Molina Clinical Policy
Retisert, Yutiq (fluocinolone acetonide intravitreal implants)
Policy No. 302

Last Approval: 4/13/2022
Next Review Due By: April 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

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.). The goal of treatment in **chronic non-infectious posterior segment uveitis** is to suppress inflammation that can lead to tissue damage and subsequent permanent loss of vision (Tan et al. 2016) and ultimately preserve vision. Local and systemic corticosteroids, in combination with immunomodulatory therapies, have been 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 (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 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 (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.

Retisert (fluocinolone acetonide intravitreal implant 0.59 mg), a non-biodegradable intravitreal implant that releases fluocinolone acetonide (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 IOP, procedural complications, and eye pain. The most common non-ocular event reported was headache (33%) (PI, 2019).

Yutiq (fluocinolone acetonide 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 IOP.

COVERAGE POLICY

Fluocinolone Acetonide (FA) Intravitreal Implant (Retisert; Yutiq) for the treatment of uveitis **may be considered medically necessary** when **ALL** of 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

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.

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

FDA Approval:
Retisert: April 2005; Yutiq:
COMPENDIAL APPROVED OFF-LABELED USES: None

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 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.

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% to 54% for the 34-week 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, and
- Reduction in the need for periocular corticosteroid injections from 50% to 65% in the 34-week pre-implementation period to 3% to 6% at 34 weeks post-implantation, and
- Improvement of 3 or more lines of visual acuity in approximately 19% to 21% of treated eyes at 34 weeks post-implantation.

Nearly all phakic eyes are expected to develop cataracts and require cataract surgery within an average post-implantation period of approximately 2 years of the FA implant. An estimated 60% of patients requiring 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 2.1 mg or 0.59 mg 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 from the 34 weeks before implantation to the 34 weeks after implantation. Visual acuity, 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. Comparatively, eyes that did not receive an implant had an increased rate of recurrences from 20% to 42%. Results from 3-year follow-up showed recurrence rates of 4, 10, and 20% at 1, 2, and 3 years (Callanan et al. 2008). At 2 years, visual acuity was significantly better in the implanted eyes, but that difference was lost at 3 years. The FA implant significantly reduced uveitis recurrences, improved visual acuity, and decreased the need for adjunctive therapy. Most of the implanted phakic eyes required cataract surgery (93% vs. 20% in nonimplanted eyes), 37% of eyes 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 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 equivalent corticosteroid monotherapy or, if deemed necessary, combination therapy with an immunosuppressive agent plus a lower dose of prednisolone or 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 between the treatment groups in gender; other baseline characteristics were similar between the two groups. The primary outcome measure was time to first recurrence of uveitis. Eyes that received Retisert experienced 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. Adverse events frequently observed in implanted eyes included elevated IOP requiring IOP-lowering surgery (21.2% of implanted eyes) and cataracts requiring extraction (87.8% of phakic implanted eyes). There was no treatment related non-ocular adverse events in the fluocinolone group compared to

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

Systemic Therapy vs. Implant Therapy

The Multicenter Uveitis Steroid Treatment (MUST) Trial Research Group

The MUST trial was a large prospective trial (255 patients, 479 eyes with uveitis) to compare the efficacy of the FA implant (n=129) versus systemic immunosuppression (n=126) with a follow-up of 24 months 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. The implant group had a much higher rate of cataract surgery (80% vs 31% in the systemic treatment group) and glaucoma surgery (26.2 versus 3.7% in the systemic treatment group). Systemic infection requiring prescription therapy was lower in the implant group (0.36 events/person-year in the implant group versus 0.60 in the systemic therapy group,), but the risk of hospitalization was similar between both groups. Health-related quality of life and health utility scores increased in both groups, slightly favoring implant therapy (not significant).

- 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 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). 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 (study 1, n=129; study 2, n=153). 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 IOP increase (by 2 mmHg in the treatment group vs. no change in the sham group) and were more likely to need cataract surgery (in 18% of patients receiving Yutiq vs. 8.6% for sham).

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 guidance notes that '*consensus guidelines for systemic treatment of*

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 Multicenter Uveitis Steroid Treatment (MUST) Trial 7-year follow-up study demonstrated that systemic therapy (corticosteroid-supplemented immunomodulatory therapy and biologics) improved visual outcomes, controlled inflammation, and reduced macular edema compared with an intravitreous 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.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes – N/A

HCPCS Codes

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

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

4/13/2022 MCPC Policy reviewed and updated; no changes in coverage criteria; updated References section.

4/5/2021 MCPC 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:
- Previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure
- At least TWO administrations of intra- or peri-ocular injection of corticosteroids for the management of uveitis (e.g., triamcinolone acetonide injection)
- At least TWO 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: A positive response to treatment is confirmed by baseline evaluations or documentations as submitted by Prescriber.

Q2 2020 P&T 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'].

05/29/2019 P&T Policy reviewed and updated references. IRO Peer Review. 2/5/2019. Practicing Physician. Board certified in Ophthalmology

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

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Prescribing Information and Drug Compendia

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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. Available here. Accessed March 3, 2022.
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Peer Reviewed Publications

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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.
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7. Thorne JE, Suhler E, Skup M, et al. Prevalence of noninfectious uveitis in the United States: A claims-based analysis. JAMA Ophthalmol. 2016;134(11):1237-1245.
8. Multicenter Uveitis Steroid Treatment (MUST) Trial Research Group
    - Kempen JH, Altaweel MM, et al. Randomized comparison of systemic anti-inflammatory therapy versus fluocinolone acetonide implant for intermediate, posterior, and panuveitis: The multicenter uveitis steroid treatment trial. Ophthalmology. 2011;118(10):1916–1926.
    - Kempen JH, Altaweel MM, Writing Committee for the MUST Trial and Follow-up Study Research Group, et al. Association between long-lasting intravitreous fluocinolone acetonide implant vs systemic anti-inflammatory therapy and visual acuity at 7 years among patients with intermediate, posterior, or panuveitis. JAMA. 2017 May 16;317(19):1993-2005. doi: 10.1001/jama.2017.5103.
    - Multicenter Uveitis Steroid Treatment Trial Research Group, Kempen JH, Altaweel MM, Holbrook JT, Jabs DA, Sugar EA. The multicenter uveitis steroid treatment trial: Rationale, design, and baseline characteristics. Am J Ophthalmol. 2010 Apr;149(4):550-561.e10. doi: 10.1016/j.ajo.2009.11.019.
    - Multicenter Uveitis Steroid Treatment (MUST) Follow-up Study Research Group. Quality of life and risks associated with systemic anti-inflammatory therapy versus fluocinolone acetonide intraocular implant for intermediate uveitis, posterior uveitis, or panuveitis: fifty-four-month results of the MUST trial and follow-up study. Ophthalmology. Oct 2015;122(10):1976-1986.
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National and Specialty Organizations

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3. Brady CJ, Villanti AC, Law HA, et al. Corticosteroid implants for chronic non-infectious uveitis. Cochrane Database Syst Rev. Feb 12 2016;2:CD010469.

APPENDIX

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