

# PHARMACY POLICY STATEMENT

## Ohio Medicaid

<b>DRUG NAME</b>	<b>Retisert (fluocinolone acetonide)</b>
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Retisert is a 0.59 mg fluocinolone acetonide intravitreal implant indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. It is released over a period of 30 months and has been shown to reduce the rate of recurrence and improve visual acuity.

Uveitis is an inflammation of the uvea (middle layer of the eye). It can be infectious or non-infectious. Non-infectious uveitis (NIU) is often associated with inflammatory conditions such as rheumatoid arthritis. If the anterior segment of the uvea is affected, it can be treated with topical glucocorticoids. If resistant or affecting the intermediate or posterior segments, more invasive or systemic treatment is needed.

Retisert (fluocinolone acetonide) will be considered for coverage when the following criteria are met:

### Uveitis

For **initial** authorization:

1. Member is at least 12 years of age; AND
2. Medication must be prescribed by or in consultation with an ophthalmologist; AND
3. Member has a diagnosis of chronic (1 year or more) non-infectious uveitis affecting the posterior segment of the eye; AND
4. Member has tried and failed at least one of the following for at least 3 months:
  - a) Systemic corticosteroid (e.g., prednisone)
  - b) Non-biologic immunosuppressive (e.g., mycophenolate mofetil, methotrexate, cyclosporine, tacrolimus); AND
5. Member has had a failed trial of Ozurdex or Yutiq; AND
6. Member does not have any active infections of the eye.
7. **Dosage allowed/Quantity limit:** One implant (0.59 mg) per eye  
Limit: 2 implants (1 per eye) per 30 months

***If all the above requirements are met, the medication will be approved for 3 months.***

For **reauthorization**:

1. Chart notes must show improved or stabilized visual acuity following treatment and/or an improved vitreous haze score; AND
2. At least 30 months have elapsed since the prior treatment (of the same eye); AND
3. Member has recurrent symptoms.

***If all the above requirements are met, the medication will be approved for an additional 3 months.***

**CareSource considers Retisert (fluocinolone acetonide) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
10/28/2021	New policy created for Retisert.
10/18/2023	Updated Cochrane reference. Added references. Added Yutiq as a trial option.
01/25/2024	Approved by ODM

References:

1. Retisert [prescribing information]. Bausch & Lomb; 2021.
2. Multicenter Uveitis Steroid Treatment (MUST) Trial Research Group, Kempen JH, Altaweel MM, et al. Benefits of Systemic Anti-inflammatory Therapy versus Fluocinolone Acetonide Intraocular Implant for Intermediate Uveitis, Posterior Uveitis, and Panuveitis: Fifty-four-Month Results of the Multicenter Uveitis Steroid Treatment (MUST) Trial and Follow-up Study. *Ophthalmology*. 2015;122(10):1967-1975. doi:10.1016/j.ophtha.2015.06.042
3. Writing Committee for the Multicenter Uveitis Steroid Treatment (MUST) Trial and Follow-up Study Research Group, Kempen JH, Altaweel MM, et al. Association Between Long-Lasting Intravitreal Fluocinolone Acetonide Implant vs Systemic Anti-inflammatory Therapy and Visual Acuity at 7 Years Among Patients With Intermediate, Posterior, or Panuveitis. *JAMA*. 2017;317(19):1993-2005. doi:10.1001/jama.2017.5103
4. Reddy A, Liu SH, Brady CJ, Sieving PC, Palestine AG. Corticosteroid implants for chronic non-infectious uveitis. *Cochrane Database Syst Rev*. 2023;1(1):CD010469. Published 2023 Jan 16. doi:10.1002/14651858.CD010469.pub3
5. Tan HY, Agarwal A, Lee CS, et al. Management of noninfectious posterior uveitis with intravitreal drug therapy. *Clin Ophthalmol*. 2016;10:1983-2020. Published 2016 Oct 13. doi:10.2147/OPHTH.S89341
6. Wu X, Tao M, Zhu L, Zhang T, Zhang M. Pathogenesis and current therapies for non-infectious uveitis. *Clin Exp Med*. 2023;23(4):1089-1106. doi:10.1007/s10238-022-00954-6
7. Ohio Administrative Code. (2022, February 23). 5160-1-01 (C) Medicaid medical necessity: definitions and principles. Retrieved February 22 2023 from codes.ohio.gov.
8. Ohio Administrative Code. (2022, July 18). 5160-26-03 Managed care: covered services. Retrieved February 22, 2023 from codes.ohio.gov.
9. Ohio Administrative Code. (2020, January 1). 5160-9-03 Pharmacy services: covered drugs and associated limitations. Retrieved February 22, 2023 from codes.ohio.gov.

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Revised date: 10/18/2023