Retisert® (fluocinolone acetonide intravitreal implant)

Document Number: IC-0271

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Dates Reviewed: 04/2016, 04/2017, 04/2018

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) [Pharmacy Benefit]:

- Retisert 0.59 mg Implant: 2 implants every 30 months

B. Max Units (per dose and over time) [Medical Benefit]:

- 2 billable units every 30 months

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

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Chronic non-infectious uveitis affecting the posterior segment of the eye †

- Patient is at least 12 years of age; **AND**
- Patient is free of ocular or periocular infections; **AND**
- Patient has had chronic disease for at least one year

† FDA Approved Indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: cataract formation, endophthalmitis, increased intra-ocular pressure, etc; **AND**

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- 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 affected eye(s) once per 30 months

VI. Billing Code/Availability Information

Jcode:

- J7311 – fluocinolone acetonide, intravitreal implant: 1 implant = 1 billable unit

NDC:

Retisert 0.59 mg Implant – 24208-0416-xx

VII. References

1. Retisert [package insert]. Rochester, NY; Bausch & Lomb, Inc.; May 2012. Accessed February 2018.

Appendix 1 – Covered Diagnosis Codes

ICD-10	Diagnosis
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
H30.111	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

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) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-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): N/A

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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
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