



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: Fluocinolone acetonide

Brand Name: Retisert

Medication Class: corticosteroid

FDA Approved Uses: chronic non-infectious uveitis affecting the posterior segment of the eye

Usual Dose: 0.59 mg intravitreal implant

Available Dosage Forms: 0.59 mg intravitreal implant

Duration of Therapy: one implant is designed to release fluocinolone acetonide at a nominal rate of 0.6mcg/day, decreasing over the first month to a steady state between 0.3 – 0.4 mcg/day over approximately 30 months. Following depletion of fluocinolone from Retisert as evidenced by recurrence of uveitis, Retisert may be replaced.

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- Must have chronic non-infectious uveitis affecting the posterior segment of the eye
 - Must be prescribed by retinal specialist
 - Must be 12 years old or over
 - Implant only one eye at a time
 - Must have failed (i.e., recurrent uveitis despite use of traditional therapy) or was intolerant to traditional treatment including steroids (systemic, periocular injection) and/or immunosuppressive agents (i.e., cyclosporine, azathioprine, methotrexate)
- Or
- Must be experiencing adverse events associated with high dose systemic steroid or immunosuppressive therapy

Not Approved if:

- Patient has a viral disease of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella.
- Patient has mycobacterial infections of the eye
- Patient has fungal diseases of ocular structures
- Patient has any contraindications to the use of Retisert
- Patient does not meet above criteria

Notes:

- Monitor for: ocular complications, elevated IOP, and development of cataracts
- Prolonged use of corticosteroids may suppress the host response and increase the hazard of secondary ocular infections.
- Since resistance to infections is known to be reduced by corticosteroids, simultaneous bilateral implantation should not be carried out, in order to limit the potential for



- bilateral post-operative infection.
- Medication to treat the underlying disease may be prescribed concurrently as deemed appropriate by physician. (Although, there should be a decrease in the use of adjunctive therapy (systemic corticosteroids and/or immunosuppressives and corticosteroid injections) post-implant.)
 - Nearly all patients will experience an immediate and temporary decrease in visual acuity in the implanted eye which lasts for approximately 1 to 4 weeks.
 - Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve. Patients must be monitored for elevated intraocular pressure (IOP).
 - Within 34 weeks post-implant, approximately 60% of patients will require IOP lowering medications. Within 2 years post-implant, approximately 32% of patients are expected to require filtering procedures to control IOP.
 - Within an average post-implantation period of approximately 2 years, nearly all phakic eyes are expected to develop cataracts and require cataract surgery.
 - Use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

P&T Approval: _____ Date: _____