

SPECIALTY GUIDELINE MANAGEMENT

XIPERE (triamcinolone acetonide injectable suspension)

POLICY

I. 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 Indication

Xipere is a corticosteroid indicated for the treatment of macular edema associated with uveitis.

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

II. CRITERIA FOR INITIAL APPROVAL

Macular edema associated with uveitis

Authorization of 12 months may be granted when all of the following criteria are met:

- A. The member has a diagnosis of macular edema associated with uveitis.
- B. The member does not have infectious uveitis.
- C. The member will not exceed a dose of 4 mg (0.1 mL) administered as a suprachoroidal injection per eye into the affected eye(s).

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment of an indication listed in Section II when the member meets all initial authorization criteria and has demonstrated a positive clinical response to therapy (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, reduction or maintenance in central subfield thickness (CST), a reduction in the rate of vision decline or the risk of more severe vision loss, reduction in inflammation).

IV. REFERENCES

1. Xipere [package insert]. Alpharetta, GA: Clearside Biomedical, Inc.; October 2021.
2. Yeh S, Khurana RN, Shah M, et al. Efficacy and Safety of Suprachoroidal CLS-TA for Macular Edema Secondary to Noninfectious Uveitis: Phase 3 Randomized Trial. *Ophthalmology*. 2020;127(7):948-955.