

# PRIOR AUTHORIZATION CRITERIA

**BRAND NAME**  
(generic)

(zileuton extended-release)

**ZYFLO**  
(zileuton)

**Status: CVS Caremark® Criteria**  
**Type: Initial Prior Authorization**

## POLICY

### FDA-APPROVED INDICATIONS

#### **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.

#### **Zyflo**

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

### 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

#### **AND**

- The patient is 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. Zileuton Extended-Release [package insert]. East Brunswick, NJ: Rising Pharmaceuticals, Inc.; March 2023.
2. Zyflo [package insert]. Cary, NC: Chiesi USA, Inc.; January 2017.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed March 15, 2023.
4. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 03/15/2023).

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5. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention. Updated 2022. Available at: <http://www.ginasthma.org>. Accessed March 15, 2023.
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 March 15, 2023.

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