

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Zyflo/Zyflo CR (zileuton/zileuton extended-release)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Zyflo/Zyflo CR (zileuton/zileuton extended-release)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Zyflo/Zyflo CR (zileuton/zileuton extended-release) may be approved if the following criteria are met:

- I. Individual is 12 years of age or older; **AND**
- II. Individual is using for the prophylaxis and chronic treatment of persistent asthma; **AND**
- III. Individual is using in combination with an orally inhaled corticosteroid (GINA 2019); **AND**
- IV. Individual has had a previous trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or a documented intolerance to zafirlukast.

Zyflo/Zyflo CR (zileuton/zileuton extended-release) may **not** be approved for the following:

- I. Individual has a diagnosis of active liver disease or persistent hepatic function enzyme elevations greater than or equal to 3 times the upper limit of normal; **OR**
- II. Individual is using to reverse bronchospasms in acute asthma attacks, including status asthmaticus.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 3, 2020.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.

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3. Fanta CH. An overview of asthma management. Last updated: October 5, 2017. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: January 16, 2020.
4. Fanta CH. Treatment of intermittent and mild persistent asthma in adolescents and adults. Last updated: October 16, 2019. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: January 16, 2020.
5. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2019. Available from: <http://ginasthma.org/gina-reports/>. Accessed on: April 4, 2020.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
7. Parsons JP, Hallstrand TS, Mastronarde JG, et al. An Official American Thoracic Society (ATS) Clinical Practice Guideline: Exercise-induced Bronchoconstriction. *Am J Respir Crit Care Med*. 2013; 187(9): 1016-1027. Available from: <http://www.thoracic.org/statements/resources/allergy-asthma/exercise-induced-bronchoconstriction.pdf>. Accessed on: April 4, 2020.
8. Seidman MD, Gurgel RK, Lin SY, et. al. American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF). Clinical Practice Guideline: Allergic Rhinitis. *Otolaryngol Head Neck Surg*. 2015; 152(1S): S1-S43. Available from: http://oto.sagepub.com/content/152/1_suppl/S1.full.pdf+html. Accessed on: April 4, 2020.
9. US Food and Drug Administration (FDA). FDA requires Boxed Warning about serious mental health side effects for asthma and allergy drug montelukast (Singulair); advises restricting use for allergic rhinitis. Last updated: March 13, 2020. Available at <https://www.fda.gov/drugs/drug-safety-and-availability/fda-requires-boxed-warning-about-serious-mental-health-side-effects-asthma-and-allergy-drug>. Accessed: April 3, 2020.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.