Subject: Retisert, Yutiq (fluocinolone acetonide intravitreal implants)	**Original Effective Date:** 12/13/2017
Policy Number: MCP-302	**Revision Date(s):** 2/2019; 05/29/2019 4/5/2021
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Contents

DISCLAIMER

This Medical Policy is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina medical coverage policy (MCP) document and provide the directive for all Medicare members.

RECOMMENDATION

This policy addresses **Fluocinolone Acetonide (FA) Intravitreal Implant (Retisert; Yutiq)** for the treatment of adult patients with **chronic non-infectious uveitis affecting the posterior segment of the eye** when appropriate criteria are met.

Molina Healthcare reserves the right to update this policy and revise coverage criteria to include or omit any off-label condition(s) as necessary based on medical literature and clinical studies that may become available.

*****FA Intravitreal Implant (Iluvien) is addressed in MCP-301*****
**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 fluocinolone acetate 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*

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Uveitis is a term that encompasses any type of inflammation involving the uvea, and is a leading cause of blindness worldwide (Foster et al.) In the United States, uveitis accounts for approximately 10% of preventable vision loss and has an estimated 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. Patients with chronic non-infectious uveitis are likely to have ocular comorbidities such as retinal disorders, glaucoma, and visual disturbances, as well as systemic autoimmune diseases, including, most commonly, rheumatoid arthritis and sarcoidosis (Foster et al; Thorne et al.).

Chronic Non-infectious Posterior Segment Uveitis

The treatment target of uveitis is to suppress inflammation that can lead to tissue damage and subsequent permanent loss of vision (Tan et al. 2016). The ultimate goal of therapy for uveitis is to preserve vision. Local and systemic corticosteroids, in combination with immunomodulatory therapies, are the standard of care for noninfectious uveitis.

- Corticosteroids are considered the standard treatment for initial control of active inflammation in uveitis regardless of the anatomic location. Local corticosteroids (i.e. 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 requires administration orally or by 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 remission of inflammation using steroids as little as possible. Guidelines recommend addition of a steroid-sparing immunosuppressive agent if, after 2 to 3 months, inflammation cannot be controlled with < 7.5 to 10 mg/d 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. Immunosupressive therapy is generally indicated for use in bilateral disease, active inflammation, failure to respond to oral glucocorticoid therapy, or severe disease that interferes with activities of daily living. Immunosupressants, while effective, may have serious and potentially life-threatening adverse effects, including renal and hepatic failure and bone marrow suppression.

- **Intraocular steroid implants** were designed for sustained release of medication, reducing the need for frequent injections. FA implant is generally reserved for patients whose noninfectious posterior requires frequent local glucocorticoid injection and in 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 (i.e. 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.

  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 in clinical trials with Retisert occurring in 50-90% of patients included: cataract, increased intraocular pressure, procedural complications, and eye pain. The most common non-ocular event reported was headache (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 adverse effects associated with Yutiq are cataract formation and elevated intraocular pressure.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

FDA-approved indication does not alone dictate coverage. Molina Clinical Policy may not recommend coverage for all FDA-approved indications. Please review this Policy in its entirety for indications covered by Molina Healthcare.

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

Available as
Retisert: 0.59 mg intravitreal implant; release of FA over approximately 30 months
Yutiq: 0.18 mg intravitreal implant; release of FA over approximately 36 months

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

Black Box Warnings/REMS: None at the time of this writing

Warnings/Precautions: Intravitreal injections have been associated with endophthalmitis, eye inflammation, increased intraocular pressure and retinal detachment. Monitor carefully after intravitreal injection. Complications may also include cataract formation, choroidal detachment, hypotony, vitreous hemorrhage, vitreous loss, and wound dehiscence. Procedure may cause optic nerve injury. Visual defects in acuity and field of vision may occur (lasting 1 to 4 weeks postoperatively). Late-onset endophthalmitis has been observed, often associated with surgical site integrity.

CLASSIFICATION: Anti-inflammatory Agent, Corticosteroid, Ophthalmic

COVERAGE CRITERIA FOR INITIAL AUTHORIZATION

FA Intravitreal Implant (Retisert; Yutiq) may be authorized for members who meet **ALL** the following criteria

1. Prescriber specialty

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

2. Diagnosis/Indication

Prescriber submits ALL supporting documentation and clinical rationale (*includes clinical notes from the member's medical records including any applicable labs and/or tests, supporting the diagnosis*): [ALL]

- ❒ Diagnosis of chronic (duration of one year or greater) non-infectious uveitis affecting the posterior segment of the eye(s)
- ❒ Diagnosis and confirmed 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 evaluations as noted in above criterion should be submitted or documented by Prescriber for re-authorization review (to confirm response to treatment).

3. Age/Gender/Restrictions

- ❒ Retisert: 12 years of age or older
  - *Safety and efficacy not established in pediatric patients 12 years of age and younger*
- ❒ Yutiq: 18 years of age or older

4. Conventional Therapy/Concurrent Therapy/Other Requirements

Documentation of ALL the following must be submitted for review: [ALL]

- ❒ Requested intravitreal implant will **NOT** be administered simultaneously (bilateral implantation) OR in combination with other intravitreal corticosteroids implants [i.e. Ozurdex (dexamethasone intravitreal implant)]
  - *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)*

- ❒ Inadequate response (i.e. 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 the following treatments, include date(s) of failed therapy or clinical event(s). Documentation required. ONE (1) of the following: **[ONE]**
  - ❍ Intravitreal steroid injection(s); OR
  - ❍ Systemic corticosteroids; OR
  - ❍ Immunosuppressives, *including but not limited to*: **[ONE]**
    - Antimetabolites: azathioprine, mycophenolate mofetil (CellCept; Myfortic), or methotrexate
    - Calcineurin inhibitors: cyclosporine or tacrolimus
    - Tumor Necrosis Factor (TNF) inhibitor: adalimumab (Humira)

5. Contraindications/Exclusions/Discontinuations

FA Intravitreal Implant will <u>not</u> be authorized if ANY of the following conditions apply:

- ❒ Hypersensitivity to fluocinolone, other corticosteroids, or any component of the formulation
  - ◆ *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.*
- ❒ 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
  - ◆ *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.*
- ❒ Concurrent treatment with other intravitreal implants [i.e. Ozurdex (dexamethasone intravitreal implant)]

6. Labs/Reports/Documentation required

All documentation for determination of medical necessity must be submitted for review. Prescriber to submit documentation as indicated in the criteria above, including but not limited to chart notes, applicable lab values and/or tests, adverse outcomes, treatment failures, or any other additional clinical information or clinical notes from the member's medical records supporting the diagnosis. Letters of support and/or explanation are often useful but are not sufficient documentation unless ALL specific information required by this MCP is included.

NOTE: Additional documentation, rationale, and/or supporting evidence may be requested for review as deemed necessary or appropriate by Molina Medical/Pharmacy staff.

- ❒ Member has been informed about the potential adverse effects of a corticosteroid intravitreal implant, including cataracts, increased intraocular pressure, or hypotony, endophthalmitis, and risk of need for additional surgical procedures.

- ❒ Requested intravitreal implant for use in which affected eye
  - ❍ Right eye
  - ❍ Left eye

REAUTHORIZATION/CONTINUATION OF THERAPY

FA Intravitreal Implant (Retisert; Yutiq) may be authorized for continuation of therapy if meet **ALL** the following criteria are met: **[ALL]**

1. Initial Coverage Criteria

- ❑ 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.

- ❒ Member meets ONE of the following: [ONE]
  - ❍ At least 30 months have passed since last treatment with Retisert
  - ❍ 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. May require a peer-to-peer.

- ❑ Member continues to meet initial coverage criteria AND member's continued need for treatment has been formally assessed and documented

2. Compliance: N/A

3. Labs/Reports/Documentation required

Prescriber submit ALL supporting documentation and clinical rationale:

- ❒ 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

  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. May require a peer-to-peer.

  MOLINA REVIEWER: A positive response to treatment is confirmed by baseline evaluations or documentations as submitted by Prescriber.

- ❒ Member is likely to benefit from re-treatment without being exposed to significant risk, according to Prescriber's clinical judgment

- ❒ Unacceptable adverse events, complications, or toxicity to implant [e.g., eye pain, ocular/conjunctival hyperemia, reduced visual acuity (long term), conjunctival hemorrhage, headache]

4. Discontinuation of Treatment

Authorization for FA Intravitreal Implant (Retisert) will not be authorized if ANY of the following conditions apply:

- ❒ Loss of visual acuity from baseline (pre-treatment values)
- ❒ Severely increased intraocular pressure (IOP), or moderately raised IOP, in treated eye
- ❒ Limited clinically meaningful benefit of treatment
- ❒ Unacceptable adverse events, complications/toxicity to implant (e.g., eye pain, ocular/conjunctival hyperemia, reduced visual acuity (long term), conjunctival hemorrhage, headache)
- ❒ Contraindications/Exclusions to therapy

  FA Intravitreal Implant will not be authorized if ANY of the following conditions apply [ANY]
  - ❍ Hypersensitivity to fluocinolone, other corticosteroids, or any component of the formulation
    - *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.*
  - ❍ 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
    - *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.*
  - ❍ Concurrent treatment with other intravitreal implants [i.e. Ozurdex (dexamethasone intravitreal implant)]
    - *The safety and efficacy of different FA intravitreal implants administered to both eyes concurrently have not been studied.*
- ❒ **EXCEPTIONS** to the above criteria may be reviewed on a case-by-case basis with relevant, supporting documentation from Prescriber

ADMINISTRATION, QUANTITY LIMITATIONS, AUTHORIZATION PERIOD

Consult the manufacturer's labeling for more detailed information on dosage and administration of this drug, cautions, precautions, contraindications, potential drug interactions, laboratory test interferences, and monitoring.

1. Recommended Dosage

- ❒ Retisert (12 years of age or older): FA is designed to be released from the implant initially at a rate of 0.6 mcg/day, decreasing over the first month to 0.3 to 0.4 mcg/day over approximately 30 months
  - *Pediatrics: Safety and efficacy have not been established in patients younger than 12 years of age*

- ❒ Yutiq: 0.18 mg (1 intravitreal implant) via intravitreal injection; provides initial drug release rate of 0.25 mcg/day and lasts for 36 months

2. Authorization Limit

- ❒ Retisert: ONE (1) intravitreal implant over a duration of 30 months, per eye

- ❒ Yutiq: ONE (1) intravitreal implant over a duration of 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.

3. Route of Administration

- ❒ FA Intravitreal Implant (Retisert; Yutiq) is considered a **provider-administered** procedure to be performed in a **provider office, outpatient setting** by a qualified ophthalmologist experienced in intravitreal injections.

- ❒ Administration of intravitreal therapy (*record in the procedure or post-procedure note following the completion of treatments*). Documentation of the following information required for review and submission of requests for subsequent treatment(s):
  - ❍ Name of the intravitreal therapy
  - ❍ Dose and frequency
    Treated eye: right eye, left eye, or both eyes

LIMITATIONS

All other uses of FA Intravitreal Implant (Retisert; Yutiq) that are not an FDA-approved indication or not included in the 'Coverage Criteria' section of this policy is considered experimental/investigational or not a covered benefit of this policy. This subject to change based on research and medical literature, or at the discretion of Molina Healthcare.

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

- ❑ Macular Edema Following Retinal Vein Occlusion: No randomized controlled trials were identified with the FA implant for the treatment of macular edema following retinal vein occlusion.

SUMMARY OF CLINICAL EVIDENCE

FA 0.59 mg (Retisert)

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

Callanan et al. randomized 278 patients to receive either the 0.59-mg FA implant (N=110) or the 2.1-mg FA implant (N=168). The recurrence rate of uveitis was reduced from 62% to 4%, 10%, and 20% during the 1-, 2-, and 3-year post-implantation periods, respectively, for the 0.59-mg dose. Reductions with 2.1-mg dose were similar. Eyes implanted with the FA implant showed the following responses:

- Visual acuity remained stable or improved over baseline in most eyes during the 3-year study period.
- An 80% reduction in the need for systemic medications to control inflammation, and this rate of reduction was greater than the rate of intravitreal injection of corticosteroids.

While implantation of FA reduced the recurrence rate of uveitis, the authors also noted the extensive risk for side effects, including: a higher incidence of intraocular pressure elevation eyes treated with an FA implant; the need for cataract extraction (93% of phakic implanted eyes compared with 20% of phakic nonimplanted eyes), and glaucoma-filtering surgery (40% of FA implanted eyes compared with 2% of nonimplanted eyes).

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

- Reduction in the recurrence rate of posterior uveitis in the treated eye from 40% (46/116) to 54% (58/108) for the 34-week pre-implantation to 7% (7/108) to 14% (16/116) at 34-weeks post-implantation
- Decrease in the need for systemic corticosteroid and/or immunosuppressive therapy was reduced from 47-63% at baseline to 5-10% at 34 weeks post-implantation, and
- Reduction in the need for periocular corticosteroid injections from 50-65% in the 34-week pre-implementation period to 3-6% at 34 weeks post-implantation, and
- 3 or more lines of visual acuity (VA) in 19-21% of treated eyes compared to 6-7% of untreated eyes.

Pavesio et al (2010) assessed the safety and effectiveness of Retisert compared with standard therapy in patients with non-infectious posterior uveitis. In a randomized, controlled, phase IIb/III, open-label, multi-center trial subjects with unilateral or bilateral non-infectious posterior uveitis (n=140) received either a 0.59 mg Retisert (n=66) or standard of care (SOC; n=74) with either systemic prednisolone or equivalent corticosteroid as monotherapy (greater than or equal to 0.2 mg/kg daily) or, if deemed necessary by the investigator, combination therapy with an immunosuppressive agent plus a lower dose of prednisolone or equivalent corticosteroid (greater than or equal to 0.1 mg/kg daily). The primary outcome measure was time to first recurrence of uveitis. Eyes that received Retisert experienced delayed onset of observed recurrence of uveitis ($p < 0.01$) and a lower rate of recurrence of uveitis (18.2 % versus 63.5 %; $p <$ or $= 0.01$) compared with SOC study eyes. Adverse events frequently observed in implanted eyes included elevated IOP requiring IOP-lowering surgery (occurring in 21.2 % of implanted eyes) and cataracts requiring extraction (occurring in 87.8 % of phakic implanted eyes). No treatment-related non-ocular adverse events were observed in the implant group, whereas such events occurred in 25.7% of subjects in the SOC group. The authors concluded that Retisert provided better control of inflammation in patients with uveitis compared with systemic therapy.

The Multicenter Uveitis Steroid Treatment (MUST) Trial is a multi-center, partially masked, randomized controlled trial comparing the safety and efficacy of the FA implant and systemic therapy with oral corticosteroids and immunosuppressive medications for patients with severe non-infectious intermediate uveitis, posterior uveitis or panuveitis. The initial study randomized 255 patients (479 eyes) to either the surgical implant (N=129) or systemic therapy (N=126).

- 24-month follow-up found similar visual acuity outcomes results between patients receiving the implants to those treated with systemic glucocorticoids and glucocorticoid-sparing immunosuppressive agents (Kempen et al. 2011).
- Visual outcomes remaining similar in a follow-up study at 54 months (Kempen et al. 2015; MUST Trial Follow-Up Research Group 2015). The 54-month confirms that the FA implant works at least as well as systemic therapy.
- After 7 years of extended follow-up, visual acuity was better in patients initially allocated to receive systemic therapy, although the study was limited by 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 only designed to be a two-year study and the five-year and seven-year data were only observational. A Retisert implant is only expected to provide inflammatory control for up to three years, after which a Retisert exchange may be needed.

FA 0.18 mg (Yutiq)

FDA approval of Yutiq was based on clinical data from 2 randomized, sham injection-controlled, double-masked stage 3 clinical trials of Yutiq with patient follow-up of 3 years (study 1, n=129; study 2, n=153). Both trials achieved the primary efficacy endpoint of prevention of recurrent uveitis flares after 6 months and 12 months. Yutiq reduces the recurrence of uveitis at 6 and 12 months after injection and extends the time to the first recurrence of uveitis within the first 12 months after injection. Recurrence was defined as either deterioration in visual acuity, vitreous haze attributable to non-infectious uveitis or need for rescue medications. In both studies, fewer patients treated with Yutiq had recurrence of uveitis flares at 6 and 12 months, compared with 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 intraocular pressure increase and were more likely to need cataract surgery.

DEFINITIONS

N/A

APPENDIX

N/A

CODING INFORMATION

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is covered or non-covered. coverage is determined by the benefit document. this list of codes may not be all inclusive.

CPT	Description
NA	

HCPCS	Description
J7311	Injection, fluocinolone acetonide intravitreal implant, 0.59 mg (Retisert)
J7314	Injection, fluocinolone acetonide intravitreal implant, 0.18 mg (Yutiq)

**CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS*)

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Policy History	MCPC
Policy Developed Peer Review. 10/2/2017. Practicing Physician. Board certified in Ophthalmology, Surgery Vitreoretina	12/13/2017
Annual Review	12/19/2018
Revision Peer Review. 2/5/2019. Practicing Physician. Board certified in Ophthalmology	P&T 5/29/2019
Annual Review	P&T Q2 2020

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'].	
Policy Revision IRO Specialist Peer Review. 1/17/2021. Practicing Physician. Board certified in Ophthalmology Revision includes: Removed the following criteria under #4 in initial therapy section: • Previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure • At least TWO administration of intra- or peri-ocular injection of corticosteroids for the management of uveitis (i.e. triamcinolone acetonide injection) • At least TWO (2) separate recurrences of uveitis requiring treatment with systemic corticosteroids or ocular injections of corticosteroids (intra- or peri-ocular injection of corticosteroid) • 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 Added the following note to #3 in 'Reauthorization/Continuation of Therapy' section: **MOLINA REVIEWER:** A positive response to treatment is confirmed by baseline evaluations or documentations as submitted by Prescriber.	MCPC 4/5/2021

**All content, clinical evidence, coverage criteria, practice guidelines, appendices and reference sections reviewed and revised with the most recent medical literature and available evidence for both 'Annual Reviews' and 'Policy Revisions.' Annual Reviews without notable changes to coverage criteria or position may not require Peer Review. Policy Revisions include notable content updates or revisions that which may have affected criteria or requires review by a practicing specialist, Peer Reviewer.*