Lifitegrast (XIIDRA) Ophthalmic Solution

Criteria for Use

October 2025

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

- ☐ Active ophthalmic infections, including herpes keratitis
- ☐ Hypersensitivity to lifitegrast or any of its ingredients

Inclusion Criteria

- ☐ Provider is a VA/VA Community Care ophthalmologist or optometrist

  AND at least ONE of the following are required to meet criteria
- ☐ Diagnosis of dry eye disease with lack of therapeutic response to at least two artificial tear agents from different categories and a trial of 0.05% cyclosporine eye drops^1^2
- ☐ Documented corneal surface damage despite frequent use of artificial tears and 0.05% cyclosporine eye drops

1. Examples of Product Categories (not all-inclusive; not all are on VA Formulary):
   A. Cellulose Derivatives (e.g. carboxymethylcellulose, hydroxypropyl methylcellulose/hypromellose)
   B. Liquid Polyols (e.g. polyethylene glycol (PEG), propylene glycol, glycerin)
   C. Polyvinyl Alcohol
   D. Oil containing (e.g. mineral oil, castor oil, flaxseed oil) E. High Viscosity: gel drops, gels, ointments
2. With cyclosporine, it can take 3 to 6 months to notice an increase in tear production or improved symptoms. Symptom relief with lifitegrast may begin as early as 2 weeks with general improvements at 6 and 12 weeks

Patients with permanent or semi-permanent punctual occlusion (10%) were included in the clinical trials; however, no subgroup analysis for efficacy and safety was conducted; co-administration should be reviewed on a patient-by-patient basis to determine optimal therapy.

Cyclosporine ophthalmic has been used in ocular graft vs. host disease and corneal transplant rejection. There are limited data on the safety and efficacy of lifitegrast in these settings.

Prepared: November 2024, revised October 2025. Contact: Matthew A. Fuller, PharmD, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services 12PBM