

Codeine Agents

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

Medications	Comments	Quantity Limit
Codeine Agents for pain	Agents may be subject to meeting quantity limit and/or duration of use override criteria.	May be subject to quantity limits
Codeine Agents for cough and cold	N/A	May be subject to quantity limits

APPROVAL CRITERIA

Requests for codeine containing agents for pain (such as, acetaminophen with codeine or single agent codeine agents) may be approved if the following criteria is met:

- I. Individual is 12 years of age or older. (FDA Safety Announcement 2017)

Requests for codeine containing cough and cold agents may be approved if the following criteria is met:

- I. Requested agent is a codeine containing cough and cold preparation including but not limited to the following: codeine/chlorpheniramine (Tuxarin ER, Tuzistra CR and generic), codeine/phenylephrine/promethazine, codeine/promethazine, codeine/pseudoephedrine/tripolidine (Triacin C); **AND**
- II. Individual is 18 years of age or older. (FDA Safety Announcement 2018)

NOTE: An FDA Safety advisory released on 4-20-2017 noted that the label for codeine containing agents would be updated to include a contraindication for use in treating pain or cough in children younger than 12 years. This is due to serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years (<https://www.fda.gov/drugs/drugsafety/ucm549679.htm>). On 1/11/2018, the FDA released a Drug Safety Announcement regarding use of opioid containing cough and cold preparations in individuals younger than 18 years of age. Per the announcement, safety labeling changes will be made for these agents containing codeine or hydrocodone to limit use to adults 18 years of age and older because the risks of these medications outweighs their benefits in children younger than 18. These risks include misuse, abuse, addiction, overdose, death and slowed or difficult breathing. More information is available at <https://www.fda.gov/Drugs/DrugSafety/ucm590435.htm>.

State Specific Mandates

State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 19, 2018.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

US Food and Drug Administration. FDA Drug Safety Communication: FDA requires labeling changes for prescription opioid cough and cold medicines to limit their use to adults 18 years and older. January 11, 2018. Available from: <https://www.fda.gov/Drugs/DrugSafety/ucm590435.htm>. Accessed January 17, 2018.