GCHP Medi-Cal Clinical Guidelines
Fluocinolone Intravitreal Implant
(Iluvien™, Retisert™, Yutiq™)

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	**Iluvien** Treatment of diabetic macular edema in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure. **Retisert & Yutiq** Treatment of chronic, noninfectious uveitis affecting the posterior segment of the eye.
Exclusion Criteria	• Active or suspected ocular or periocular infection (viral, bacterial or fungal). • Use in combination with another corticosteroid implant / insert / injection or ophthalmic topical solution or suspension.
Required Medical Information	**Iluvien –** Must meet **ALL** of the following: • Diagnosis of macular edema. • Confirmation that the patient does not have glaucoma. • Previously received a treatment course with corticosteroids and did not have a clinically significant rise in intraocular pressure. **Retisert –** Must meet **ALL** of the following: • Diagnosis of chronic (equal to or greater than one year) of non-infectious uveitis affecting the posterior segment of the eye. • Tried and failed (e.g., recurrent uveitis despite use of traditional therapy) or was intolerant to traditional treatment including intravitreal steroid injection, systemic corticosteroids and/or immunosuppressive agents (e.g., cyclosporine, azathioprine, methotrexate) or experienced adverse events associated with high dose systemic steroid or immunosuppressive therapy. **Yutiq –** Must meet **ALL** of the following: • Diagnosis of chronic (equal to or greater than one year) of non-infectious uveitis affecting the posterior segment of the eye. • Tried and failed or intolerance of at least two administrations of intra- or peri-ocular injections of corticosteroids, OR one conventional therapy, such as i. Systemic or topical corticosteroids (e.g., prednisone, prednisolone acetate). ii. Immunosuppressive agents (e.g., azathioprine, cyclosporine, methotrexate, or mycophenolate). iii. Tumor Necrosis Factor (TNF) inhibitors (e.g., adalimumab [Humira]).

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<tr><td></td><td>iv. Experienced at least two separate recurrences of uveitis requiring treatment with systemic corticosteroids or ocular injections of corticosteroids.</td></tr>
<tr><td>Age Restriction</td><td>Iluvien & Yutiq – 18 years of age and older
Retisert – 12 years of age and older</td></tr>
<tr><td>Prescriber Restrictions</td><td>Ophthalmologist</td></tr>
<tr><td>Coverage Duration</td><td>Iluvient & Yutiq – One dose per eye every 36 months.
Retisert – One dose per eye every 30 months.</td></tr>
<tr><td>Other Criteria / Information</td><td>
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<tr><th>HCPCS</th><th>Description</th><th>Dosing, Units</th></tr>
<tr><td>J7313</td><td>Injection, fluocinolone acetonide, intravitreal implant, 0.01mg (Iluvien™)</td><td>0.19mg (19 units) intravitreal implant in the affected eye. Releases fluocinolone at an initial rate of 0.25mcg/day lasting 36 months.</td></tr>
<tr><td>J7314</td><td>Injection, fluocinolone acetonide, intravitreal implant, 0.01mg (Yutiq™)</td><td>0.18mg (18 units) intravitreal implant in the affected eye. Releases fluocinolone at an initial rate of 0.25mcg/day lasting 36 months.</td></tr>
<tr><td>J7311</td><td>Injection, fluocinolone acetonide, intravitreal implant, 0.01mg (Retisert™)</td><td>0.59mg (59 units) intravitreal implant in the affected eye. Releases fluocinolone at an initial rate of 0.6mcg/day decreasing over 30 days to a steady state release of 0.3 – 0.4 mcg/day for 30 months.</td></tr>
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STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	8/5/2024	8/5/2024	Yoonhee Kim, Interim Director of Pharmacy Services	N/A
Approved	N/A	8/14/2024	Pharmacy & Therapeutics (P&T) Committee	3/1/2025