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 Next Review Due By: 10/2025
 Policy Number: C11706-A

Retisert, Yutiq (fluocinolone acetonide) Intravitreal Implants

PRODUCTS AFFECTED

Retisert (fluocinolone acetonide intravitreal implant), Yutiq (fluocinolone acetonide intravitreal implant)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

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.

DIAGNOSIS:

Non-infectious uveitis

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. NON-INFECTIOUS UVEITIS:

1. Documented diagnosis of non-infectious posterior segment uveitis

NOTE: Retisert and Yutiq are not for use in *anterior* uveitis or in uveitis caused by infection
 AND

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2. Documentation of member's baseline best-corrected visual acuity (BCVA) in order to measure efficacy with notation of eye(s) being treated [DOCUMENTATION REQUIRED]
AND
3. Prescriber attests or clinical reviewer has found that Retisert or Yutiq (fluocinolone acetonide intravitreal implant) will NOT be administered simultaneously (bilateral implantation) and is NOT intended for administration with other intravitreal implants [i.e., Ozurdex (dexamethasone intravitreal implant), Iluvien (fluocinolone acetonide intravitreal Implant)]
MOLINA REVIEWER 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) of an appropriate trial, serious side effects, or contraindication to formulary topical glucocorticoids OR an intravitreal steroid (e.g., triamcinolone, dexamethasone) OR a systemic corticosteroid
AND
5. Documented trial and failure, serious side effects, or contraindication to an anti-metabolite (e.g., methotrexate, azathioprine, mycophenolate) OR a calcineurin inhibitor (e.g., cyclosporine, tacrolimus)
AND
6. Member was previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure
AND
7. Prescriber attests 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
AND
8. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Retisert (fluocinolone acetonide intravitreal implant) include: active viral, bacterial, mycobacterial and fungal infections of ocular structures. Contraindications to Yutiq (fluocinolone acetonide intravitreal implant) include: ocular or periocular infections, hypersensitivity.)

CONTINUATION OF THERAPY:

A. NON-INFECTIOUS UVEITIS:

1. Reauthorization request is for the same eye as initial authorization AND at least 30 months have passed since last treatment with Retisert OR at least 36 months have passed since last treatment with Yutiq
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. Documentation of positive response to treatment as indicated by lack of recurrence, greater than 15 letters (3 lines) in BCVA from baseline or the member achieved driving visual acuity, or visual acuity maintained to at least 50% of the best recorded following diagnosis of uveitis
AND
3. Prescriber attests member is likely to benefit from re-treatment without being exposed to significant risk, according to Prescriber's clinical judgment
AND
4. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity (e.g., eye pain, ocular/conjunctival hyperemia, reduced visual acuity [long term], conjunctival hemorrhage, headache)

DURATION OF APPROVAL:

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Initial authorization: Retisert: 30 months per eye; Yutiq: 36 months per eye, Continuation of therapy:
Retisert: 30 months per eye; Yutiq: 36 months per eye

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified ophthalmologist or retinal specialist experienced in the administration of intravitreal injections [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

Retisert: 12 years of age and older
Yutiq: 18 years of age and older

QUANTITY:

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

PLACE OF ADMINISTRATION:

The recommendation is that intravitreal injectable medications in this policy will be for pharmacy or medical benefit coverage and the intravitreal injectable products administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Ophthalmic intravitreal injection

DRUG CLASS:

Anti-inflammatory Agent, Corticosteroid, Ophthalmic

FDA-APPROVED USES:

Indicated for treatment of chronic, noninfectious uveitis affecting the posterior segment of the eye

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Uveitis is a term that encompasses any type of inflammation involving the uvea and is a leading cause of blindness worldwide (Foster et al. 2016). 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. 2016; Thorne et al. 2016). There are three types of uveitis, classified according to the part of the uvea that is affected: anterior, 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. 2016; Thorne et al. 2016). The goal of treatment in **chronic non-infectious posterior segment uveitis** is to suppress inflammation, which can lead to tissue damage and

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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 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. A 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 (Papaliodis 2023). FA intravitreal implants (Retisert; Yutiq) are indicated for treatment of chronic noninfectious uveitis affecting the posterior segment of the eye.

The 2018 Ophthalmology Guidance on Noncorticosteroid Systemic Immunomodulatory Therapy in Noninfectious Uveitis: Fundamentals Of Care for Uveitis (FOCUS) Initiative notes that biologic and other systemic non-corticosteroid immunomodulatory agent use has increased in patients whose uveitis is not controlled with corticosteroids alone. Therapeutic corticosteroids referenced in the guidelines are periocular steroid injections, topical corticosteroids, and systemic steroids. The guidelines also note the Multicenter Uveitis Steroid Treatment (MUST) Trial 7-year study demonstrated that systemic therapy (corticosteroid-supplemented immunomodulatory therapy and biologics) improved visual outcomes, controlled inflammation, and reduced macular edema compared with an intravitreal fluocinolone acetonide implant in patients with intermediate uveitis, posterior uveitis, or panuveitis.

The Ophthalmology journal also published the Periocular Triamcinolone vs. Intravitreal Triamcinolone vs. Intravitreal Dexamethasone Implant for the Treatment of Uveitic Macular Edema (POINT) trial which concluded intravitreal triamcinolone acetonide and intravitreal dexamethasone implant were superior to periocular triamcinolone for treating uveitic macular edema with modest increases in the risk of intraocular pressure elevation.

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 IOP, procedural complications, and eye pain. Headache was the most reported non-ocular event (33%) (Retisert 2021).

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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 events associated with Yutiq are cataract formation and elevated IOP (Yutiq 2022).

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of fluocinolone acetonide intravitreal implant are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to fluocinolone acetonide intravitreal implant include: active viral, bacterial, mycobacterial and fungal infections of ocular structures, ocular or periocular infections, hypersensitivity.

OTHER SPECIAL CONSIDERATIONS:

None

CODING/BILLING INFORMATION

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. 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. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCP CODE	DESCRIPTION
J7311	Injection, fluocinolone acetonide, intravitreal implant (retisert), 0.01 mg
J7314	Injection, fluocinolone acetonide, intravitreal implant (Yutiq), 0.01 mg

AVAILABLE DOSAGE FORMS:

Retisert IMPL 0.59MG

Yutiq IMPL 0.18MG

REFERENCES

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2. Yutiq (fluocinolone acetonide intravitreal implant) 0.18 mg, for intravitreal injection [prescribing information]. Watertown, MA: EyePoint Pharmaceuticals US, Inc; June 2023.
3. 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(9):1191-201. doi: 10.1001/archophth.126.9.1191. PMID: 18779477.
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SUMMARY OF REVIEW/REVISIONS	DATE
<p>REVISION- Notable revisions: Coding/Billing Information Template Update Required Medical Information Background References</p>	Q4 2024
MCP Conversion	Q2 2024
Policy reviewed, no changes to criteria.	04/10/2024
Policy reviewed and updated. No changes in coverage criteria. Updated References section	04/13/2023
Policy reviewed and updated. No changes in coverage criteria. updated References section.	04/13/2022
<p>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:</p> <ul style="list-style-type: none"> •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 <p>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.</p>	04/05/2021
<p>Policy reviewed and updated, no changes in coverage section, 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'].</p>	Q2 2020
<p>Policy reviewed and updated references. IRO Peer Review. 2/5/2019. Practicing Physician. Board certified in Ophthalmology</p>	05/29/2019
<p>Policy reviewed and updated, no changes in coverage criteria, updated references.</p>	12/19/2018

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New policy. IRO Peer Review. 10/4/2017. Practicing Physician. Board certified in Ophthalmology, Surgery Vitreoretinal.	12/13/2017
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