Draft Revised Policy: Do Not Implement

Fluocinolone Acetonide Implant (Iluvien®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- Treatment of diabetic macular edema (DME) in patients who have previously been treated with corticosteroids and did not exhibit a clinically significant rise in intraocular pressure
- Treatment of chronic non-infectious uveitis affecting posterior segment of the eye

All other indications are considered experimental/investigational and not medically necessary.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has a diagnosis of chronic-non-infectious uveitis affecting the posterior segment of the eye **OR**
  - The patient has a diagnosis of diabetic macular edema (DME) ~~: **AND**~~
- ~~The patient~~ and has been previously treated with a course of corticosteroids and did NOT have a clinically significant rise in intraocular pressure from corticosteroid treatment ~~**AND**~~
- The patient does NOT have an active or suspected ocular or periocular infection: ~~**AND**~~
- The patient does NOT have glaucoma with a cup-to-disc ratio of greater than 0.8

LENGTH OF AUTHORIZATION

Approval may be provided for 12 months. Administration may also be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Iluvien [package insert]. Alpharetta, GA; Alimera Sciences, Inc; March 2025. Accessed March 2025.
2. Iluvien. In: Clinical Pharmacology. Tampa (FL): Elsevier. Revised April 2023. Accessed July 2023.
3. Micromedex Healthcare Series. Drugdex Evaluations. (2025, March). Fluocinolone Acetonide. Retrieved March 2025 from Micromedex Healthcare Series.

EFFECTIVE DATE

ID_BT