

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Dry Eye Disease Agents PDL Edit
<b>First Implementation Date:</b>	January 1, 2020
<b>Revised Date:</b>	February 24, 2022
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

**Why Issue Selected:** Dry eye disease (DED), also known as keratoconjunctivitis sicca, is a condition in which a person lacks enough quality tears to lubricate and nourish the eye and effects 6.8 percent of the US adult population. Treatments for DED aim to restore or maintain the normal amount of tears in the eye to minimize dryness and related discomfort. This can be achieved by supplementing tear production, slowing resorption and evaporation of tears from the surface of the eye, or reducing inflammation. Topical cyclosporine (Restasis® and Cequa™) and topical lifitegrast (Xiidra®) are the market leaders in treatment of DED. Cyclosporine is a topical immunosuppressive that prevents activation and nuclear translocation of cytoplasmic transcription factors that are required for T-cell activation and inflammatory cytokine production. Lifitegrast is a lymphocyte function-associated antigen 1 (LFA-1) antagonist which works via integrin inhibition that ultimately down-regulates inflammation mediated T lymphocytes.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> <li>Restasis®</li> <li>Xiidra®</li> </ul>	<ul style="list-style-type: none"> <li>Cequa™</li> <li><b>Cyclosporine 0.05% Eye Emulsion</b></li> <li>Restasis Multidose®</li> </ul>

**Type of Criteria:**  Increased risk of ADE  Preferred Drug List  
 Appropriate Indications  Clinical Edit

**Data Sources:**  Only Administrative Databases  Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Dry Eye Disease Agents
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents:
  - Documented trial period for preferred agents **OR**
  - Documented ADE/ADR to preferred agents

## Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

## Required Documentation

Laboratory Results:  
MedWatch Form:


Progress Notes:  
Other:


## Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)  
Rule Type: PDL

## Default Approval Period

1 year

## References

1. Evidence-Based Medicine and Fiscal Analysis: "Dry Eye Agents – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; July 2021.
2. Farrand K, Fridman M, Stillman I, Schaumberg D. Prevalence of Diagnosed Dry Eye Disease in the United States Among Adults Aged 18 Years and Older. *Am J Ophthalmol* 2017;182:90-8.
3. Evidence-Based Medicine Analysis: "Xerophthalmia (Dry Eye) Products", UMKC-DIC; July 2021.
4. USPDI, Micromedex; 2021.
5. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.