Yutiq™ (fluocinolone acetonide implant)
(Intravitreal)

Document Number: SHP-0406

Last Review Date: 05/01/2020
Date of Origin: 12/02/2018
Dates Reviewed: 12/2018, 05/2019, 05/2020

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

- 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.

Coverage is provided in the following conditions:

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

Universal Criteria

- Patient is free of ocular and periocular infections; **AND**
- Must not be used in combination with other sustained-release intravitreal corticosteroids (e.g., dexamethasone implant); **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(s)

IV. Renewal Criteria

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 the following: cataract formation, endophthalmitis, increased intra-ocular 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	Administer 0.18 mg fluocinolone acetonide intravitreal implant inserted into the affected eye(s), in a non-bioerodable 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.; October 2018. Accessed April 2020.
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.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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), 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: 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/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, 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