SmartPA Criteria Proposal

Drug/Drug Class:	Corticosteroids, Ophthalmic “Soft” PDL Edit
First Implementation Date:	July 11, 2019
Proposed Date:	April 18, 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: Topical corticosteroids are effective in reducing anterior segment inflammation but are associated with adverse drug reactions including elevation of intraocular pressure and cataract formulation. Newer “soft” ophthalmic corticosteroids have been developed with improved therapeutic indices through retrometabolic drug design. The retrometabolic drug design principles appear to achieve the necessary balance between solubility/lipophilicity, tissue distribution, glucocorticoid receptor binding, and metabolic deactivation to be effective as a topical ophthalmic steroid. The “soft” steroids are safe and effective in treating a wide variety of ocular inflammatory conditions including giant papillary conjunctivitis, seasonal allergic conjunctivitis, and uveitis as well as in the treatment of ocular inflammation and pain following cataract surgery. Clinical studies have confirmed the retrometabolic design of “soft” steroids minimized adverse reactions such as cataract formation and intraocular pressure elevation.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• **Difluprednate** • Lotemax® 0.5% Gel/Susp	• Alrex® • **Durezol®** • Eysuvis® • Inveltys® • Lotemax® 0.5% Oint • Lotemax® SM • Loteprednol

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

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

Setting & Population

- Drug class for review: Corticosteroids, Ophthalmic “Soft”
- 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 of 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 and Fiscal Analysis: “Therapeutic Class Review: OPHTHALMIC: “Soft” Corticosteroids”, Gainwell Technologies; Last updated February 15, 2023.
- Evidence-Based Medicine Analysis: “Corticosteroids, Ophthalmic "Soft" Steroids”, UMKC-DIC; Last updated January 2023.
- USPDI, Micromedex; 2023.
- Facts and Comparisons eAnswers (online); 2023 Clinical Drug Information, LLC.