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; **AND**
- Patient has not received any of the following sustained-release intravitreal corticosteroids:
  - Dexamethasone – within the prior 4 months (i.e., Ozurdex®)
  - Triamcinolone acetonide – within the prior 12 weeks (i.e., Xipere®)
  - Fluocinolone acetonide – 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 non-infectious 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 flucinolone 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 can be renewed based upon the following criteria:

- Patient continues to meet 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, 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

Indication	Dose
Chronic posterior non-infectious 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); 1 billable unit = 0.01 mg

NDC:

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

VII. References

1. Ozurdex [package insert]. Irvine, CA; Allergan, Inc.; May 2018. Accessed March 2019.
2. Yutiq [package insert]. Watertown, MA; EyePoint Pharmaceuticals, Inc.; October 2018. Accessed March 2019.
3. Retisert [package insert]. Bridgewater, NJ; Bausch & Lomb, a division of Bausch Health US, LLC.; January 2021. Accessed August 2022.

4. Brady CJ, Villanti AC, Law HA, et al. Corticosteroid implants for chronic non-infectious uveitis. Cochrane Database Syst Rev. 2016; 2: CD010469.
5. 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
6. 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.
7. 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.
8. 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.

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
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

ICD-10	Diagnosis
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)

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 Determination (NCD) and Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered 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 Government Benefit Administrators, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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