

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

Zileuton Extended-Release tablets are not indicated for use in the reversal of bronchospasm in acute asthma attacks. Therapy with Zileuton Extended-Release tablets 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 or older

Duration of Approval (DOA):

- 5090-A: DOA: 12 months

### 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 August 8, 2023.
4. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 07/13/2023).

Zileuton PA Policy 5090-A UDR 10-2023.docx

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