

OPIOID COUGH MEDICATIONS**Codeine with phenylephrine and promethazine****Codeine with promethazine****Hydrocodone polistirex, chlorpheniramine polistirex extended-release suspension****Hydromet/Hycodan (hydrocodone bitartrate, homatropine)****Tuxarin ER (codeine, chlorpheniramine)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Opioids, such as codeine and hydrocodone, are often used in prescription cough medications to suppress cough. Many formulations of opioid cough medications include other drugs that treat cough and cold including chlorpheniramine (an antihistamine), pseudoephedrine (a decongestant). The FDA has drastically increased safety measures regarding opioids in the past few years, including opioid use in children. It is now required that a contraindication label be on all codeine products stating that these products should not be used in children less than 12 years of age. Additionally, the FDA recently held an expert round table to address the use of cough and cold medications in individuals less than 18 years of age and ultimately decided that in most cases, the risks of using prescription opioid cough products outweigh the potential benefits. Specifically regarding cough medications, alternative medications should be utilized such as over the counter (OTC) cough suppressants like dextromethorphan and legend benzonatate products (1-2).

Regulatory Status

FDA approved indications: Opioid cough medications are indicated for the temporary relief of coughs, nasal congestion, and upper respiratory symptoms associated with allergy or the common cold (3-9).

Limitations of Use:

Boxed warning regarding the use of codeine in adolescents: Life-threatening respiratory depression and death have occurred in children who received codeine. Most of the reported cases occurred following tonsillectomy and/or adenoidectomy and many of the children had evidence of being an ultra-rapid metabolizer of codeine due to a CYP2D6 polymorphism. Codeine containing compounds are contraindicated in children under 12 years of age (1-4, 8).

Boxed warning for all opioid products: Concomitant use of opioids with benzodiazepines or other

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central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Avoid use of opioid cough medications in patients taking benzodiazepines, other CNS depressants, or alcohol (3-8).

This policy does not apply to Robitussin AC or its therapeutic equivalents as it is excluded from coverage by the plan.

Summary

Opioids, such as codeine and hydrocodone, are often used in prescription cough medications to suppress cough. It is now required that a contraindication label be on all codeine products stating that these products should not be used in children less than 12 years of age. Additionally, the FDA recently held an expert round table to address the use of cough and cold medications in individuals less than 18 years of age and ultimately decided that in most cases, the risks of using prescription opioid cough products outweigh the potential benefits (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of opioid cough medications while maintaining optimal therapeutic outcomes.

References

1. FDA News Release. FDA acts to protect kids from serious risks of opioid ingredients contained in some prescription cough and cold products by revising labeling to limit pediatric use. January 11, 2018. Website: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592109.htm>.
2. 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. Website: <https://www.fda.gov/Drugs/DrugSafety/ucm590435.htm>.



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3. Codeine with phenylephrine and promethazine [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc.; August 2017.
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5. Hydromet [package insert]. Parsippany, NJ: Actavis Pharma, Inc.; January 2017.
6. Hydrocodone polistirex and chlorpheniramine polistirex [package insert]. Monmouth Junction, NJ: Tris Pharma, Inc.; May 2021.
7. Tussigon [package insert]. New York, NY: Pfizer Inc.; February 2018.
8. Tuxarin ER [package insert]. Irvine, CA: Nexgen Pharma, Inc.; January 2017.