NCT04469595].

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, and/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. Vascular endothelial growth factor 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) NOR 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. Designation of affected eye (Right OR Left) intended for intravitreal implant.
   c.

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

Ehlers et al. (2022) wrote a report by the American Academy of Ophthalmology reviewing the safety and efficacy evidence for diabetic macular edema (DME) treatments. The review revealed that the current intravitreal pharmacotherapies, such as anti-VEGF injections and corticosteroid implants, are safe and effective. Corticosteroid

implants carry a higher risk of increased intraocular pressure (IOP) related adverse effects compared to anti- VEGF therapeutics. As there is a lack of robust comparative analysis evidence between anti- VEGF, corticosteroid implants, and combination therapies the authors emphasize that the choice of therapy is up to physician discretion and that access to all therapeutic options is imperative for appropriate care of individual patients.

Brambati et al (2022) conducted a retrospective cohort study on ten eyes from ten subjects with type 2 non-proliferative diabetic retinopathy and DME at baseline treated with Iluvien. A minimum of two 6 × 6-mm optical coherence tomography angiography (OCTA) scans were required to ensure that all cases had a baseline OCTA and an OCTA performed at 4 months of follow-up. Mean parafoveal perfusion density (PD) at baseline was 64.1 ± 1.8% at baseline, increasing to 66.1 ± 2.9% (p = 0.013) at the 4-month follow-up visit. In the qualitative assessment, 60 regions (10 areas for each subject) were graded to assess changes in retinal perfusion between the baseline and follow-up visits. This assessment revealed that 24 regions (40.0%) were characterized by a qualitative increase in perfusion after treatment, while 22 (36.7%) and 14 (23.3%) regions were featured by a stability and reduction in retinal perfusion, respectively.

Mansour et al. (2021) conducted a 24-month prospective observational study of participants treated with Iluvien to confirm safety and efficacy of the fluocinolone acetonide (FAc) intravitreal implant. Ninety-five participants (115 study eyes) were included in the study. The participants were previously steroid-challenged patients for up to 36 months pre-FAc and followed 24 months post-FAc implant. Mean IOP for the overall population remained stable post-FAc compared with pre-FAc implant. IOP- lowering therapies necessary were as follows, two trabeculoplasties and four IOP-lowering surgeries post-FAc. Mean visual acuity was stable post-FAc (mean improvement of 1-3 letters) and fewer DME treatments were required per year following FAc implant. Mean central subfield thickness was significantly reduced at 24 months post-FAc implant ($p<0.001$) and the percentage of patients with central subfield thickness ≤300 μm was significantly increased ($p=0.041$). Positive efficacy outcomes were noted after treatment, with stabilization of vision and reduction in inflammation. The FAc implant is a favorable treatment option for DME, especially when administered after a prior steroid challenge (Clinicaltrials.gov)

Adan et al. (2020) reviewed current literature and clinical practice to compile a clinical decision criterion to identify recurrent diabetic macular edema patients suitable for Iluvien, complete with follow up recommendations. The authors analyzed the data and concluded there is progressive and continuous improvement of the macula and visual outcomes with FAc. In response to clinical trial and real world evidence, the recommendations conclude that FAc implants should be positioned earlier in the DME treatment algorithm for those who have received one or two previous dexamethasone injections and continue to show presence of DME 3-4 post injection, as this indicates the patient has reoccurring DME and will require continued injections for a long period of time; moving to the FAc implant treatment will prevent patients from being subjected to a high number of unnecessary injections of suboptimal treatment. The recommendations conclude the main patient profile that could benefit from the FAc implant is for patients with a complete anatomical response after one injection of dexamethasone implant for those patients whom the retina layers are preserved; however, the FAc implant has shown efficacy even in those patients that had insufficient response to previous therapies.

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 most 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.

Chakravarthy et al. (2019) conducted a multicenter open-label observational study collecting real-world data on the safety and effectiveness of five hundred and sixty-three patients (593 eyes) treated with the fluocinolone acetonide (FAc) intravitreal implant. Mean IOP for the overall population remained within the normal range throughout follow-up and 76.7% of patients did not require IOP-lowering therapy following treatment of the FAc implant. Sixty-nine per cent of eyes did not require additional DME treatments. Mean visual acuity in the overall population increased from 51.9 letters at baseline to 55.6 letters at month 12, with a significant increase of 2.9 letters at last observation. Patients with short-term DME experienced greater visual acuity gains than those with long-term DME. This data reinforces the safety and efficacy of the FAc treatment, and the benefit of early FAc treatment.

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 (Current Procedural Terminology) Codes

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 (Healthcare Common Procedure Coding System) Code

HCPCS	Description
J7313	Injection, fluocinolone acetonide intravitreal implant (Iluvien), 0.01 mg

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

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

10/12/2023 MCPC	Policy reviewed and updated, no changes in coverage criteria, updated references.
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 by a practicing board certified in Ophthalmology physician.
Q4 2020 P&T	Policy reviewed and updated, no changes in coverage criteria, updated references.
Q4 2019 P&T	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 by a practicing board certified in Ophthalmology, and Vitreoretinal Surgery physician.

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APPENDIX

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