

## 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

**Uveitis** is a term that encompasses any type of inflammation involving the uvea and is a leading cause of blindness worldwide (Foster et al.). Uveitis accounts for approximately 10% of preventable vision loss in the United States, with a prevalence of 133 per 100,000 individuals (Foster et al.; Thorne et al.). There are three types of uveitis, classified according to the part of the uvea that is affected: anterior uveitis, intermediate, and posterior (NORD 2021). **Posterior uveitis** is the rare form of the disorder and is the type of uveitis most associated with loss of vision. Posterior uveitis may affect the retina and/or the optic nerve and may lead to permanent loss of vision. There are many infectious and non-infectious causes of posterior uveitis. **Chronic non-infectious uveitis** patients are more likely to have ocular comorbidities such as retinal disorders, glaucoma, and visual disturbances, as well as systemic autoimmune diseases such as rheumatoid arthritis and sarcoidosis (Foster et al.; Thorne et al.). The goal of treatment in **chronic non-infectious posterior segment uveitis** is to suppress inflammation, which can lead to tissue damage and subsequent permanent loss of vision (Tan et al. 2016) and ultimately preserve vision. The standard of care for noninfectious uveitis has been local and systemic corticosteroids in combination with immunomodulatory therapies.

*Corticosteroids* are considered the standard treatment for initial management of active inflammation in uveitis irrespective of its anatomical location. Local corticosteroids (e.g., prednisolone acetate and similar topical corticosteroids) generally do not penetrate the posterior segment in adequate concentrations to resolve vitreous inflammation, so these are usually insufficient as the primary therapy for posterior uveitis. Uveitis involving the posterior segment necessitates administration orally or via local injection. In comparison to other immunosuppressive options, steroids have a faster onset of action in controlling inflammation; however, long-term use is limited due to their side effect profile. The overall goal is to achieve long-term inflammation remission while using as few steroids as possible. Guidelines recommend the inclusion of a steroid-sparing immunosuppressive drug if, after 2 to 3 months, inflammation cannot be managed with 7.5 to 10 mg/day of prednisone (or equivalent) (Jabs et al. 2018; Dick et al. 2018).

*Immunosuppressive drugs* [e.g., antimetabolites, alkylating agents, T-cell inhibitors, and tumor necrosis factor (TNF)-inhibitors] may be used in the case of corticosteroids failure or insufficient control of inflammation to prevent corticosteroid-induced side effects, and to treat high-risk uveitis syndromes. Immunosuppressive therapy is generally indicated for use in bilateral disease, active inflammation, failure to respond to oral glucocorticoid therapy, or severe disease that interferes with daily activities. Immunosuppressants, while effective, can have serious and potentially fatal side effects, such as renal and hepatic failure and bone marrow suppression.

*Intraocular steroid implants* were designed to provide sustained medication release, reducing the need for frequent injections. Fluocinolone acetonide (FA) implant is typically reserved for patients with a noninfectious posterior that necessitates frequent local glucocorticoid injection and for whom systemic use of glucocorticoids or other immune modulators may be particularly problematic. It should be noted that while an intraocular fluocinolone-releasing implant offers an alternative to systemic therapy, it may result in complications that require surgical intervention (e.g., cataract and glaucoma). In addition, its long-term safety has not been fully studied (Rosenbaum 2019). FA intravitreal implants (Retisert; Yutiq) are indicated for treatment of chronic noninfectious uveitis affecting the posterior segment of the eye.

**Molina Clinical Policy**  
**Retisert, Yutiq (fluocinolone acetonide) Intravitreal Implants**  
**Policy No. 302**

Last Approval: 4/13/2023  
Next Review Due By: April 2024



**Retisert (FA intravitreal implant 0.59 mg)**, a non-biodegradable intravitreal implant that releases FA locally to the posterior segment of the eye, is indicated for the treatment of chronic non-infectious posterior uveitis. The device provides sustained delivery of 0.59 mg FA with initial release rate of approximately 0.6 µg/day, which decreases over the 1st month to a steady rate of 0.3-0.4 µg per day over approximately 30 months. The most frequently reported ocular adverse events (AEs) in clinical trials with Retisert occurring in 50-90% of patients included: cataract, increased IOP, procedural complications, and eye pain. Headache was the most reported non-ocular event (33%) (PI, 2019).

**Yutiq (FA intravitreal implant 0.18 mg)**, a sterile non-bioerodible intravitreal implant containing 0.18 mg FA, is indicated for the treatment of chronic non-infectious posterior uveitis. It releases the drug at an initial rate of 0.25 µg/day in a 36-month sustained-release drug delivery system. The most common reported AEs associated with Yutiq are cataract formation and elevated IOP.

**COVERAGE POLICY**

FA intravitreal implant (Retisert; Yutiq) for the treatment of uveitis **may be considered medically necessary** when **ALL** the following clinical criteria are met:

1. Diagnosis of chronic (duration of one year or greater) non-infectious uveitis affecting the posterior segment of the eye(s); **AND**
2. Confirmed disease progression (history of progressive visual loss or worsening of anatomic appearance) as documented by fluorescein angiography, Optical Coherence Tomography (OCT) or Scanning Computerized Ophthalmic Diagnostic Imaging (SCODI)

**MOLINA REVIEWER:** Baseline evaluations as noted in above criterion should be submitted or documented by Prescriber for re-authorization review (to confirm response to treatment).

**AND**

3. Requested intravitreal implant will **NOT** be administered simultaneously (bilateral implantation) OR in combination with other intravitreal corticosteroids implants [e.g., Ozurdex (dexamethasone 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 produced by corticosteroids).*

**AND**

4. Documentation of inadequate response (e.g., recurrent uveitis despite use of therapy) or clinically significant adverse effects associated with high-dose systemic steroid, immunosuppressive therapy, or intravitreal steroid injection; labeled contraindication, or clinical rationale supporting the inappropriateness of at least **ONE** of the following treatments:
  - a. Intravitreal steroid injection(s); OR
  - b. Systemic corticosteroids; OR
  - c. Immunosuppressives, *including but not limited to:*
    - Antimetabolites: azathioprine, mycophenolate mofetil (CellCept; Myfortic), or methotrexate
    - Calcineurin inhibitors: cyclosporine or tacrolimus
    - Tumor Necrosis Factor (TNF) inhibitor: adalimumab (Humira)

**AND**

5. 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

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**CONTINUATION OF THERAPY**

1. Reauthorization request is for the same eye as initial authorization.

**NOTE:** The continuation of therapy criteria is only for the same previously treated eye. If member has developed condition in an untreated eye, Prescriber must submit new request with Initial Coverage criteria.

**AND**

2. Member meets **ONE** of the following:
  - a. At least 30 months have passed since last treatment with Retisert; **OR**
  - b. At least 36 months have passed since last treatment with Yutiq.

**EXCEPTION:** For requests preceding the recommended labeled dose (prior to 30 months for Retisert and prior to 36 months for Yutiq), Prescriber submit clinical rationale and relevant supporting documentation to Molina Medical Director for clinical review. Peer-to-peer may be required.

**AND**

3. Member continues to meet initial coverage criteria AND continued need for treatment has been formally assessed and documented; **AND**
4. Positive response to treatment as indicated by an improvement in uveitis and lack of recurrence within the preceding 30 months for Retisert OR 36 months for Yutiq. A positive response to treatment is confirmed by baseline evaluations or documentations as submitted by Prescriber.

**EXCEPTION:** For requests preceding the recommended labeled dose (prior to 30 months for Retisert and prior to 36 months for Yutiq), Prescriber submit clinical rationale and relevant supporting documentation to Molina Medical Director for clinical review. Peer-to-peer may be required.

**AND**

5. No evidence of unacceptable adverse events, complications, or toxicity to implant (e.g., eye pain, ocular/conjunctival hyperemia, reduced visual acuity [long term], conjunctival hemorrhage, headache).

**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. Concurrent treatment with other intravitreal implants (e.g., Ozurdex [dexamethasone intravitreal implant]).

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 or moderately raised IOP, in treated eye
3. Limited clinically meaningful benefit of treatment
4. Unacceptable adverse events, complications/toxicity to implant (e.g., eye pain, ocular/conjunctival hyperemia, reduced visual acuity (long-term), conjunctival hemorrhage, headache)

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

1. Any indications other than those listed above  
*Informational Note: Macular Edema Following Retinal Vein Occlusion: No RCTs were identified with the FA implant for the treatment of macular edema following retinal vein occlusion.*

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**DURATION OF APPROVAL** Retisert: 30 months per eye; Yutiq: 36 months per eye.

**EXCEPTION:** For requests preceding the duration of the recommended labeled dose (prior to 30 months for Retisert and prior to 36 months for Yutiq), Prescriber submit clinical rationale and relevant supporting documentation to Molina Medical Director for clinical review. May require a peer-to-peer.

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

**AGE RESTRICTIONS**

Retisert: 12 years of age or older *Safety and efficacy have not been established in patients younger than 12 years of age*  
Yutiq: 18 years of age or older *Safety and effectiveness of Yutiq in pediatric patients have not been established.*

**DOSING CONSIDERATIONS**

Retisert: One implant (0.59 mg) into the posterior segment of the affected eye by intravitreal injection. The implant is designed to initially release 0.6 mcg/day, decreasing over 30 days to a steady state release of 0.3 to 0.4 mcg/day for ~30 months. Recurrence of uveitis denotes depletion of tablet, requiring reimplantation.

Yutiq: One implant (0.18 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**

Retisert: ONE intravitreal implant over a duration of 30 months, per eye  
Yutiq: ONE intravitreal implant over a duration of 36 months, per eye

**ADMINISTRATION**

1. FA Intravitreal Implant (Retisert; Yutiq) is considered a **provider-administered** procedure to be performed by an ophthalmologist, retinal specialist, or retinal surgeon experienced in ophthalmic intravitreal injections.
2. Refer to MHI Policy & Procedure: 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:** Uveitis

Treatment of chronic, noninfectious uveitis affecting the posterior segment of the eye

FDA Approval: Retisert: April 2005; Yutiq: October 2018

Retisert is not FDA approved for the treatment of DME at this time. However, Iluvien, another brand of FA is indicated for DME. **Iluvien (FA intravitreal implant) is addressed in MCP-301**

## SUMMARY OF MEDICAL EVIDENCE

### Retisert (FA intravitreal implant, 0.59 mg)

The FA intravitreal implant was evaluated in three large multicenter clinical trials during its development: 34-week (Jaffe et al., 2006) and 3-year (Callanan et al., 2008) of the first trial, and the 2-year (Pavesio 2010) results of the second trial have been previously published.

The prescribing information summarizes information from 2 studies in which 227 patients with chronic (1 year or greater history) noninfectious posterior uveitis in one or both eyes were treated with a FA 0.59 mg intravitreal implant. In two independent randomized, double-masked, multicenter, controlled clinical trials, participants were randomized to receive a single 0.59-mg implant in the more severely affected eye in patients with bilateral disease. In both trials, the recurrence of uveitis at all post-implantation time points was compared to the 34-week pre-implantation time point. Treatment with FA demonstrated *statistically significant improvements* of the following:

- Reduction in the recurrence rate of posterior uveitis in the treated eye from 40% to 54% at 34 weeks pre-implantation to 7% to 14% at 34 weeks post-implantation
- Decrease in the need for systemic corticosteroid and/or immunosuppressive therapy was reduced from 47% to 63% at baseline to 5 to 10% at 34 weeks post-implantation,
- Reduction in the need for periocular corticosteroid injections from 50% to 65% in the 34-week pre-implementation period to 3% to 6% at the 34-week post-implementation period, and
- Improvement in 3 or more lines of visual acuity in approximately 19% to 21% of treated eyes at 34 weeks post-implantation.

Approximately 2 years after the FA implant, nearly all phakic eyes are expected to develop cataracts and require cataract surgery within an average post-implantation period. An estimated 60% of patients require IOP-lowering medications within 34 weeks, and 32% are expected to require filtering procedures to control IOP within 2 years.

Jaffe et al. (2006) randomized 278 patients with noninfectious posterior uveitis to an implant containing either 2.1mg or 0.59mg of FA in a prospective, dose-masked, dose-randomized, historically controlled, multicenter trial. The primary efficacy outcome was a comparison of the recurrence rate in the implanted eye between 34 weeks before and after implantation. Visual acuity, the need for adjunctive therapy, and safety also were assessed. After implantation, uveitis medications and systemic immunosuppression were tapered within a 6-week period. The uveitis recurrence rate (for both doses) decreased from 51% to 6% in the first 34 weeks after implantation. In comparison, eyes that did not receive an implant had a recurrence rate that ranged from 20% to 42%. Results from a 3-year follow-up showed recurrence rates of 4, 10, and 20% at 1, 2, and 3 years (Callanan et al. 2008). Visual acuity in the implanted eyes was significantly better at 2 years, but that difference was lost at 3 years. The FA implant significantly reduced uveitis recurrences, improved visual acuity, and reduced the need for adjunctive therapy. The majority of implanted phakic eyes required cataract surgery (93% vs. 20% in nonimplanted eyes); 37% required glaucoma surgery; and 75% required pressure-lowering medications.

Pavesio et al. (2010) compared the Retisert (FA 0.59 mg implant) with standard of care (SOC) in subjects with unilateral or bilateral noninfectious posterior uveitis in a 3-year, open-label, randomized, phase 2b/3 superiority study. Subjects were randomized to a 0.59-mg fluocinolone implant (n = 66) or SOC (n = 74) with either systemic prednisolone or an equivalent corticosteroid monotherapy or, if deemed necessary, combination therapy with an immunosuppressive agent plus a lower dose of prednisolone or an equivalent corticosteroid. Approved immunosuppressants included cyclosporine A, methotrexate, cyclophosphamide, mycophenolate mofetil, azathioprine, and tacrolimus. It was not possible to mask study treatments; however, efforts were made to avoid selection bias. There was a statistically significant difference in gender between the treatment groups; other baseline characteristics were similar between the two groups. The primary outcome measure was time to the first recurrence of uveitis. Eyes that received Retisert experienced a delayed onset of observed recurrence of uveitis and a lower rate of recurrence of uveitis (18.2% versus 63.5%) compared with SOC study eyes. The most common AEs observed in implanted eyes were elevated IOP necessitating IOP-lowering surgery (21.2% of implanted eyes) and cataracts necessitating extraction (87.8% of phakic implanted eyes). There were no treatment-related non-ocular

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AEs in the fluocinolone group, compared to 25.6% of subjects receiving SOC. The authors concluded that the FA intravitreal implant provided better inflammation control in uveitis patients than standard of care, but IOP and lens clarity in implanted eyes required close monitoring (NCT00468871).

**Systemic Therapy vs. Implant Therapy**

*The Multicenter Uveitis Steroid Treatment (MUST) Trial Research Group*

MUST was a large prospective trial (255 patients, 479 eyes with uveitis) that compared the efficacy of the FA implant (n = 129) versus systemic immunosuppression (n = 126) with a 24-month follow-up in patients with severe non-infectious intermediate uveitis, posterior uveitis, or panuveitis. Visual acuity improvement was comparable between both groups, with a gain of 6 letters in the implant group and of 3.2 letters in the systemic therapy group at 24 months. Control of uveitis was more frequent in the implant group (88% vs. 71%). Although the number of patients with macular edema significantly decreased in the implant group at 6 months, the proportion of patients with macular edema was similar between both groups at 24 months. Cataract surgery was performed at a much higher rate in the implant group (80% vs 31% in the systemic treatment group) as well as glaucoma surgery (26.2 vs 3.7% in the systemic treatment group). The risk of systemic infection requiring prescription therapy was lower in the implant group (0.36 events/person-year versus 0.60 in the systemic therapy group), but the risk of hospitalization was the same in both groups. Health-related quality of life and utility scores improved in both groups, with implant therapy slightly outperforming.

- A 24-month follow-up found that patients receiving the implants had similar visual acuity outcomes to those treated with systemic glucocorticoids and glucocorticoid-sparing immunosuppressive agents (Kempen et al. 2011).
- Visual outcomes remained similar in a 54-month follow-up study (Kempen et al. 2015; MUST Trial Follow-Up Research Group 2015). The 54-month results show that the FA implant is at least as effective as systemic therapy.
- After 7 years of extended follow-up, visual acuity was better in patients who were initially assigned to receive systemic therapy, despite a 30% loss to follow-up in both groups (Writing Committee for the MUST Trial and Follow-up Study Research Group, 2017).

\* It should be noted that the MUST study was designed to be a 2-year study. The 5-year and 7-year data were observational. A Retisert implant is only expected to provide inflammatory control for up to 3 years, after which a Retisert exchange may be needed.

**Yutiq (FA intravitreal implant, 0.18 mg)**

FDA approval of Yutiq was based on clinical data from 2 randomized, sham injection-controlled, double-masked Phase 3 clinical trials with up to 3 years of follow-up (NCT01694186 and NCT02746991). After 6 and 12 months, both trials met the primary efficacy endpoint of preventing recurrent uveitis flares. Yutiq reduces uveitis recurrence at 6 and 12 months after injection and delays the first recurrence of uveitis within the first 12 months after injection (study 1, n=129; study 2, n=153). Recurrence was defined as a decline in visual acuity, vitreous haze caused by non-infectious uveitis, or the need for rescue medications. In both studies, patients treated with Yutiq had fewer recurrence of uveitis flares at 6 and 12 months compared to sham injection:

- Study 1: 18% for Yutiq vs 79% for sham at 6 months; 28% vs 86% at 12 months
- Study 2: 22% for Yutiq vs 54% for sham at 6 months; 33% vs 60% at 12 months

The treatment was generally well-tolerated, but treated patients had a higher mean IOP increase (by 2 mmHg in the treatment group vs. no change in the sham group) and were more likely to require cataract surgery (18% of patients Yutiq patients vs. 8.6% for sham patients).

**National and Specialty Organizations**

**Fundamentals of Care for Uveitis (FOCUS) International Consensus Group**

*Guidance on Noncorticosteroid Systemic Immunomodulatory Therapy in Noninfectious Uveitis (2018)*

FOCUS is an international, expert-led consensus initiative to develop systematic, evidence-based recommendations for the treatment of noninfectious uveitis. The guidelines state that “consensus guidelines for systemic treatment of

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*noninfectious uveitis were published last in 2000 reflected the opinions of only 12 United States physicians and predated the use of biologic therapy” (Jabs et al. 2000). FOCUS also noted that the 7-year follow-up study of the Multicenter Uveitis Steroid Treatment (MUST) Trial found that systemic therapy (corticosteroid-supplemented immunomodulatory therapy and biologics) improved visual outcomes, controlled inflammation, and reduced macular edema compared to an intravitreal FA implant in patients with intermediate uveitis, posterior uveitis, or panuveitis (Kempen et al. 2017); therefore, new evidence-based guidelines are required to facilitate a move toward optimized treatment by ophthalmologists and others in the care of patients with noninfectious uveitis.*

**CODING & BILLING INFORMATION**

CPT Codes – N/A

**HCPCS Codes**

HCPCS	Description
J7311	Injection, fluocinolone acetonide intravitreal implant (Retisert) 0.01mg
J7314	Injection, fluocinolone acetonide intravitreal implant (Yutiq) 0.01 mg

**AVAILABLE DOSAGE FORMS:**

Retisert: 0.59 mg non-biodegradable intravitreal implant; release of FA over approximately 30 months  
 Yutiq: 0.18 mg non-biodegradable intravitreal implant; release of FA over approximately 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**

<b>4/13/2023 MCPC</b>	Policy reviewed and updated. No changes in coverage criteria. Updated References section.
<b>4/13/2022 MCPC</b>	Policy reviewed and updated. No changes in coverage criteria. updated References section.
<b>4/05/2021 MCPC</b>	Policy reviewed and revised. Updated references. IRO Specialist Peer Review. 1/17/2021. Practicing Physician. Board certified in Ophthalmology. Content update includes: Removal of the following criteria under #4 in initial therapy section: <ul style="list-style-type: none"> <li>• Previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure</li> <li>• At least TWO administrations of intra- or peri-ocular injection of corticosteroids for the management of uveitis (e.g., triamcinolone acetonide injection)</li> <li>• At least TWO separate recurrences of uveitis requiring treatment with systemic corticosteroids or ocular injections of corticosteroids (intra- or peri-ocular injection of corticosteroid)</li> <li>• Removed 'Advanced glaucoma: Glaucoma with cup to disc ratios of greater than 0.8' criterion in 'Contraindications/Exclusions/Discontinuations' section for Initial and Continuation of Therapy</li> </ul> Added the following note to #3 in 'Reauthorization/Continuation of Therapy' section: A positive response to treatment is confirmed by baseline evaluations or documentations as submitted by Prescriber.
<b>Q2 2020 P&amp;T</b>	Policy reviewed and updated, no changes in coverage criteria, updated references. Clarified duration of therapy criteria for each implant in 'Continuation of Therapy' section: 'At least 30 months have passed since last treatment with Retisert; At least 36 months have passed since last treatment with Yutiq' [Criterion previously stated '30 months since the previous intravitreal implant'].
<b>5/29/2019 P&amp;T</b>	Policy reviewed and updated references. IRO Peer Review. 2/5/2019. Practicing Physician. Board certified in Ophthalmology
<b>12/19/2018 MCPC</b>	Policy reviewed and updated, no changes in coverage criteria, updated references.
<b>12/13/2017 MCPC</b>	New policy. IRO Peer Review. 10/4/2017. Practicing Physician. Board certified in Ophthalmology, Surgery Vitreoretinal.

**REFERENCES**

**Government Agency**

- Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (search: fluocinolone acetonide intravitreal implant, retisert). No NCD identified. Accessed February 2023. <https://www.cms.gov/medicare-coverage-database/search.aspx>.

# Molina Clinical Policy

## Retisert, Yutiq (fluocinolone acetonide) Intravitreal Implants

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#### Prescribing Information and Drug Compendia

1. Retisert (fluocinolone) [prescribing information]. Bridgewater, NJ: Bausch & Lomb Incorporated; January 2021.
2. Yutiq (fluocinolone acetonide intravitreal implant) [prescribing information]. Watertown, MA: EyePoint Pharmaceuticals US, Inc; May 2021.
3. American Society of Health-System Pharmacists. 2022. AHFS Drug Information® - 2022nd Ed. Bethesda, MD. American Society of Health-System Pharmacists®. ISBN-10: 1-58528-684-2, ISBN-13: 978-1-58528-684-3. ISSN: 8756-6028. STAT!Ref Online Electronic Medical Library. Accessed March 3, 2022. <https://online.statref.com/document/BjXS4n0B6Lp7RqgJUlp4Ut>.
4. Clinical Pharmacology [database online]. Elsevier; 2023. Available from ClinicalPharmacology. Registration and login required. Accessed February 2023. Registration and login required.
5. Drug Facts and Comparisons. Facts & Comparisons eAnswers [online]. UpToDate 2023. Available from Wolters Kluwer Health, Inc. Accessed February 2023.

#### Peer Reviewed Publications

1. Callanan DG, Jaffe GJ, Martin DF, et al. Treatment of posterior uveitis with a fluocinolone acetonide implant: three-year clinical trial results. Arch Ophthalmol. 2008 Sep; 126:1191-1201. doi: 10.1001/archophth.126.9.1191.
2. Foster CS, Kothari S, Anesi SD, et al. The Ocular Immunology and Uveitis Foundation preferred practice patterns of uveitis management. Surv Ophthalmol. 2016;61(1):1-17. doi: 10.1016/j.survophthal.2015.07.001. Epub 2015 Jul 9.
3. Jabs DA. Immunosuppression for the Uveitides. Ophthalmology. 2018;125(2):193-202. doi:10.1016/j.ophtha.2017.08.007.
4. Jaffe GJ, Martin D, Callanan D, Fluocinolone Acetonide Uveitis Study Group, et al. Fluocinolone acetonide implant (Retisert) for noninfectious posterior uveitis: Thirty-four-week results of a multicenter randomized clinical study. Ophthalmology. 2006 Jun;113(6):1020-7. doi: 10.1016/j.ophtha.2006.02.021.
5. Pavesio C, Zierhut M, Bairi K, Fluocinolone Acetonide Study Group, et al. Evaluation of an intravitreal fluocinolone acetonide implant versus standard systemic therapy in noninfectious posterior uveitis. Ophthalmology. 2010; 117(3):567-575. doi: 10.1016/j.ophtha.2009.11.027.
6. Tan HY, Agarwal A, Lee CS, et al. Management of noninfectious posterior uveitis with intravitreal drug therapy. Clinical Ophthalmology (Auckland, NZ). 2016;10:1983-2020. doi:10.2147/OPTH.S89341.
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8. Multicenter Uveitis Steroid Treatment (MUST) Trial Research Group
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