

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Leukotriene Receptor Modifiers PDL Edit
<b>First Implementation Date:</b>	January 3, 2008
<b>Proposed Date:</b>	March 17, 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:** 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
	<ul style="list-style-type: none"> <li>Montelukast</li> </ul>	<ul style="list-style-type: none"> <li>Accolate®</li> <li>Singulair®</li> <li>Zafirlukast</li> <li>Zileuton ER</li> <li>Zyflo®</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: 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**
  - **For documented diagnosis of 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
  - Documented diagnosis of neuropsychiatric disorder
- 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:   
 MedWatch Form:

Progress Notes:   
 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; January 2022.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.

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