Hydrocodone Containing Cough and Cold Agents

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

Medications	Quantity Limit
Hydrocodone Containing Cough and Cold Agents	May be subject to quantity limit

APPROVAL CRITERIA

Requests for hydrocodone containing cough and cold agents may be approved when the following criteria are met:

I. Requested agent is a hydrocodone containing cough and cold agent, including but not limited to the following: hydrocodone/guaifenesin (FlowTuss, Obredon, and generics), hydrocodone/pseudoephedrine/guaifenesin (Hycofenix, Rezira, and generics), hydrocodone/chlorpheniramine (Tussionex Pennkinetic, Vituz, and generics), hydrocodone/chlorphiniramine/pseudoephedrine (Zutripro and generic), hydrocodone/homatropine; **AND**

II. Individual is 18 years of age or older.

NOTE: 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.

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.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
4. 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.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.