Retisert® (fluocinolone acetonide implant)
(Intravitreal)

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I. Length of Authorization

Coverage will be provided for 1 implant per eye every 30 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Retisert 0.59 mg intravitreal implant: 2 implants every 30 months

B. Max Units (per dose and over time) [HCPCS Unit]:

- 118 billable units every 30 months

(Quantity Limits/Max Units are based on administration to BOTH eyes)

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

Universal Criteria

- Patient is free of ocular or periocular infections, including but not limited to, active epithelial herpes simplex keratitis; AND
- Patient has not received any of the following sustained-release corticosteroids in the same eye:
    - Dexamethasone intravitreal implant – within the prior 4 months (i.e., Ozurdex®)
    - Dexamethasone intracanalicular insert – within the prior 30 days (i.e., Dextenza®)
    - Triamcinolone acetonide suprachoroidal injection – within the prior 12 weeks (i.e., Xipere®)
    - Fluocinolone acetonide intravitreal implant – within the prior 36 months (i.e., Iluvien®/Yutiq®); AND
- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; AND

- Patient's intraocular pressure is measured at baseline and periodically throughout therapy; **AND**

Chronic Noninfectious Uveitis Affecting the Posterior Segment of the Eye † Φ

- Patient has had an inadequate response (i.e., recurrent or unresolved uveitis) or has contraindications to BOTH of the following, dexamethasone implant (Ozurdex) and fluocinolone acetonide 0.18 mg implant (Yutiq) unless patient does not meet FDA dosing adult age criteria of 18 and older to be eligible for Ozurdex and Yutiq. *(Note: Retisert is approved for ages 12 and up. Specific contraindications must be provided).*
- Patient is at least 12 years of age; **AND**
- Patient has had chronic disease for at least one year; **AND**
- Other causes of uveitis have been ruled out (e.g., infection, malignancy, etc.)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and indication specific criteria as identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: cataract formation, endophthalmitis and surgical complications (e.g., choroidal detachment, hypotony, retinal detachment, etc.), increased intraocular pressure, etc.; **AND**
- Disease response as indicated by:
    - Stabilization of visual acuity or improvement in BCVA score when compared to baseline; **OR**
    - Improvement in vitreous haze score (decrease in inflammation)

V. Dosage/Administration [1]

Indication	Dose
Chronic posterior noninfectious uveitis	0.59 mg fluocinolone acetonide intravitreal implant inserted into the affected eye(s) once per 30 months

VI. Billing Code/Availability Information

HCPCS Code:

- J7311 – Injection, fluocinolone acetonide, intravitreal implant (retisert), 0.01 mg; 1 billable unit = 0.01 mg

NDC:

- Retisert 0.59 mg intravitreal implant: 24208-0416-xx

VII. References

1. Retisert [package insert]. Bridgewater, NJ; Bausch & Lomb, a division of Bausch Health US, LLC.; November 2023. Accessed April 2024.
2. Brady CJ, Villanti AC, Law HA, et al. Corticosteroid implants for chronic non-infectious uveitis. Cochrane Database Syst Rev. 2016; 2: CD010469.
3. Jaffe GJ, Martin D, Callanan D, et al. Fluocinolone Acetonide Implant (Retisert) for Noninfectious Posterior Uveitis: Thirty-Four–Week Results of a Multicenter Randomized Clinical Study. Ophthalmol. 2006;113(6):1020-1027
4. 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;126(9):1191-201.
5. Sangwan VS, Pearson PA, Paul H, et al. Use of the fluocinolone acetonide intravitreal implant for the treatment of noninfectious posterior uveitis: 3-year results of a randomized clinical trial in a predominantly Asian population. Ophthalmol Ther. 2015;4(1):1-19.
6. Jabs DA, Nussenblatt RB, Rosenbaum JT., Standardization of Uveitis Nomenclature (SUN) Working Group. Standardization of uveitis nomenclature for reporting clinical data. Results of the First International Workshop. Am J Ophthalmol. 2005 Sep;140(3):509-16.
7. Pavesio, C., Heinz, C. Non-infectious uveitis affecting the posterior segment treated with fluocinolone acetonide intravitreal implant: 3-year fellow eye analysis. Eye 36, 1231–1237 (2022). https://doi.org/10.1038/s41433-021-01608-9
8. Ozurdex [package insert]. Irvine, CA; Allergan, Inc.; May 2018. Accessed March 2019.
9. Yutiq [package insert]. Watertown, MA; EyePoint Pharmaceuticals, Inc.; October 2018. Accessed March 2019.

Appendix 1 – Covered Diagnosis Codes

ICD-10	Diagnosis
H30.001	Unspecified focal chorioretinal inflammation, right eye
H30.002	Unspecified focal chorioretinal inflammation, left eye
H30.003	Unspecified focal chorioretinal inflammation, bilateral
H30.009	Unspecified focal chorioretinal inflammation, unspecified eye
H30.011	Focal chorioretinal inflammation, juxtapapillary, right eye
H30.012	Focal chorioretinal inflammation, juxtapapillary, left eye
H30.013	Focal chorioretinal inflammation, juxtapapillary, bilateral
H30.019	Focal chorioretinal inflammation, juxtapapillary, unspecified eye
H30.021	Focal chorioretinal inflammation of posterior pole, right eye
H30.022	Focal chorioretinal inflammation of posterior pole, left eye
H30.023	Focal chorioretinal inflammation of posterior pole, bilateral
H30.029	Focal chorioretinal inflammation of posterior pole, unspecified eye
H30.031	Focal chorioretinal inflammation, peripheral, right eye

ICD-10	Diagnosis
H30.032	Focal chorioretinal inflammation, peripheral, left eye
H30.033	Focal chorioretinal inflammation, peripheral, bilateral
H30.039	Focal chorioretinal inflammation, peripheral, unspecified eye
H30.041	Focal chorioretinal inflammation, macular or paramacular, right eye
H30.042	Focal chorioretinal inflammation, macular or paramacular, left eye
H30.043	Focal chorioretinal inflammation, macular or paramacular, bilateral
H30.049	Focal chorioretinal inflammation, macular or paramacular, unspecified eye
H30.101	Unspecified disseminated chorioretinal inflammation, right eye
H30.102	Unspecified disseminated chorioretinal inflammation, left eye
H30.103	Unspecified disseminated chorioretinal inflammation, bilateral
H30.109	Unspecified disseminated chorioretinal inflammation, unspecified eye
H30.111	Disseminated chorioretinal inflammation of posterior pole, right eye
H30.112	Disseminated chorioretinal inflammation of posterior pole, left eye
H30.113	Disseminated chorioretinal inflammation of posterior pole, bilateral
H30.119	Disseminated chorioretinal inflammation of posterior pole, unspecified eye
H30.121	Disseminated chorioretinal inflammation, peripheral, right eye
H30.122	Disseminated chorioretinal inflammation, peripheral, left eye
H30.123	Disseminated chorioretinal inflammation, peripheral, bilateral
H30.129	Disseminated chorioretinal inflammation, peripheral, unspecified eye
H30.131	Disseminated chorioretinal inflammation, generalized, right eye
H30.132	Disseminated chorioretinal inflammation, generalized, left eye
H30.133	Disseminated chorioretinal inflammation, generalized, bilateral
H30.139	Disseminated chorioretinal inflammation, generalized, unspecified eye
H30.90	Unspecified chorioretinal inflammation, unspecified eye
H30.91	Unspecified chorioretinal inflammation, right eye
H30.92	Unspecified chorioretinal inflammation, left eye
H30.93	Unspecified chorioretinal inflammation, bilateral

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC