

Leukotriene Inhibitors Effective 11/01/2025

Plan	☐ MassHealth UPPL ☒ Commercial/Exchange	Program Type	☐ Prior Authorization
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		☐ Quantity Limit ☒ Step Therapy
Specialty Limitations	N/A		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

Prescriptions that meet the initial step therapy requirements will adjudicate automatically at the point of sale. If the prescription does not meet the initial step therapy requirements, the prescription will deny with a message indicating that prior authorization (PA) is required. Refer to the criteria below and submit a PA request for the members who do not meet the initial step therapy requirements at the point of sale.

Initial Step-Therapy Requirements:

First-Line: Medications listed on first-line are covered without prior-authorization.

Second-Line: Second-line medications will pay if the member has filled all first-line medications or a second-line medication within the past 180 days.

Coverage Guidelines

Authorization may be granted for members new to the plan within the last 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

If a member does not meet the initial step therapy requirements, then approval of a second-line medication will be granted if the member has had an inadequate response, side effect, or a contraindication to both first-line medications

FIRST-LINE	SECOND-LINE
montelukast zafirlukast	zileuton ER

Limitations

- Approvals will be granted for 36 months.
- The following quantity limits apply:

Drug Name and Dosage Form	Quantity Limit
Montelukast tablets, chewable tablets, granules	1 unit per day
Zafirlukast tablet	2 tablets per day
Zileuton ER tablet	4 tablets per day

References

1. Dykewicz MS, Wallace DV, Baroody F, Bernstein J, et al. Treatment of seasonal allergic rhinitis: An evidence-based focused 2017 guideline update. *Ann Allergy Asthma Immunol*. 2017;119(6):489-511.e41.[PubMed 29103802]10.1016/j.anai.2017.08.012
2. Pacor ML, Di Lorenzo G, Corrocher R. Efficacy of leukotriene receptor antagonist in chronic urticaria. A double-blind, placebo-controlled comparison of treatment with montelukast and cetirizine in patients with chronic urticaria with intolerance to food additive and/or acetylsalicylic acid. *Clin Exp Allergy*. 2001;31(10):1607-1614.[PubMed 11678862]
3. Reimers A, Pichler C, Helbling A, Pichler WJ, Yawalkar N. Zafirlukast has no beneficial effects in the treatment of chronic urticaria. *Clin Exp Allergy*. 2002;32(12):1763-1768.[PubMed 12653169]
4. Seidman MD, Gurgel RK, Lin SY, et al; Guideline Otolaryngology Development Group. AAO-HNSF. Clinical practice guideline: Allergic rhinitis. *Otolaryngol Head Neck Surg*. 2015;152(1 Suppl):S1-S43.[PubMed 25644617]
5. Singulair (montelukast sodium) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; June 2021.
6. Szeffler SJ, Carlsson LG, Uryniak T, Baker JW. Budesonide inhalation suspension versus montelukast in children aged 2 to 4 years with mild persistent asthma. *J Allergy Clin Immunol Pract*. 2013;1(1):58-64.[PubMed 24229823]
7. Zflo (zileuton) [prescribing information]. Lexington, MA: Cornerstone Therapeutics; May 2017.
8. Zflo CR (zileuton) [prescribing information]. Cary, NC: Chiesi USA Inc; March 2019.

Review History

09/26/05 – Updated
 06/26/06 – Reviewed
 06/18/07 – Updated
 10/22/07 – Bi-weekly Drug File
 04/09/08 – Cetirizine/Zyrtec
 06/16/08 – Updated
 04/27/09 – Updated
 10/06/09 – Specialist consult questions
 11/23/09 – Updated
 02/04/10 – Zflo IR
 11/22/10 – Reviewed
 01/12/11 – Zafirlukast 12/20/10 file);
 04/04/11 – Dulera look-backs after NDR reviewed
 04/11/11 – Allergic rhinitis with fexofenadine OTC
 11/28/11 – Reviewed
 08/08/12 – Montelukast tabs/chews generic
 11/26/12 – Updated



12/01/12 – Montelukast granules
11/25/13 – Reviewed
11/24/14 – Updated
11/23/15 – Reviewed
09/19/16 – Move Montelukast to 1st line
11/27/17 – Reviewed
11/26/18 – Reviewed
09/22/21 – Reviewed Sept P&T; no clinical changes; references updated.
04/10/24 – Reviewed April P&T; Removed inhaled corticosteroids from first line agents. Moved montelukast and zafirlukast to first-line, Zflo (brand) moved to NF. Effective 5/1/2024
08/13/2025 – Reviewed and updated for August P&T. Added prior authorization language. Removed Zflo from the quantity limits section, as brand is nonformulary. Effective 11/01/2025.

