



**UnitedHealthcare Individual & Family ACA Marketplace Plans
Clinical Pharmacy Program Guidelines for Leukotriene Modifiers**

Program	Step Therapy
Medication	Zileuton extended-release (generic Zflo CR)
Issue Date	9/2020
Pharmacy and Therapeutics Approval Date	3/2023
Effective Date	5/2023

1. Background:

Zileuton extended-release (generic Zflo CR) is a leukotriene modifier 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 one of two alternative leukotriene modifiers – montelukast 10mg tablets or chewable (generic Singulair) or zafirlukast (generic Accolate) – prior to receiving coverage for zileuton extended-release (generic Zflo CR).

2. Coverage Criteria ^a:

<p>A. Zileuton extended-release will be approved based on one of the following criteria:</p> <ul style="list-style-type: none">1. History of therapeutic failure to one of the following:<ul style="list-style-type: none">a. montelukast 10mg tablets or chewable (generic Singulair)b. zafirlukast (generic Accolate) <p align="center">-OR-</p> <ul style="list-style-type: none">2. Contraindication or intolerance to both of the following:<ul style="list-style-type: none">a. montelukast 10mg tablets or chewable (generic Singulair)b. zafirlukast (generic Accolate) <p>Authorization will be issued for 12 months.</p> <p>^a 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>

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.

4. References:

1. Zileuton extended-release [package insert]. Baltimore, MD: Lupin Pharmaceuticals, Inc; August 2020.
2. Global Initiative for Asthma: Global Strategy for Asthma Management and prevention. 2022. Available from: www.ginasthma.org.

Program	Step Therapy – Leukotriene Modifiers
Change Control	
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.
10/2020	Renamed policy to Leukotriene Modifiers, revised background, removed Zyflo and reference as a step therapy target, and removed brand Singulair exclusion language.
11/2020	Updated ST alternatives to align build file and set up for UHC Value & Balance Exchange for 1/2021 implementation.
2/2021	Modified step to require a failure of one or a contraindication or intolerance to both step one medications.
9/2021	Review for 2022 implementation. Removed markets in scope and step therapy detailed definition in the background. Updated brand/generic language to align with 2022 guidance.
3/2022	Annual review. Updated references.
3/2023	Annual review. Updated references.