SmartPA Criteria Proposal

Drug/Drug Class:	Keratoconjunctivitis Agents PDL Edit *(formerly Dry Eye Disease Agents PDL Edit)*
First Implementation Date:	January 1, 2020
Proposed Date:	October 17, 2023
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: Keratoconjunctivitis sicca, also known as dry eye disease (DED), 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. 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. Verkazia® was approved for the treatment of vernal keratoconjunctivitis (VKC) in children and adults in 2022 and was followed by the approval of Miebo™ for DED in 2023.

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 • **Miebo™** • Restasis Multidose® • Tyrvaya™ • **Verkazia®**

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: Keratoconjunctivitis 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
- **For Verkazia: Therapeutic trial of brand name Restasis and Cequa**

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; April 2023.
- Evidence-Based Medicine and Fiscal Analysis: “Keratoconjunctivitis – Therapeutic Class Review”, Gainwell Technologies; last updated July 28, 2023.
- 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; 2023.
- Facts and Comparisons eAnswers (online); 2023 Clinical Drug Information, LLC.