

PRIOR AUTHORIZATION CRITERIA

**BRAND NAME
(generic)****ZYFLO
(zileuton)****(zileuton extended-release)****Status: CVS Caremark Criteria****Type: Initial Prior Authorization****POLICY****FDA-APPROVED INDICATIONS****Zyflo**

Zyflo is indicated for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older.

Zileuton extended-release

Zileuton extended-release tablet is indicated for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older.

Zileuton extended-release tablet is not indicated for use in the reversal of bronchospasm in acute asthma attacks.

Therapy with zileuton extended-release tablet can be continued during acute exacerbations of asthma.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the prophylaxis or chronic treatment of asthma in a patient 12 years of age and older

AND

- The patient has experienced an inadequate treatment response to any of the following: A) An orally inhaled corticosteroid (ICS), B) A combination product containing an orally inhaled corticosteroid and long-acting beta agonist (ICS/LABA)

[Note: The patient may continue to use an ICS containing product.]

OR

- The patient has experienced an intolerance to any of the following: A) An orally inhaled corticosteroid (ICS), B) A combination product containing an orally inhaled corticosteroid and long-acting beta agonist (ICS/LABA)

OR

- The patient has a contraindication that would prohibit a trial of any of the following: A) An orally inhaled corticosteroid (ICS), B) A combination product containing an orally inhaled corticosteroid and long-acting beta agonist (ICS/LABA)

REFERENCES

1. Zyflo [package insert]. Cary, NC: Chiesi USA, Inc.; January 2017.
2. Zileuton Extended-Release [package insert]. Upper Saddle River, NJ: DASH Pharmaceuticals LLC; November 2020.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: UpToDate, Inc.; 2021; Accessed February 18, 2022.
4. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed February 18, 2022.
5. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention. 2021. Available at: <http://www.ginasthma.org>. Accessed February 2022.

6. 2020 Focused Updates to the Asthma Management Guidelines. A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. Available at: <https://www.nhlbi.nih.gov/health-topics/asthma-management-guidelines-2020-updates>. Accessed February 2022.
7. National Heart, Lung, and Blood Institute National Asthma Education and Prevention Program Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma Full Report 2007. Available at <http://www.nhlbi.nih.gov/health-pro/guidelines/current/asthma-guidelines>. Accessed February 2022.