SmartPA Criteria Proposal

Drug/Drug Class:	Leukotriene Receptor Modifiers PDL Edit
First Implementation Date:	January 3, 2008
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: Leukotriene receptor antagonists work selectively and competitively on cysteinyl leukotriene receptors, which are components of slow-reacting substance of anaphylaxis. Leukotriene production and receptor occupation have been correlated with the pathophysiology of asthma and allergy, including airway edema, smooth muscle constriction and altered cellular activity associated with the inflammatory process. These agents are not recommended as first line therapy by the National Asthma Education and Prevention Program guidelines but instead alternatives for moderate persistent and mild persistent asthma for both pediatric and adult participants.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Montelukast	• Accolate® • Singulair® • Zafirlukast • Zileuton ER • Zyflo®

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: Leukotriene Modifiers
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documented compliance on current therapy regimen (90/120 days) **OR**

- Failure to achieve desired therapeutic outcomes with trial on 1 or more preferred agents
  - Documented trial period of preferred agents
  - Documented ADE/ADR to preferred agents **AND**
- For montelukast:
  - Documented compliance on current therapy regimen **OR**
  - For documented diagnosis of moderate to severe asthma:
    - Documented compliance on ICS/LABA (defined as 90/120 days) **OR**
    - Clinical Consultant Review
  - For documented diagnosis of allergies:
    - Documented compliance on a second generation antihistamine (defined as 120/150 days) **AND**
    - Documented compliance on intranasal corticosteroid (defined as 90/120 days) **OR**
    - Clinical Consultant Review
  - Documented diagnosis of eosinophilic gastroenteritis or obstructive sleep apnea/sleep disorder breathing

Denial Criteria

- Lack of adequate trial on required preferred agents
- For Singulair (montelukast): Documented diagnosis of suicide attempt
- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Unit/Day
ACCOLATE 10 MG TABLET	ZAFIRLUKAST	2 tablets
ACCOLATE 20 MG TABLET	ZAFIRLUKAST	2 tablets
SINGULAIR 4 MG GRANULES	MONTELUKAST	1 packet
SINGULAIR 4 MG CHEW	MONTELUKAST	1 tablet
SINGULAIR 5 MG CHEW	MONTELUKAST	1 tablet
SINGULAIR 10 MG TABLET	MONTELUKAST	1 tablet
ZYFLO 600 MG TABLET	ZILEUTON	4 tablets
ZYFLO CR 600 MG TABLET	ZILEUTON	4 tablets

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: “Leukotriene Modifiers – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; January 2022.

- Evidence-Based Medicine Analysis: “Leukotriene Modifiers”, UMKC-DIC; Last updated December 2022.
- USPDI, Micromedex; 2023.
- Facts and Comparisons eAnswers (online); 2023 Clinical Drug Information, LLC.