Yutiq® (fluocinolone acetonide implant)
(Intravitreal)

Document Number: SHP-0406

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Dates Reviewed: 12/2018, 05/2019, 05/2020, 09/2021, 09/2022, 09/2023

I. Length of Authorization

Coverage will be provided for 1 implant per eye every 36 months and may be renewed.

II. Dosing Limits

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

- Yutiq 0.18 mg intravitreal implant: 2 implants every 36 months

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

- 36 billable units every 36 months

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

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Member meets the following or has contraindications to triamcinolone acetonide intravitreal injection – the specific contraindications must be provided:
  - At least ONE of the following:
    - Member has had an inadequate response (i.e., unresolved uveitis) to treatment with triamcinolone acetonide intravitreal injection
    - Member is receiving triamcinolone acetonide intravitreal injection but requires injections more often than every 12 weeks.

- Patient is at least 18 years of age; **AND**

Universal Criteria

- Patient does not have an ocular or periocular infection, including but not limited to, active epithelial herpes simplex keratitis; **AND**
- Patient has not received any of the following sustained-release intravitreal corticosteroids:

- 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 30 months (i.e., Retisert®) or 36 months (i.e., Iluvien®); **AND**

- Patient does not have a torn or ruptured posterior lens capsule; **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 †

- 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; ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and indication-specific relevant criteria as identified in section III; **AND**
- Disease response with treatment 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); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: cataract formation, endophthalmitis, increased or decreased intra-ocular pressure, glaucoma, choroidal or retinal detachments, etc.

V. Dosage/Administration

Indication	Dose
Chronic posterior non-infectious uveitis	Administer 0.18 mg fluocinolone acetonide intravitreal implant inserted into the affected eye(s), in a non-bioerodible intravitreal implant drug delivery system, once per 36 months

VI. Billing Code/Availability Information

HCPCS code:

- J7314 – Injection, fluocinolone acetonide, intravitreal implant (yutiq), 0.01 mg; 1 billable unit = 0.01 mg

NDC:

- Yutiq 0.18 mg intravitreal implant: 71879-0136-xx

VII. References

1. Yutiq [package insert]. Watertown, MA; EyePoint Pharmaceuticals, Inc.; February 2022. Accessed August 2023.
2. Brady CJ, Villanti AC, Law HA, et al. Corticosteroid implants for chronic non-infectious uveitis. Cochrane Database Syst Rev. 2016; 2: CD010469.
3. Testi I, Pavesio C. Preliminary evaluation of YUTIQ™ (fluocinolone acetonide intravitreal implant 0.18 mg) in posterior uveitis. Ther Deliv. 2019 Oct;10(10):621-625. doi: 10.4155/tde-2019-0051. Epub 2019 Oct 30.
4. 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	ICD-10 Description
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

ICD-10	ICD-10 Description
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)

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), 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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, 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