

Retisert® (fluocinolone acetonide implant) (Intravitreal)

Document Number: IC-0271

Last Review Date: 09/01/2022

Date of Origin: 04/26/2016

Dates Reviewed: 04/2016, 04/2017, 04/2018, 05/2019, 05/2020, 09/2021, 09/2022

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 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); Ⓢ 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

HCPSC 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. Retisert [package insert]. Bridgewater, NJ; Bausch & Lomb, a division of Bausch Health US, LLC.; January 2021. Accessed August 2022.
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.

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
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

ICD-10	Diagnosis
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
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

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PCHP:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, taiaajiila qarqaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

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Minneapolis, MN 55459-0212
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Fax: 763.847.4010
customerservice@preferredone.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

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