

Reference number(s)
5090-A

Initial Prior Authorization

Zileuton

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
zileuton extended-release (brand unavailable)	zileuton extended-release
Zyflo	zileuton

Indications

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.

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Coverage Criteria

Asthma

Authorization may be granted when the requested drug is being prescribed for the prophylaxis or chronic treatment of asthma when the following criteria is met:

- 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.; May 2024.
2. Zylflo [package insert]. Cary, NC: Chiesi USA, Inc.; January 2017.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed July 30, 2025.
4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 07/30/2025).