



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2024 P 3069-11
Program	Step Therapy – Leukotriene Modifiers
Medication	Zileuton extended-release, Zflo <sup>®</sup> (zileuton)
P&T Approval Date	2/2016, 2/2017, 2/2018, 3/2019, 3/2020, 2/2021, 3/2022, 3/2023, 4/2024
Effective Date	7/1/2024

**1. Background:**

Zileuton extended-release and Zflo (zileuton) are leukotriene modifiers indicated for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older.

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try either montelukast (generic Singulair) or zafirlukast (generic Accolate) prior to receiving coverage for Zflo or Zflo CR.

Members who have received at least a 90 day supply of zileuton extended-release (generic Zflo CR) or Zflo in the past 120 days as documented in claims history, will be allowed continued coverage of their current therapy.

**2. Coverage Criteria <sup>a</sup>:**

<p><b>A. Zileuton extended-release or Zflo</b> will be approved based on <b><u>ONE</u></b> of the following criteria:</p> <p>1. History of therapeutic failure to <b><u>one</u></b> of the following:</p> <ul style="list-style-type: none"><li>a. montelukast (generic Singulair)*</li><li>b. zafirlukast (generic Accolate)</li></ul> <p style="text-align: center;"><b>-OR-</b></p> <p>2. Contraindication or intolerance to <b><u>both</u></b> of the following:</p> <ul style="list-style-type: none"><li>a. montelukast (generic Singulair)*</li><li>b. zafirlukast (generic Accolate)</li></ul> <p><b>Authorization will be issued for 12 months.</b></p> <p><sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.</p>
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**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

\*Brand Singulair tablets and chewable tablets are typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

**4. References:**

1. Global Initiative for Asthma: Global Strategy for Asthma Management and prevention. 2023. Available from: [www.ginasthma.org](http://www.ginasthma.org).
2. Zileuton extended-release [package insert]. East Brunswick, NJ: Rising Pharmaceuticals, Inc; March 2023.
3. Zyflo [package insert]. Cary, NC: Chiesi USA, Inc; January 2017.

Program	Step Therapy – Leukotriene modifiers
<b>Change Control</b>	
Date	Change
2/2016	New program.
7/2016	Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
2/2017	Removed supply limits from additional clinical rules.
2/2018	Annual review. Updated state mandate language. Updated references.
3/2019	Annual review. Added statement regarding use of automated process and updated references.
3/2020	Annual review. Added an authorization look back for current users and updated references.
2/2021	Modified step to require a failure of one or a contraindication or intolerance to both step one medications.
3/2022	Annual review. Updated references.
3/2023	Annual review. Updated references.
4/2024	Annual review. Updated references.