

Leukotriene Inhibitors
 Effective 11/26/2018

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input checked="" type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
Exchange	Phone: 855-582-2022	Fax: 855-245-2134	
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
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 at least four first-line medications or a second-line medication within the past 180 days.

Coverage Guidelines

	FIRST-LINE	SECOND-LINE
Asthma	Inhaled corticosteroids (ICS): <u>Single-entity, oral</u> beclomethasone budesonide ciclesonide flunisolide fluticasone mometasone triamcinolone <u>Combination, oral</u>	Leukotriene Inhibitors: montelukast* granules zafirlukast Zyflo zileuton ER (Zyflo CR)

	FIRST-LINE	SECOND-LINE
	Advair (fluticasone propionate/salmeterol) Symbicort (budesonide/formoterol) Dulera (mometasone/formoterol) Breo Ellipta (fluticasone furoate/vilanterol) Leukotriene Inhibitors: montelukast* tablets & chewables	
Allergies/Allergic Rhinitis	cetirizine fexofenadine/Allegra OTC products loratadine Inhaled <u>nasal</u> steroids Leukotriene Inhibitors: montelukast* tablets & chewables	Leukotriene Inhibitors: montelukast* granules zafirlukast Zyflo Zyflo CR

* Covered as 1st-line for asthma in patients < 5 years of age

If a member does not meet the initial step therapy requirements, then approval of a second-line medication will be granted if the member meets the following criteria:

Montelukast granules

1. Member has a diagnosis of asthma or **AND**
 2. Member is four years of age or younger **AND**
 3. Prescriber has submitted clinical justification why tablets and chewables are not appropriate.
- OR**
1. Member has a diagnosis of **mild persistent** asthma/reactive airway disease with symptoms that require daily maintenance therapy with a controller medication ** to control symptoms **AND**
 2. Prescriber has submitted clinical justification why tablets and chewables are not appropriate.
- OR**
1. Member has a diagnosis of **moderate or severe persistent** disease asthma/reactive airway disease with symptoms that require daily maintenance therapy with a controller medication ** to control symptoms **AND**
 2. Member is currently on a combination oral ICS product (e.g., Advair, Symbicort, Dulera, Breo Ellipta, etc.) **OR** the member has had an inadequate response, intolerance, or allergy with trial of at least one single-entity ICS product within the previous 3 months (see table above for list) * **AND**
 3. Prescriber has submitted clinical justification why tablets and chewables are not appropriate.
- OR**
1. Member has a diagnosis of exercise-induced bronchoconstriction **AND**
 2. Member has had a documented allergy, intolerance, or inadequate response to a “rescue” short acting beta agonist (e.g., albuterol HFA or Xopenex HFA **AND**
 3. Prescriber has submitted clinical justification why tablets and chewables are not appropriate.
- OR**
1. Member has a diagnosis of allergies/allergic rhinitis **AND**
 2. Prescriber has submitted clinical justification why tablets and chewables are not appropriate.
- AND**
3. Member has had an inadequate response, intolerance, or allergy to ALL the following medications:



- a. Loratadine (**trial not required for members 5 years of age or younger**)
- b. Cetirizine
- c. nasal steroid (**trial not required for members 5 years of age or younger**)
- d. fexofenadine OTC (**trial not required for members who are pregnant or breastfeeding**)

OR

- 1. Member has a diagnosis of chronic hives/urticaria **AND**
- 2. Member has had an inadequate response, intolerance, or allergy to least two different non-sedating antihistamines for this indication (e.g., cetirizine, loratadine, fexofenadine, etc.) **AND**
- 3. Prescriber has submitted clinical justification why tablets and chewables are not appropriate.

Note:

*Inadequate response is defined as asthma remaining uncontrolled despite daily adherence to an oral ICS

** Controller meds: ICS's (see table above), long-acting beta agonists (salmeterol, formoterol, vilanterol, etc.), combo products (Advair, Symbicort, Dulera, Breo Ellipta, etc.), Cromolyn, Nedocromil, theophylline. **Short-acting beta agonists (albuterol & Xopenex) are NOT controller meds.**

Zafirlukast

- 1. Member has a diagnosis of **mild persistent** asthma with symptoms that require daily maintenance therapy with a controller medication** to control **AND**
- 2. Member is 5 years of age or older

OR

- 1. Member has a diagnosis of **moderate or severe persistent** asthma with symptoms that require daily maintenance therapy with a controller medication** to control **AND**
- 2. Member is 5 years of age or older **AND**
- 3. Member is currently on a combination oral ICS product (e.g., Advair, Symbicort, Dulera, Breo Ellipta, etc.) **OR** the member has had an inadequate response, intolerance, or allergy with trial of at least one single-entity ICS product within the previous 3 months (see table above for list)

Note:

*Inadequate response is defined as asthma remaining uncontrolled despite daily adherence to an oral ICS

** Controller meds: ICS's (see table above), long-acting beta agonists (salmeterol, formoterol, vilanterol, etc.), combo products (Advair, Symbicort, Dulera, Breo Ellipta, etc.), Cromolyn, Nedocromil, theophylline. **Short-acting beta agonists (albuterol & Xopenex) are NOT controller meds.**

Zyflo/Zyflo CR

- 1. Member has a diagnosis of **mild persistent** asthma with symptoms that require daily maintenance therapy with a controller medication** to control **AND**
- 2. Member is 12 years of age or older

OR

- 1. Member has a diagnosis of **moderate or severe persistent** asthma with symptoms that require daily maintenance therapy with a controller medication** to control **AND**
- 2. Member is 12 years of age or older **AND**



- Member is currently on a combination oral ICS product (e.g., Advair, Symbicort, Dulera, Breo Ellipta, etc.) OR the member has had an inadequate response, intolerance, or allergy with trial of at least one single-entity ICS product within the previous 3 months (see table above for list)

Note:

*Inadequate response is defined as asthma remaining uncontrolled despite daily adherence to an oral ICS

** Controller meds: ICS’s (see table above), long-acting beta agonists (salmeterol, formoterol, vilanterol, etc.), combo products (Advair, Symbicort, Dulera, Breo Ellipta, etc.), Cromolyn, Nedocromil, theophylline. **Short-acting beta agonists (albuterol & Xopenex) are NOT controller meds.**

Limitations

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

montelukast	30 units per month
zafirlukast	60 tablets per month
Zyflo & zileuton ER	120 tablets per month

References

- Zyflo (zileuton) [prescribing information]. Lexington, MA: Cornerstone Therapeutics; May 2017.
- Zyflo CR (zileuton) [prescribing information]. Cary, NC: Chiesi USA Inc; March 2019.
- Singulair (montelukast sodium) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; June 2021.
- Zafirlukast. Lexi-Interact [database online]. Hudson, OH: Lexicomp Inc; 2015. <http://online.lexi.com>.
- 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]
- 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]
- Singulair (montelukast sodium) granule; tablet, chewable; tablet, film coated [package insert]. Whitehouse Station, NJ: Merck & Company, Inc; 2009
- 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]
- 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
- 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]
- Global Initiative for Asthma. Global strategy for asthma management and prevention. http://www.ginasthma.org/pdf/GINA_Report_2021.pdf.

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 – Zyflo 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
09/22/2021 – Reviewed Sept P&T; no clinical changes; references updated.

