

Policy: MBP 129.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Iluvien (fluocinolone acetonide)

I. Policy:

Iluvien (fluocinolone acetonide)

II. Purpose/Objective:

To provide a policy of coverage regarding Iluvien (fluocinolone acetonide)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Iluvien (fluocinolone acetonide) is an ophthalmic corticosteroid in the form of an intraocular implant indicated for the treatment of diabetic macular edema in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Iluvien requires prior authorization unless the diagnosis code for diabetic macular edema is submitted. For all other diagnosis codes submitted for the commercial, exchange, CHIP and Medicare lines of business the following criteria must be met:

- Medical record documentation of a diagnosis of diabetic macular edema

AUTHORIZATION DURATION: Approval will be for a total of one implant (0.19 mg) over a duration of 36 months. Subsequent approvals for re-implantation will require medical director review based on medical necessity.

LIMITATIONS: If criteria are met, approval will be limited to one implant.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Iluvien [prescribing information]. Alpharetta, GA: Alimera Sciences Inc; January 2022.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 5/19/15

Revised: 1/16/23 (LOB carve out), 12/30/23 (references added)

Reviewed: 3/31/16, 3/30/17, 3/29/18, 2/28/19, 2/1/20, 1/19/21, 1/18/22

MA UM Committee approval: 12/31/23