SmartPA Criteria Proposal

Drug/Drug Class:	Dry Eye Disease Agents PDL Edit
First Implementation Date:	January 1, 2020
Proposed Date:	September 15, 2022
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐ Existing Criteria ☒ Revision of Existing Criteria ☐ 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 (Restatsis® 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 cytoline 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. The newest addition to the class, Tyrvaya™, is a varenicline-based product that functions as a nicotinic activator of muscarinic receptors. Tyrvaya is available as a nasal spray which allows for the activation of the trigeminal nerve and resultant induction of tear production.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Restasis® • Xiidra®	• Cequa™ • **Cyclosporine 0.05% Eye Emulsion** • Restasis Multidose® • **Tyrvaya™**

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:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☐

Disposition of Edit

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

Default Approval Period

1 year

References

- Evidence-Based Medicine Analysis: "Xerophthalmia (Dry Eye) Products", UMKC-DIC; July 2022.
- Evidence-Based Medicine and Fiscal Analysis: "Dry Eye Agents – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; July 2021.
- 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.
- Tyrvaya [prescribing information]. Princeton, NY: Oyster Pointe Pharma, Inc; October 2021.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.