

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY	Cough & Cold	P&T DATE	12/13/2017
THERAPEUTIC CLASS	Infectious Disease	REVIEW HISTORY	9/16, 2/12
LOB AFFECTED	Medi-Cal	(MONTH/YEAR)	

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

OVERVIEW

Common colds are the number one cause of children missing school and adults missing work.¹ Most otherwise healthy people recover within 7-10 days without need for intervention. However, people with respiratory conditions or weak immune systems can develop serious complications. Peak cough & cold season is typically during winter and spring.

There is no cure for a cold. This is why it is important for patients to practice good hand hygiene to reduce risk of catching a cold. Non-pharmacologic therapies (e.g., rest, oral hydration, humidifiers, lozenges/hard candies) can help expedite the recovery process. Prescription and OTC cough & cold medications only help relieve symptoms. Patients and providers should also be aware of three potential risks of taking cough and cold medications:

1. Many of these products have age restrictions based on the ingredients. In general, the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) recommend that parents and caregivers should not administer cough and cold medications to children < 2 years of age without first consulting a health care provider due to risks for toxicity, lack of dosing recommendations for this age group, and limited evidence of effectiveness.^{2,3}
2. Many of the active ingredients used for cough & cold symptoms are available in combination products. The CDC recommends that clinicians always ask caregivers about the use of OTC combination medications to avoid overdose from therapeutic duplications.²
3. Some of the active ingredients have properties that can lead to abuse potential. Namely, dextromethorphan-, codeine-, hydrocodone- and pseudoephedrine-containing products have been associated with abuse.⁴

The purpose of this coverage policy is to review the coverage criteria of HPSJ's formulary cough & cold agents (Table 1).

Table 1: Available Cough & Cold Medications

Generic	Brand	Strength & Dosage form	Formulary Limits	Cost per Rx*	Notes
Antitussives – Non-Narcotic					
Benzonatate	Tessalon Perle	100 mg capsule	-	\$4.68	
		200 mg capsule	-	\$7.66	
Dextromethorphan HBr	Triaminic Cough, Robitussin Pediatric Cough	7.5 mg/5 ml syrup	QL; FL	\$4.65	Limit 240 ml per fill and 7 fills per year
	Adult Robitussin	15 mg/5 ml syrup	QL; FL	\$3.85	
Dextromethorphan Polistirex	Delsym, Robitussin 12 Hour	30 mg/5 ml ER suspension	NF	\$8.80	
Decongestants					
Oxymetazoline	Afrin	0.05 % nasal spray, aerosol	-	\$1.45	
Pseudoephedrine HCl	Pediacare	7.5 mg/0.8 ml oral drops	-	--	
	Children's Sudafed	15 mg/5 ml oral liquid	-	\$2.30	
	Nasal Decongestant	30 mg/5 ml oral liquid	-	\$1.23	
	Sudafed	30mg tablet	-	\$1.48	
		60 mg tablet	-	\$1.34	
	Sudafed 12 Hour	120 mg XR tablet	-	\$5.83	
Sudafed 24 Hour	240 mg XR tablet	NF	\$9.55		
Pseudoephedrine Sulfate	12 Hour Cold Relief	120 mg XR tablet	-	--	

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*Cost/Rx based on HPSJ Medi-Cal utilization historical data from November 2016 through October 2017

Generic	Brand	Strength & Dosage form	Form. Limits	Cost per Rx*	Notes
Phenylephrine HCl	Little Noses	0.125% nasal drops	-	\$2.97	
	Ephrine, Nose Drops	1% nasal drops	-	\$3.80	
	Neo-Synephrine	0.25% nasal spray	-	\$3.23	
	Neo-Synephrine	0.5% nasal spray	-	\$2.91	
	4-Way, Nasal Four, Neo-Synephrine	1% nasal spray	-	\$1.64	
	Sudafed PE	5 mg tablet	-	--	
10 mg tablet		-	\$0.66		
Expectorants					
Guaifenesin	Robitussin, Iophen-NR, Medifin Expectorant Mucus Relief, Robafen, Tussin Chest Congestion	100 mg/5 ml oral liquid	-	\$0.74	
	Liquituss GG, Diabetic Tussin, Mucus Relief	200 mg/5 ml oral liquid	-	--	
	Coughtab, Organidin NR	200 mg tablet	-	\$4.43	
	Allfen, Mucosa, Refenesen	400 mg tablet	NF	\$5.78	
	Mucus Relief	600 mg ER tablet	-	\$6.76	
	Mucinex ER	1200 mg ER tablet	NF	\$26.18	
1st Generation Antihistamine, Decongestant					
Promethazine/ Phenylephrine	Phenergan VC	6.25 mg-5 mg/5 ml syrup	AL; FL	\$11.47	Must be greater than or equal to 2 years of age. Children 2-5.9 years: limit 1 fill per 365 days.
Brompheniramine/ Phenylephrine	Brohist D, Ru-hist	4 mg-10 mg tablet	NF	--	
	Brovex Peb	4 mg-10 mg/5 ml liquid	NF	--	
	Child Triaminic Cold & Allergy, Dimetapp	1 mg-2.5 mg/5 ml solution	-	\$2.52	
Brompheniramine/ Pseudoephedrine	Lodrane D	4 mg-60 mg capsule	NF	--	
	Brotapp, Rynex Pse, V-R Valu-Tapp	1 mg-15 mg/5 ml liquid	-	\$3.42	
Triprolidine/ Pseudoephedrine	Aprodine, Ed A-Hist PSE	2.5 mg-60 mg tablet	-	\$4.59	
	Ritifed	1.25 mg-30 mg/5 ml syrup	-	--	
Antitussive – Non-Narcotic, 1st Generation Antihistamine					
Dextromethorphan/ Promethazine	Phenergan DM	6.25 mg-15 mg/5 ml syrup	QL; FL; AL	\$3.22	Limit 240 ml per fill and 7 fills per year. Must be greater than or equal to 2 years of age. Children 2-5.9 years: limit 1 fill per 365 days.
Antitussive – Non-Narcotic, Decongestant					
Dextromethorphan/ Pseudoephedrine	Pedia Relief Infant	7.5 mg-2.5 mg/0.8 ml oral drops	QL; FL	--	Limit 240 ml per fill and 7 fills per year
	Expectorant Max Strength	30 mg-15 mg/5 ml oral liquid	QL; FL	--	

PA = Prior Authorization; QL = Quantity Limit; FL = Fill Limit; AL = Age Limit; NF = Non-formulary

*Cost/Rx based on HPSJ Medi-Cal utilization historical data from November 2016 through October 2017

Generic	Brand	Strength & Dosage form	Formulary Limits	Cost per Rx*	Notes
Antitussive – Non-Narcotic, Expectorant					
Guaifenesin/ Dextromethorphan	Adult Robitussin Peak Cold, Diabetic Tussin DM, Iophen DM-Nr, Tussin Cough & Chest Congestion	10 mg-100 mg/5 ml oral liquid	QL; FL	\$3.78	Limit 240 ml per fill and 7 fills per year
	Robitussin DM Cough, Adult Tussin DM, Tussin DM Clear	10 mg-100 mg/5 ml syrup	QL; FL	\$2.62	
	Robitussin DM Max, Diabetic Tussin Max, Tussin DM Max	10 mg-200 mg/5 ml oral liquid	QL; FL	\$3.16	
	Biospec Dmx	15 mg-25 mg/5 ml oral liquid	QL; FL	--	
	Tussin DM	15 mg-100 mg/5 ml syrup	QL; FL	--	
	Scot-Tussin Senior	15 mg-200 mg/5 ml oral liquid	QL; FL	--	
	Double Tussin DM	20 mg-300 mg/5 ml oral liquid	QL; FL	--	
	Neo-Tuss	30 mg-200 mg/5 ml oral liquid	QL; FL	--	
	Alka-Seltzer Plus Mucus-Congestion, Coricidin HBP	10 mg-200 mg capsule	QL; FL	\$5.04	
	Mucus Relief DM, Tussin DM	20 mg-400 mg tablet	QL; FL	\$2.73	
	Mucinex DM	30 mg-600 mg XR tablet	QL; FL	--	
	Mucus DM Max	60 mg-1,200 mg XR tablet	QL; FL	--	
	Child Mucus Relief Cough, DM Max	5 mg-100 mg/5 ml oral liquid	QL; FL	\$1.42	
Antitussive – Narcotic, 1st Generation Antihistamine					
Hydrocodone/ Phenyltoloxamine	Tussionex	5 mg-10 mg/5 ml suspension	NF	--	
		5 mg-10 mg tablets	NF	--	
Promethazine/ Codeine	Phenergan with codeine	6.25 mg-10 mg/5 ml syrup	QL; FL; AL	\$5.90	Limit 240 ml per fill and 4 fills per year. Must be greater than or equal to 12 years of age.
Antitussive – Narcotic, Anticholinergic					
Hydrocodone/ Homatropine	Hydromet	5 mg-1.5 mg/5 ml syrup	QL; FL	\$16.72	Limit 240ml per fill and 4 fills per year
Antitussive – Narcotic, Expectorant					
Guaifenesin/ Codeine Phosphate	Cheratussin AC, Iophen C-NR, Virtussin AC	10 mg-100 mg/5 ml oral liquid	QL; FL	\$11.76	Limit 240ml per fill and 4 fills per year. Must be greater than or equal to 12 years of age.
Decongestant, Analgesic					
Pseudoephedrine/ Acetaminophen	Daytime Sinus Relief	30 mg-325 mg capsule	-	--	
	Nexafed Sinus Pressure + Pain	30 mg -325 mg tablet	NF	--	
	Tavist, Max Strength Non-Drowsy Sinus, Pain Reliever PM, Sinus Headache Decongestant	30 mg-500 mg tablet	-	--	
Decongestant, NSAID (COX-nonspecific)					
Pseudoephedrine/ Ibuprofen	Ibuprofen Cold	15 mg-100 mg/5 ml oral suspension	-	--	

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Generic	Brand	Strength & Dosage form	Formulary Limits	Cost per Rx*	Notes
Expectorant, Decongestant					
Guaifenesin/ Pseudoephedrine	Triaminic, Triacting Expectorant	15 mg-50 mg/5 ml syrup	-	--	
	Tussin PE	30 mg-100 mg/5 ml syrup	-	--	
	Suphedrin Non-Drying Sinus	30 mg-200 mg capsule	-	--	
	Congestac	60 mg-400 mg tablet	-	--	
	Mucinex D	60 mg-600 mg XR tablet	-	\$11.24	
	Mucinex D Maximum Strength	120 mg-1,200 mg XR tablet	-	\$21.03	
1st Generation Antihistamine, Decongestant, Analgesic					
Pseudoephedrine/ Acetaminophen/ Chlorpheniramine	Non-Aspirin Child's Cold	0.5 mg-7.5 mg-80 mg chewable tablet	-	--	
1st Generation Antihistamine, Decongestant, NSAID (COX-nonspecific)					
Chlorpheniramine/ Pseudoephedrine/ Ibuprofen	Advil Allergy Sinus	2 mg-30 mg-200 mg tablet	-	\$9.78	
Antitussive - Non-Narcotic, 1st Generation Antihistamine, Decongestant					
Brompheniramine/ Phenylephrine/ Dextromethorphan	Dimetapp DM	1 mg-2.5 mg-5 mg/5 ml Oral Solution	QL; FL	\$1.19	Limit 240 ml per fill and 7 fills per year
Dextromethorphan/ Phenylephrine/ Chlorpheniramine	Cardec DM, Virdec DM	1 mg-3.5 mg-3 mg/ml oral drops	QL; FL	--	Limit 240 ml per fill and 7 fills per year
Dextromethorphan/ Pseudoephedrine/ Brompheniramine	Bio-Dtuss Dmx	1 mg-30 mg-20 mg/5 ml oral liquid	QL; FL	--	Limit 240 ml per fill and 7 fills per year
	Bromfed DM, Dimetane-diagnosis	2 mg-30 mg-10 mg/5 ml syrup	QL; FL	\$17.71	
	Bromphenex DM	4 mg-60 mg-30 mg/5 ml syrup	QL; FL	--	
	Bromaline DM, Brotapp DM, Medi-Brom, Q-Tapp DM	1 mg-15 mg-5 mg/5 ml oral elixir	QL; FL	\$5.18	
Dextromethorphan/ Pseudoephedrine/ Chlorpheniramine	Pediicare Cough-Cold, Triacting Multi-Symptom Cough-Cold	1 mg-15 mg-5 mg/5 ml oral liquid	QL; FL	\$1.61	Limit 240 ml per fill and 7 fills per year
	Mesehist DM, M-End DM	2 mg-15 mg-15 mg/5 ml syrup	QL; FL	--	
	Rescon-DM	2 mg-30 mg-10 mg/5 ml oral liquid	QL; FL	--	
Antitussive - Non-Narcotic, Decongestant, Analgesic					
Dextromethorphan/ Pseudoephedrine/ Acetaminophen	Infants' Non-Aspirin Cold	15 mg-5 mg-160 mg/1.6 ml oral drops	QL; FL	--	Limit 240 ml per fill and 7 fills per year
Antitussive - Non-Narcotic, Decongestant, Expectorant					
Guaifenesin/ Dextromethorphan/ Phenylephrine	Robitussin Cough & Cold CF, Adult Tussin Multi-Symptom Cold	5 mg-10 mg-100 mg/5 ml oral liquid	QL; FL	\$2.89	Limit 240 ml per fill and 7 fills per year
Guaifenesin/ Dextromethorphan/ Pseudoephedrine	Tussin CF	30 mg-10 mg-100 mg/5 ml syrup	QL; FL	--	
Antitussive - Non-Narcotic, 1st Generation Antihistamine, Decongestant, Analgesic					
Dextromethorphan/ Pseudoephedrine/ Acetaminophen/ Chlorpheniramine	Alka-Seltzer Plus-D Sinus-Cold	2 mg-30 mg-10 mg-325 mg capsule	QL; FL	--	Limit 240 ml per fill and 7 fills per year
	Tylenol Cold	30 mg-15 mg-325 mg tablet	QL; FL	--	
Dextromethorphan/ Pseudoephedrine/ Acetaminophen/ Doxylamine	Tylenol Cold & Flu Severe	12.5 mg-60 mg-30 mg-1000 mg/30 ml oral liquid	QL; FL	--	

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Generic	Brand	Strength & Dosage form	Formulary Limits	Cost per Rx*	Notes
Antitussive – Narcotic, 1st Generation Antihistamine, Decongestant					
Promethazine/ Phenylephrine/ Codeine	Phenergan VC With Codeine	6.25 mg-5 mg-10 mg/5 ml syrup	QL; FL; AL	\$59.76	Limit 240 ml per fill and 4 fills per year. Must be greater than or equal to 12 years of age.
Pseudoephedrine/ Codeine/ Chlorpheniramine	Phenylhistine DH	2 mg-30 mg-10 mg/5 ml oral liquid	QL; FL; AL	--	
Antitussive – Narcotic, Decongestant, Expectorant					
Pseudoephedrine/ Codeine/ Guaifenesin	Cheratussin DAC	30 mg-10 mg-100 g/5 ml syrup	QL; FL; AL	\$44.10	Limit 240 ml per fill and 4 fills per year. Must be greater than or equal to 12 years of age.

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⊞ **EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION**

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed & approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HSPJ Medical Review Guidelines (UM06).

Antitussives – Non-Narcotic
<i>Benzonatate (Tessalon Perle), Dextromethorphan HBr (Triaminic Cough, Robitussin Pediatric Cough, Adult Robitussin)</i>

Benzonatate ((Tessalon Perle)

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None

Dextromethorphan HBr (Triaminic Cough, Robitussin Pediatric Cough, Adult Robitussin).

Dextromethorphan Polistirex (Delsym, Robitussin 12 Hour)

- Coverage Criteria:** None
- Limits:** 240 ml per fill; 7 fills per year
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Dextromethorphan Polistirex (Delsym, Robitussin 12 Hr)

Decongestants
<i>Oxymetazoline (Afrin), Pseudoephedrine HCl (Sudafed), Pseudoephedrine Sulfate (12 Hour Cold Relief), Phenylephrine (Little Noses, Ephrine, Neo-Synephrine, Sudafed PE)</i>

Pseudoephedrine HCl (Pediaware, Children’s Sudafed, Nasal Decongestant, Sudafed, Sudafed 12 Hour), Pseudoephedrine sulfate (12 Hour Cold Relief), Phenylephrine (Little Noses, Ephrine, Neo-Synephrine, Sudafed PE)

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Pseudoephedrine HCl (Sudafed 24 Hour)

Expectorants*Guaifenesin (Allfen, Mucosa, Refenesen, Robitussin, Tussin, Robafen, Iophen, Mucus Relief, Mucinex ER)***Guaifenesin 100 mg/5 ml, 200 mg/5 ml liquid; 200 mg tablet; 600 mg ER tablet**

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** 400 mg tablet (Allfen, Mucosa, Refenesen); 1200 mg ER tablet (Mucinex ER)

1st Generation Antihistamine, Decongestant*Promethazine/ Phenylephrine (Phenergan VC), Brompheniramine/Phenylephrine (Brohist D, Ru-hist, Brovex Peb, Child Triaminic Cold & Allergy, Dimetapp), Brompheniramine/Pseudoephedrine (Lodrane D, Brotapp), Triprolidine/Pseudoephedrine (Aprodine, Ed A-Hist PSE, Ritifed)***Promethazine/Phenylephrine (Phenergan VC)**

- Coverage Criteria:** None
- Limits:** Must be greater than or equal to 2 years of age. Children 2-5.9 years: limit 1 fill per 365 days.
- Required Information for Approval:** N/A
- Other Notes:** None

Brompheniramine/Phenylephrine 1 mg-2.5 mg/5 ml solution, Brompheniramine/Pseudoephedrine 1 mg-15 mg/5 ml liquid (Brotapp), Triprolidine/Pseudoephedrine (Aprodine, Ed A-Hist PSE, Ritifed)

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Brompheniramine/Phenylephrine 4 mg-10 mg tablet (Brohist D, Ru-hist); Brompheniramine/Phenylephrine 4 mg-10 mg/5 ml liquid (Brovex Peb); Brompheniramine/Pseudoephedrine 4 mg-60 mg capsule (Lodrane D)

Antitussive – Non-Narcotic, 1st Generation Antihistamine*Dextromethorphan/Promethazine (Phenergan DM)*

- Coverage Criteria:** None
- Limits:** 240 ml per fill; 7 fills per year; Must be greater than or equal to 2 years of age. Children 2-5.9 years: limit 1 fill per 365 days.
- Required Information for Approval:** N/A
- Other Notes:** None

Antitussive – Non-Narcotic, Decongestant*Dextromethorphan/Pseudoephedrine (Expectorant Max Strength, Pedia Relief Infant)*

- Coverage Criteria:** None
- Limits:** 240 ml per fill; 7 fills per year
- Required Information for Approval:** N/A
- Other Notes:** None

Antitussive – Non-Narcotic, Expectorant*Guaifenesin/Dextromethorphan (Adult Robitussin Peak Cold, Iophen DM-NR, Alka-Seltzer Plus Mucus-Congestion, Coricidin HBP, Mucinex DM)*

- Coverage Criteria:** None
- Limits:** 240 ml per fill; 7 fills per year
- Required Information for Approval:** N/A
- Other Notes:** None

Antitussive – Narcotic, 1st Generation Antihistamine*Promethazine/Codeine (Phenergan with Codeine)*

- Coverage Criteria:**
- Limits:** 240 ml per fill; 4 fills per year; patient must be greater than or equal to 12 years of age
- Required Information for Approval:** N/A
- Other Notes:** Oxycodone- and hydrocodone-containing products can also help relieve cough. Furthermore, both oxycodone and hydrocodone are more potent cough suppressants than codeine. Therefore, use of codeine-containing cough syrup plus oxycodone- or hydrocodone-containing products is a therapeutic duplication. Potential for codeine syrup abuse is well-documented and should be strongly considered for those concurrently on regular hydrocodone/oxycodone therapy.
- Non-Formulary:** Hydrocodone/Phenyltoloxamine (Tussionex)

Antitussive – Narcotic, Anticholinergic*Hydrocodone/Homatropine (Hydromet)*

- Coverage Criteria:** None
- Limits:** 240 ml per fill; 4 fills per year
- Required Information for Approval:** N/A
- Other Notes:** None

Antitussive – Narcotic, Expectorant*Guaifenesin/Codeine Phosphate (Cheratussin AC, Iophen C-NR, Virtussin AC)*

- Coverage Criteria:** None
- Limits:** 240 ml per fill; 4 fills per year; patient must be greater than or equal to 12 years of age
- Required Information for Approval:** N/A
- Other Notes:** Oxycodone- and hydrocodone-containing products can also help relieve cough. Furthermore, both oxycodone and hydrocodone are more potent cough suppressants than codeine. Therefore, use of codeine-containing cough syrup plus oxycodone- or hydrocodone-containing products is a therapeutic duplication. Potential for codeine syrup abuse is well-documented and should be strongly considered for those concurrently on regular hydrocodone/oxycodone therapy.

Decongestant, Analgesic*Pseudoephedrine/Acetaminophen (Daytime Sinus Relief, Tavist)*

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None
- Non-Formulary:** Pseudoephedrine/Acetaminophen (Nexafed Sinus Pressure + Pain)

Decongestant, NSAID (COX-nonspecific)*Pseudoephedrine/Ibuprofen (Ibuprofen Cold)*

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None

Expectorant, Decongestant*Guaifenesin/Pseudoephedrine (Triaminic, Tussin PE, Suphedrin Non-Drying Sinus, Congestac, Mucinex D)*

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None

1st Generation Antihistamine, Decongestant, Analgesic*Pseudoephedrine/Acetaminophen/Chlorpheniramine (Non-Aspirin Child's Cold)*

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None

1st Generation Antihistamine, Decongestant, NSAID (COX-nonspecific)*Chlorpheniramine/Pseudoephedrine/Ibuprofen (Advil Allergy Sinus)*

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None

Antitussive – Non-Narcotic, 1st Generation Antihistamine, Decongestant*Brompheniramine/Phenylephrine/Dextromethorphan (Dimetapp DM), Dextromethorphan/Phenylephrine/Chlorpheniramine (Cardec DM, Virdec DM), Dextromethorphan/Pseudoephedrine/Brompheniramine (Bio-Dtuss DMX, Bromfed DM, Bromphenex DM, Bromaline DM) Dextromethorphan/Pseudoephedrine/Chlorpheniramine (Pediacare Cough-Cold, Mesehist DM, Rescon-DM)*

- Coverage Criteria:** None
- Limits:** 240 ml per fill; 7 fills per year
- Required Information for Approval:** N/A
- Other Notes:** None

Antitussive – Non-Narcotic, Decongestant, Analgesic*Dextromethorphan/Pseudoephedrine/Acetaminophen (Infants' Non-Aspirin Cold)*

- Coverage Criteria:** None
- Limits:** 240 ml per fill; 7 fills per year
- Required Information for Approval:** N/A
- Other Notes:** None

Antitussive – Non-Narcotic, Decongestant, Analgesic*Guaifenesin/Dextromethorphan/Phenylephrine (Robitussin Cough & Cold CF),
Guaifenesin/Dextromethorphan/Pseudoephedrine (Tussin CF)*

- Coverage Criteria:** None
- Limits:** 240 ml per fill; 7 fills per year
- Required Information for Approval:** N/A
- Other Notes:** None

Antitussive – Non-Narcotic, 1st Generation Antihistamine, Decongestant, Analgesic*Dextromethorphan/Pseudoephedrine/Acetaminophen/Chlorpheniramine (Alka-Seltzer Plus-D Sinus-Cold, Tylenol Cold), Dextromethorphan/Pseudoephedrine/Acetaminophen/Doxylamine (Tylenol Cold & Flu Severe)*

- Coverage Criteria:** None
- Limits:** 240 ml per fill; 7 fills per year
- Required Information for Approval:** N/A
- Other Notes:** None

Antitussive – Narcotic, 1st Generation Antihistamine, Decongestant*Promethazine/Phenylephrine/Codeine (Phenergan VC With Codeine),
Pseudoephedrine/Codeine/Chlorpheniramine (Phenylhistine DH)*

- Coverage Criteria:** None
- Limits:** 240 ml per fill; 4 fills per year; patient must be greater than or equal to 12 years of age
- Required Information for Approval:** N/A
- Other Notes:** Oxycodone- and hydrocodone-containing products can also help relieve cough. Furthermore, both oxycodone and hydrocodone are more potent cough suppressants than codeine. Therefore, use of codeine-containing cough syrup plus oxycodone- or hydrocodone-containing products is a therapeutic duplication. Potential for codeine syrup abuse is well-documented and should be strongly considered for those concurrently on regular hydrocodone/oxycodone therapy.

Antitussive – Narcotic, Decongestant, Expectorant

Pseudoephedrine/Codeine/Guaifenesin (Cheratussin DAC)

- Coverage Criteria:** None
- Limits:** 240 ml per fill; 4 fills per year; patient must be greater than or equal to 12 years of age
- Required Information for Approval:** N/A
- Other Notes:** Oxycodone- and hydrocodone-containing products can also help relieve cough. Furthermore, both oxycodone and hydrocodone are more potent cough suppressants than codeine. Therefore, use of codeine-containing cough syrup plus oxycodone- or hydrocodone-containing products is a therapeutic duplication. Potential for codeine syrup abuse is well-documented and should be strongly considered for those concurrently on regular hydrocodone/oxycodone therapy.

⊕ CLINICAL JUSTIFICATION

HPSJ's cough & cold policy is based on recommendations by the *British Thoracic Society (BTS)*, *American College of Chest Physicians (ACCP)*, *American Academy of Pediatrics (AAP)*, *National Institute for Health and Clinical Excellence (NICE)*. The BTS Guidelines define acute cough as recent onset lasting < 3 weeks, while chronic cough lasts > 8 weeks.^{5,6} These guidelines stress the importance of identifying the source of the cough and treating underlying conditions if possible. Some examples of underlying conditions are 1. upper respiratory tract infections (e.g., bacterial bronchitis), which can be treated with antibiotics, or 2. cough variant asthma, which can be identified with appropriate testing and a trial of anti-asthma therapy for 8-12 weeks. The BTS Guidelines also found that OTC medications are as effective as placebo for acute cough with head colds in children; however, antihistamines and intranasal steroids are beneficial for children with allergic cough in the pollen season.⁵ Both BTS and AAP Guidelines for pediatric patients recommend fluids, rest and humidity over cough suppressants because coughing can be a protective mechanism for clearing the airway and there is limited evidence of efficacy in these patients.^{5,7} The age restriction for codeine-containing products is in place due to the FDA's Black Box Warning and contraindication in children < 6 years of age, based on reports of respiratory depression and death occurring in children ages 2 to 5.^{8,9}

The ACCP 2006 Guidelines recommend that suppressant therapy be used for short-term reduction of coughing. These guidelines recommend codeine and dextromethorphan specifically for short-term relief in patients with chronic bronchitis, while antihistamine/decongestant combination therapy may be used for acute cough due to the common cold.¹⁰ The quantity and fill limits for codeine- and hydrocodone-containing cough syrups allow patients sufficient quantity for short-term relief of acute cough and are in alignment with these ACCP recommendations. These limits are in place to reduce potential for overuse.

The British Thoracic Society (BTS) 2008 and American College of Chest Physicians (ACCP) 2016 guidelines recommend that chronic cough (lasting >8 weeks) should be managed by first identifying the underlying cause and addressing treatment for that condition.^{5,11} The Drug Enforcement Administration (DEA) lists dextromethorphan as a potential drug of abuse.^{12,13}

The European Medicines Agency published a recommendation in July 2013 stating that codeine should only be used to relieve acute moderate pain in children older than 12 years of age if treatment failure to other painkillers such as acetaminophen or ibuprofen.^{14,15} The Food and Drug Administration is also investigating literature and safety data in children under age 12, and a safety update is forthcoming.^{16,17} Health Canada announced a safety recommendation against the use of pain and cough medications containing codeine in children younger than 12 years.¹⁸ The American Academy of Pediatrics published a clinical report in September 2016 calling for more formal restrictions regarding its use in children and suggesting the use of genetic variability in drug metabolism to guide physicians in safe and effective treatment.¹⁹

The Food and Drug Administration 2004 Safety Labeling Change for promethazine-containing products added a contraindication in children under age 2.^{20,21} This safety labeling change also added a Black Boxed Warning stating that caution should be used in children over 2 years old (use lowest possible dose and avoid other respiratory depressant drugs). Because of the FDA contraindication for children < 2 years of age, promethazine will be restricted to age 2 and up. The FDA issued a warning in 2008 that promethazine-codeine combination is contraindicated in pediatric patients < 6 years old.²²

An FDA safety announcement on April 20, 2017 reported the results of their review of adverse event reports from January 1969 to May 2015—which identified 64 cases of serious breathing problems (including 24 deaths) with codeine-containing medicines in children under 18 and 9 cases of serious breathing problems (including 3 deaths) with the use of tramadol in children under 18 years from. The majority of serious side effects with these medications occurred in children younger than 12 years, and some cases occurred after a single dose of the medicine. Based on these results, the FDA added a contraindication to all prescription codeine- and tramadol-containing products to avoid use in all children under 12. The labeling change also added the following warnings:²⁴

- Tramadol is contraindicated in children under 18 to treat pain after surgery to remove tonsils and/or adenoids
- Codeine or tramadol should not be used in adolescents between 12-18 who are obese or have condition such as obstructive sleep apnea or severe lung disease, which may increase risk of serious breathing problems
- Codeine or tramadol should not be used in breastfeeding mothers due to the increased risk of adverse reactions (increased sleepiness, difficulty breastfeeding, breathing problems, death) in breastfed infants

On August 21, 2017, FDA Commissioner Scott Gottlieb announced that the FDA Pediatric Advisory Committee were meeting on 9/11/17-9/12/17 to discuss the use of prescription opioid products containing hydrocodone or codeine for treatment of cough in pediatric patients, including current treatment practices and benefit-risk considerations. The FDA is also funding research to develop comprehensive, consumer-centered approaches on best practices for the safe use of pediatric cough and cold medications in general—not just those that contain an opioid.²⁵ During the meeting, the majority of committee members voted that the benefit/risk was not favorable for use of codeine or hydrocodone cough suppressants in children under 18 years of age, comments included that cough due to cold is self-limited and emphasis should be treatment of the underlying cause of the cough.²⁶

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REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Codeine DUR summary 2-21-2012.docx	02/2012	Jonathan Szkotak, PharmD, BCACP
Update to Policy	HPSJ Coverage Policy – Infectious Disease – Cough & Cold 2016-09.docx	09/2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Infectious Disease – Cough & Cold 2017-12.docx	12/2017	Johnathan Yeh, PharmD

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy

 Please review the **Seasonal Allergies Coverage Policy** for coverage criteria of allergy products.