Effective Date **1/15/2024**
Next Review Date… **1/15/2025**
Coverage Policy Number **IP0586**

Antitussives

Table of Contents

Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for formulary exceptions to the following non-covered antitussive products:

- **Benzonatate** 150 mg
- **Hycodan®** (hydrocodone-homatropine)
- **Hydrocodone bitrate - Chlorpheniramine maleate**
- **Hydrocodone polistirex -Chlorpheniramine polistirex**
- **Hydrocodone-Chlorpheniramine - Pseudoephedrine**
- **Hydrocodone - Guaifenesin**
- **Hydrocodone - Homatropine**
- **Promethazine - Codeine**
- **Promethazine - Phenylepherine-Codeine**
- **TussiCaps™** (hydrocodone polistirex / chlorpheniramine polistirex)
- **Tuxarin ER™** (chlorpheniramine maleate-codeine phosphate)
- **Tuzistra XR®** (chlorpheniramine polistirex-codeine polistirex)

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for products **in below table:**

Non-Covered Product	Criteria
Benzonatate 150 mg	Documented failure or intolerance to **BOTH** of the following: 1. Benzonatate 100 mg capsule 2. Benzonatate 200 mg capsule
Hycodan (hydrocodone-homatropine)	**Symptomatic relief of cough.** Individual meets **ALL** of the following criteria: 1. Age 18 years or older 2. Documented failure, contraindication, or intolerance to **TWO** nonopioid pharmacologic therapies intended to treat cough (for example, benzonatate 100 mg or 200 mg, promethazine / dextromethorphan)
Hydrocodone bitrate - Chlorpheniramine maleate	**Symptomatic relief of cough.** Individual meets **ALL** of the following criteria: 1. Age 18 years or older 2. Documented failure, contraindication, or intolerance to **TWO** nonopioid pharmacologic therapies intended to treat cough (for example, benzonatate 100 mg or 200 mg, promethazine / dextromethorphan)
Hydrocodone polistirex - Chlorpheniramine polistirex	**Symptomatic relief of cough.** Individual meets **ALL** of the following criteria: 1. Age 18 years or older 2. Documented failure, contraindication, or intolerance to **TWO** nonopioid pharmacologic therapies intended to treat cough (for example, benzonatate 100 mg or 200 mg, promethazine / dextromethorphan)
Hydrocodone-Chlorpheniramine - Pseudoephedrine	**Symptomatic relief of cough.** Individual meets **ALL** of the following criteria: 1. Age 18 years or older 2. Documented failure, contraindication, or intolerance to **TWO** nonopioid pharmacologic therapies intended to treat cough (for example, benzonatate 100 mg or 200 mg, promethazine / dextromethorphan)
Hydrocodone-Guaifenesin	**Symptomatic relief of cough.** Individual meets **ALL** of the following criteria: 1. Age 18 years or older 2. Documented failure, contraindication, or intolerance to **TWO** nonopioid pharmacologic therapies intended to treat cough (for example, benzonatate 100 mg or 200 mg, promethazine / dextromethorphan)
Hydrocodone-Homatropine	**Symptomatic relief of cough.** Individual meets **ALL** of the following criteria: 1. Age 18 years or older 2. Documented failure, contraindication, or intolerance to **TWO** nonopioid pharmacologic therapies intended to treat cough (for example, benzonatate 100 mg or 200 mg, promethazine / dextromethorphan)
Promethazine-Codeine	**Symptomatic relief of cough.** Individual meets **ALL** of the following criteria: 1. Age 18 years or older 2. Documented failure, contraindication, or intolerance to **TWO** nonopioid pharmacologic therapies intended to treat cough (for example, benzonatate 100 mg or 200 mg, promethazine / dextromethorphan)

Non-Covered Product	Criteria
Promethazine-Phenylepherine-Codeine	**Symptomatic relief of cough.** Individual meets **ALL** of the following criteria: 1. Age 18 years or older 2. Documented failure, contraindication, or intolerance to **TWO** nonopioid pharmacologic therapies intended to treat cough (for example, benzonatate 100 mg or 200 mg, promethazine / dextromethorphan)
TussiCaps (hydrocodone polistirex / chlorpheniramine polistirex)	**Symptomatic relief of cough.** Individual meets **ALL** of the following criteria: 1. Age 18 years or older 2. Documented failure, contraindication, or intolerance to **TWO** nonopioid pharmacologic therapies intended to treat cough (for example, benzonatate 100 mg or 200 mg, promethazine / dextromethorphan)
Tuxarin ER (chlorpheniramine maleate-codeine phosphate)	**Symptomatic relief of cough.** Individual meets **ALL** of the following criteria: 1. Age 18 years or older 2. Documented failure, contraindication, or intolerance to **TWO** nonopioid pharmacologic therapies intended to treat cough (for example, benzonatate 100 mg or 200 mg, promethazine / dextromethorphan)
Tuzistra XR (chlorpheniramine polistirex-codeine polistirex)	**Symptomatic relief of cough.** Individual meets **ALL** of the following criteria: 1. Age 18 years or older 2. Documented failure, contraindication, or intolerance to **TWO** nonopioid pharmacologic therapies intended to treat cough (for example, benzonatate 100 mg or 200 mg, promethazine / dextromethorphan)

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of non-covered antitussive products is considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 3 months
Reauthorization approval duration: up to 3 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW
FDA Indications
Benzonatate capsules are FDA indicated for the symptomatic relief of cough.[1]

Hydrocodone-Chlorpheniramine-Pseudoephedrine and Promethazine-Phenylephrine-Codeine are indicated for the temporary relief of cough and upper respiratory symptoms, including nasal congestion, associated with allergy or the common cold in patients 18 years of age and older.[2,8]
Hydrocodone polistirex-Chlorpheniramine polistirex, Hydrocodone bitrate-Chlorpheniramine maleate, Promethazine-Codeine, TussiCaps, Tuxarin ER and Tuzistra XR are for the temporary relief of cough and upper respiratory symptoms associated with allergy or the common cold in patients 18 years of age and older.[3,4,7,9,10,11]
Hydrocodone-Guaifenesin is indicated for the symptomatic relief of cough and to loosen mucus associated with the common cold in patients 18 years of age and older.[5]
Hydrocodone-Homatropine is indicated for the symptomatic relief of cough in patients 18 years of age and older.[6]

FDA Dosing
Benzonatate: For adults and children over 10 years of age, the usual dose is one 100 mg, 150 mg, or 200 mg capsule three times a day as needed for cough. If necessary to control cough, up to 600 mg daily in three divided doses may be given.[1]
Hydrocodone-Chlorpheniramine-Pseudoephedrine and Hydrocodone-Chlorpheniramine: The usual dose for adults 18 years of age and older is 5 mL every 4 to 6 hours as needed, not to exceed 4 doses (20 mL) in 24 hours.[2,4]
Hydrocodone polistirex-Chlorpheniramine polistirex: The usual dose for adults 18 years of age and older is 5 mL every 12 hours as needed, not to exceed 2 doses (10 mL) in 24 hours.[3]
Hydrocodone-Guaifenesin: The usual dose for adults 18 years of age and older is 10 mL every 4 to 6 hours as needed, not to exceed 6 doses (60 mL) in 24 hours.[5]
Hydrocodone-homatropine: The usual dose for adults 18 years of age and older is one (1) tablet or 5 mL of the oral solution every 4 to 6 hours as needed; not to exceed six (6) tablets or 30 mL in 24 hours.[6]
Promethazine-Codeine and Promethazine-Phenylephrine-Codeine: The usual dose for adults 18 years of age and older is 5 mL every 4 to 6 hours as needed, not to exceed 6 doses (30 mL) in 24 hours.[7,8]
Tussicaps: The usual dose for adults is one (1) full-strength extended-release capsule every 12 hours, not exceed 2 capsules in 24 hours.[9]
Tuxarin ER: The usual dose for adults 18 years of age and older is one (1) tablet every 12 hours as needed, not to exceed 2 tablets in 24 hour.[10]
Tuzistra XR: The usual dose for adults 18 years of age and older is 10 mL every 12 hours as needed, not to exceed 2 doses (20 mL) in 24 hours.[11]

FDA Safety Communication
In January 2018, the FDA issued a drug safety communication restricting the use of prescription codeine and hydrocodone pain and cough medicines in children. The FDA required safety labeling changes for all cough and cold medicines containing codeine or hydrocodone to limit the use of these products to adults 18 years and older stating the risks of these medicines outweigh their benefits in children younger than eighteen. FDA gave an additional directive that all products are required to have a Boxed Warning regarding the risks of misuse, abuse, addiction, overdose, death , and slowed or difficult breathing.[12] Tussicaps product label has not yet been updated to reflect these FDA requirements.

References

1. Benzonatate [prescribing information], Montvale, NJ: Ascend Laboratories, LLC.; October 2014.
2. Hydrocodone-chlorpheniramine-pseudoephedrine [package insert], Morristown, NJ: Hawthorn Pharmaceuticals, Inc.; June 2018.
3. Hydrocodone polistirex-Chlorpheniramine polistirex [package insert], Smyrna, GA: UCB Inc.; June 2018.
4. Hydrocodone bitrate-chlorpheniramine maleate [package insert], Morristown, NJ: Hawthorn Pharmaceuticals, Inc.; June 2018.
5. Hydrocodone-Guaifenesin [package insert], Wilmington, DE: BBK Pharmaceuticals, LLC; June 2018.
6. Hydrocodone-homatropine [package insert], Malver, PA: Endo Pharmaceuticals Inc.; June 2018.
7. Promethazine with codeine oral solution [package insert], Morton Grove, IL: Morton Grove Pharmaceuticals, Inc.; November 2018.
8. Promethazine-phenylephrine-codeine [package insert], Lincolnton, NC: Actavis Mid Atlantic LLC; February 2013.

9. TussiCaps™ [prescribing information], St. Louis, MI: Mallinckrodt Inc.; January 2007.
10. Tuxarin ER [package insert], Louisville, KY: MainPointe Pharmaceuticals, LLC; August 2018.
11. Tuzistra XR [package insert], Berwyn, PA: Vernalis Pharmaceuticals, Inc.; August 2018.
12. FDA Safety Communication: FDA requires labeling changes for prescription opioid couch and cold medicine to limit their use to adults 18 years and older. January 11, 2018. FDA website. https://www.fda.gov/Drugs/DrugSafety/ucm590435.htm. Accessed October 31, 2023.