



### Texas Prior Authorization Program Clinical Criteria

### **Cough/Cold Medications**

#### NOTE:

- The FDA 05/18/2018 Special Features publication on Safety Information for Parents and Caregivers states that cough and cold products that contain a decongestant or antihistamine should not be given to children under 2 years of age because serious and possibly life-threatening side effects could occur. Therefore, claims for cough and cold products for clients less than 2 years of age are not covered by Texas Medicaid. Prior authorization for these agents will not be accepted.
- The Food and Drug Administration (FDA) has issued an advisory to consumers about using cough and cold medicines with multiple ingredients in pediatric patients due to the risk of accidental overdose. For safety purposes, claims for cough and cold products containing acetaminophen or ibuprofen are not covered by Texas Medicaid for ages ≥ 2 to < 6 years of age.
- In January 2018, the FDA issued a safety announcement requiring labeling changes for prescription cough and cold products containing codeine or hydrocodone to limit the use of these products to adults aged 18 years and older. Cough and cold products containing opioids are not covered by Texas Medicaid for ages < 18. Prior authorization for these agents will not be accepted.

#### Clinical Criteria Information Included in this Document

Cough and Cold Medications (Table A – drugs requiring prior authorization for children ages ≥ 2 to < 4 years of age)

- **Drugs requiring prior authorization**: the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic**: a description of how the prior authorization request will be evaluated against the clinical criteria rules
- Logic diagram: a visual depiction of the clinical criteria logic
- **References**: clinical publications and sources relevant to this clinical criteria

**Note**: Click the hyperlink to navigate directly to that section.

### Cough and Cold Medications (Table B – drugs requiring prior authorization for children ages ≥ 2 to < 6 years of age)

- **Drugs requiring prior authorization**: the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic**: a description of how the prior authorization request will be evaluated against the clinical criteria rules
- Logic diagram: a visual depiction of the clinical criteria logic
- **References**: clinical publications and sources relevant to this clinical criteria

**Note**: Click the hyperlink to navigate directly to that section.

### Cough and Cold Medications (Table C – drugs requiring prior authorization for children ages ≥ 2 to < 10 years of age)

- **Drugs requiring prior authorization**: the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- Logic diagram: a visual depiction of the clinical criteria logic
- References: clinical publications and sources relevant to this clinical criteria

**Note**: Click the hyperlink to navigate directly to that section.

### Cough and Cold Medications (Table D – drugs requiring prior authorization for children ages ≥ 2 to < 12 years of age)

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- Logic diagram: a visual depiction of the clinical criteria logic
- **References:** clinical publications and sources relevant to this clinical criteria

**Note**: Click the hyperlink to navigate directly to that section.

### **Cough and Cold Medications (Table E – Products Containing Opioids)**

• **Drugs Containing Opioids:** the list of drugs containing opioids

### Cough and Cold Medications (Table F – Products Containing Acetaminophen or Ibuprofen)

• **Drugs Containing Acetaminophen or Ibuprofen:** the list of drugs containing acetaminophen or ibuprofen

#### **Revision Notes**

Added GCN for Robafen DM liquid (45903) to Table D



### Cough and Cold Medications Table A

Drugs Requiring Prior Authorization for Children Ages
≥ 2 to < 4 Years

- Claims for cough and cold products for clients less than 2 years of age are not covered by Texas Medicaid. Prior authorization for these agents will not be accepted.
- Claims for cough and cold products containing acetaminophen or ibuprofen are not covered by Texas Medicaid for ages ≥ 2 to < 6 years of age.
- Cough and cold products containing opioids are not covered by Texas Medicaid for ages < 18. Prior authorization for these agents will not be accepted.
- The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

Table A	
Drugs Requiring Prior Authorization for Children ≥ 2 to < 4 Years of Age	
Label Name	GCN
APRODINE TABLET	96445
CHEST CONGESTION RELIEF SOLN	02512
CHEST CONGESTION RELIEF TABLET	18906
CHILD MUCINEX CHEST 100 MG PACKET	97123
CHLO TUSS LIQUID	35393
DECONEX IR TABLET	42022
DEXBROMPHENIR-PHENYLEPH 2-10MG	28379
ED BRON GP LIQUID	54250
HISTEX-PE SYRUP	29581
MUCUS RELIEF 400 MG TABLET	18906
MUCUS RELIEF SINUS TABLET	97358
MUCUS-CHEST CONG 200 MG/10 ML	02512
POLY-HIST PD LIQUID	34839
POLY-VENT IR TABLET	34787
RESCON-GG LIQUID	54250
ROBAFEN 100 MG/5 ML SYRUP	02512
RU-HIST D 10-4 MG TABLET	96609
RYNEX PE LIQUID	27207
RYNEX PSE LIQUID	12933
SILTUSSIN SA 100 MG/5 ML SYR	02512
STAHIST AD TABLET	31036

Table A	
Drugs Requiring Prior Authorization for Children ≥ 2 to < 4 Years of Age	
Label Name	GCN
TUSSIN MUCUS-CONG 200 MG/10 ML	02512



# Cough and Cold Medications Table A

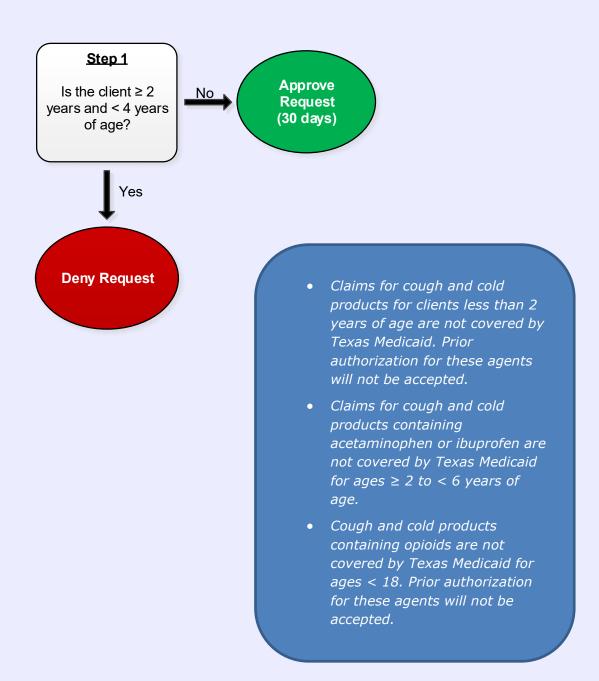
**Clinical Criteria Logic** 

1.	Is the client greater than or equal to $(\geq)$ 2 years and less than $(<)$ 4 years of
	age?
	[ ] Yes – Deny
	[] No – Approve (30 days)

- Claims for cough and cold products for clients less than 2 years of age are not covered by Texas Medicaid. Prior authorization for these agents will not be accepted.
- Claims for cough and cold products containing acetaminophen or ibuprofen are not covered by Texas Medicaid for ages ≥ 2 to < 6 years of age.
- Cough and cold products containing opioids are not covered by Texas Medicaid for ages < 18. Prior authorization for these agents will not be accepted.



### Cough and Cold Medications Table A





### Cough and Cold Medications Table B

Drugs Requiring Prior Authorization for Children Ages
≥ 2 to < 6 Years

- Claims for cough and cold products for clients less than 2 years of age are not covered by Texas Medicaid. Prior authorization for these agents will not be accepted.
- Claims for cough and cold products containing acetaminophen or ibuprofen are not covered by Texas Medicaid for ages ≥ 2 to < 6 years of age.
- Cough and cold products containing opioids are not covered by Texas Medicaid for ages < 18. Prior authorization for these agents will not be accepted.
- The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

Table B	
Drugs Requiring Prior Authorization for Children ≥ 2 to < 6 Years of Age	
Label Name	GCN
ALAHIST CF TABLET	43882
ALAHIST DM LIQUID	42443
ALAHIST PE 2-7.5 MG TABLET	48268
BROMPHEN-PSE-DM 2-30-10 MG/5 ML	96136
BROTAPP DM 1-15-5 MG/5 ML LIQUID	12934
CHEST CONGESTION RELIEF DM LIQ	53491
CHILD COUGH DM ER 30 MG/5 ML	17802
CHILD DELSYM COUGH 30 MG/5 ML	17802
CHILD MUCINEX COUGH 5-100 MG PK	99068
CHILD MUCINEX MULTI-SYMPTOM LQ	28875
CHILD MUCUS RELIEF M-S COLD LQ	28875
CHILD MUCUS-COUGH RELIEF LIQ	53497
CHILDREN COLD-COUGH LIQUID	26808
COUGH DM 30 MG/5 ML SUSPENSION	17802
COUGH DM SYRUP	53495
DECONEX DMX TABLET 17.5-400-10 MG TAB	46479
DELSYM 30 MG/5 ML SUSPENSION	17802
DELSYM COUGH+CHEST CONGST DM LQ	53497
DEXTROMETHORPHAN ER 30 MG/5 ML	17802
DIMAPHEN DM ELIXIR	26808
DM-GUAIF-PE 17.5-385-10 MG TAB	42056
DM-GUAIF-PE 18-200-10 MG/15 ML	34782
DOXYLAMINE-PHENYLEPH 7.5-10 MG	35587
ED A-HIST DM TABLET	37388
ED A-HIST LIQUID	14148
ED-A-HIST 4 MG-10 MG TABLET	25462

Table B	
Drugs Requiring Prior Authorization for Ch	ildren ≥ 2 to < 6 Years of Age
Label Name	GCN
ED-A-HIST DM LIQUID	19347
ENDACOF-DM LIQUID	26808
GS TUSSIN DM LIQUID	53495
GUAIFENESIN-PSE 375-60MG TAB	30316
HISTEX-DM SYRUP	36311
LOHIST-D LIQUID	44021
LOHIST-DM SYRUP	15847
M-END DMX LIQUID	30801
MUCINEX FAST-MAX CONGEST-COUGH	36524
MUCINEX FAST-MAX DM MAX LIQUID	53497
MUCUS RELIEF DM 20-400 MG TAB	23807
MUCUS RELIEF DM COUGH TABLET	23807
MUCUS RELIEF DM MAX LIQUID	53497
NASAL DECONGESTANT 0.05% SPRAY	34062
NASAL SPRAY 0.05%	34062
NASOPEN PE LIQUID	32676
NINJACOF LIQUID	37227
NOHIST-DM LIQUID	19347
NOHIST-LQ LIQUID	14148
PEDIATRIC COUGH-COLD LIQUID	96138
POLY HIST FORTE 10.5-10 MG TAB	46499
POLY HIST FORTE 7.5-10 MG TAB	35587
POLY-HIST DM LIQUID	34835
POLYTUSSIN DM SYRUP	44218
POLY-VENT DM TABLET	34799
PROMETHAZINE-DM SYRUP	13975
RESCON-DM LIQUID	93335
ROBAFEN CF LIQUID	53090
•	
ROBAFEN DM COUCH LIQUID	53495
ROBAFEN DM COUGH LIQUID	53491
RYMED TABLET	28476
RYNEX DM LIQUID	26808
SILTUSSIN DM COUGH SYRUP	53495
SILTUSSIN DM DAS 100-10 MG/5 ML	53491
SM NASAL SPRAY 0.05%	34062
SM TUSSIN DM LIQUID	53491
SM TUSSIN DM SYRUP	53495
TUSSIN CF MULTI-SYMPTOM COLD	53090
TUSSIN DM 400-20 MG/20 ML LIQ	53497
TUSSIN DM LIQUID	53491
TUSSIN DM SYRUP	53495
VANACOF DM 18-200-10 MG/15 ML	34782
VANACOF DMX 18-396-10 MG/15 ML	47463
VANACOF LIQUID	99788
VANATAB DM CAPLET	43602



## Cough and Cold Medications Table B

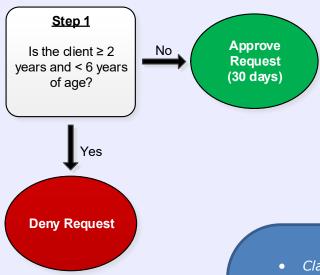
**Clinical Criteria Logic** 

1.	Is the client greater than or equal to $(\geq)$ 2 years and less than $(<)$ 6 years of
	age?
	[ ] Yes – Deny
	[ ] No – Approve (30 days)

- Claims for cough and cold products for clients less than 2 years of age are not covered by Texas Medicaid. Prior authorization for these agents will not be accepted.
- Claims for cough and cold products containing acetaminophen or ibuprofen are not covered by Texas Medicaid for ages ≥ 2 to < 6 years of age.
- Cough and cold products containing opioids are not covered by Texas Medicaid for ages < 18. Prior authorization for these agents will not be accepted.



### Cough and Cold Medications Table B



- Claims for cough and cold products for clients less than 2 years of age are not covered by Texas Medicaid. Prior authorization for these agents will not be accepted.
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### Cough and Cold Medications Table C

Drugs Requiring Prior Authorization for Children Ages
≥ 2 to < 10 Years

- Claims for cough and cold products for clients less than 2 years of age are not covered by Texas Medicaid. Prior authorization for these agents will not be accepted.
- Claims for cough and cold products containing acetaminophen or ibuprofen are not covered by Texas Medicaid for ages ≥ 2 to < 6 years of age.
- Cough and cold products containing opioids are not covered by Texas Medicaid for ages < 18. Prior authorization for these agents will not be accepted.
- The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

Table C	
Drugs Requiring Prior Authorization for Children ≥ 2 to < 10 Years of Age	
Label Name	GCN
BENZONATATE 100 MG CAPSULE	29840
BENZONATATE 150 MG CAPSULE	28229
BENZONATATE 200 MG CAPSULE	93007



# Cough and Cold Medications Table C

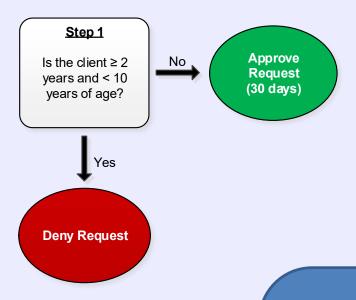
**Clinical Criteria Logic** 

1.	Is the client greater than or equal to $(\geq)$ 2 years and less than $(<)$ 10 years of
	age?
	[ ] Yes – Deny
	[] No – Approve (30 days)

- Claims for cough and cold products for clients less than 2 years of age are not covered by Texas Medicaid. Prior authorization for these agents will not be accepted.
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## Cough and Cold Medications Table C



- Claims for cough and cold products for clients less than 2 years of age are not covered by Texas Medicaid. Prior authorization for these agents will not be accepted.
- Claims for cough and cold products containing acetaminophen or ibuprofen are not covered by Texas Medicaid for ages ≥ 2 to < 6 years of age.
- Cough and cold products containing opioids are not covered by Texas Medicaid for ages < 18. Prior authorization for these agents will not be accepted.



### Cough and Cold Medications Table D

Drugs Requiring Prior Authorization for Children Ages
≥ 2 to < 12 Years

- Claims for cough and cold products for clients less than 2 years of age are not covered by Texas Medicaid. Prior authorization for these agents will not be accepted.
- Claims for cough and cold products containing acetaminophen or ibuprofen are not covered by Texas Medicaid for ages ≥ 2 to < 6 years of age.
- Cough and cold products containing opioids are not covered by Texas Medicaid for ages < 18. Prior authorization for these agents will not be accepted.
- The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

Table D	
Drugs Requiring Prior Authorization for Children ≥ 2 to < 12 Years of Age	
Label Name	GCN
DEXTROMETHORPHAN 15 MG LIQ GEL	17770
GUAIFENESIN/PSE ER 600-60 MG	54980
GUAIFENESIN-PSE ER 1200-120 MG	89731
MUCINEX D ER 1,200-120 MG TABLET	89731
MUCINEX D ER 600-60 MG TABLET	54980
MUCINEX DM ER 1,200-60 MG TAB	93677
MUCINEX DM ER 600-30 MG TABLET	53550
MUCINEX ER 1,200 MG TABLET	98863
MUCINEX ER 600 MG TABLET	35905
MUCUS DM MAX ER 1,200-60 MG TAB	93677
MUCUS RELIEF D ER 600-60 MG TB	54980
MUCUS RELIEF ER 1,200 MG TAB	98863
MUCUS RELIEF ER 600 MG TABLET	35905
MUCUS RLF DM ER 600-30 MG TAB	53550
MUCUS RLF DM MAX ER 1200-60 MG	93677
NIGHTTIME COUGH LIQUID	26684
RESCON TABLET	31879
ROBAFEN COUGH 15 MG LIQUIDGEL	17770
ROBAFEN DM 200-20 MG/20 ML LIQ	45903
SINUS RELIEF 1% NASAL SPRAY	34124
SUDOGEST SINUS & ALLERGY TAB	44023



### Cough and Cold Medications Table D

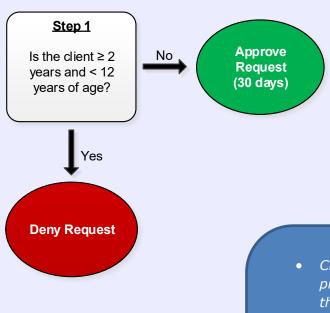
Clinical Criteria Criteria Logic

1.	Is the client greater than or equal to $(\geq)$ 2 years and less than $(<)$ 12 years of
	age?
	[ ] Yes – Deny
	[ ] No – Approve (30 days)

- Claims for cough and cold products for clients less than 2 years of age are not covered by Texas Medicaid. Prior authorization for these agents will not be accepted.
- Claims for cough and cold products containing acetaminophen or ibuprofen are not covered by Texas Medicaid for ages ≥ 2 to < 6 years of age.
- Cough and cold products containing opioids are not covered by Texas Medicaid for ages < 18. Prior authorization for these agents will not be accepted.



# Cough and Cold Medications Table D



- Claims for cough and cold products for clients less than 2 years of age are not covered by Texas Medicaid. Prior authorization for these agents will not be accepted.
- Claims for cough and cold products containing acetaminophen or ibuprofen are not covered by Texas Medicaid for ages
   ≥ 2 to < 6 years of age.</li>
- Cough and cold products containing opioids are not covered by Texas Medicaid for ages < 18. Prior authorization for these agents will not be accepted.



# Cough and Cold Medications Table E

#### **Products Containing Opioids**

- Claims for cough and cold products for clients less than 2 years of age are not covered by Texas Medicaid. Prior authorization for these agents will not be accepted.
- Claims for cough and cold products containing acetaminophen or ibuprofen are not covered by Texas Medicaid for ages ≥ 2 to < 6 years of age.
- Cough and cold products containing opioids are not covered by Texas Medicaid for ages < 18. Prior authorization for these agents will not be accepted.
- The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

Table E		
Products Containing Opioids		
Label Name	GCN	
CODEINE-GUAIFEN 10-100 MG/5 ML	91713	
GUAIATUSSIN AC LIQUID	91713	
GUAIFEN-CODEINE 100-10 MG/5 ML	91713	
GUAIFENESIN-CODEINE SYRUP	91713	
HYDROCODONE-CHLORPHEN ER SUSP	13974	
HYDROCODONE-HOMATROPINE 5-1.5	96041	
HYDROCODONE-HOMATROPINE SOLN	13973	
HYDROMET 5 MG-1.5 MG/5 ML SOLN	13973	
NINJACOF-XG LIQUID	30677	
PROMETHAZINE-CODEINE SOLUTION	13971	
PROMETHAZINE-CODEINE SYRUP	13971	
VIRTUSSIN AC 10-100 MG/5 ML LQ	91713	
VIRTUSSIN AC W-ALC 10-100 MG/5	91713	
VIRTUSSIN DAC LIQUID	54670	



## Cough and Cold Medications Table F

#### **Products Containing Acetaminophen or Ibuprofen**

- Claims for cough and cold products for clients less than 2 years of age are not covered by Texas Medicaid. Prior authorization for these agents will not be accepted.
- Claims for cough and cold products containing acetaminophen or ibuprofen are not covered by Texas Medicaid for ages ≥ 2 to < 6 years of age.
- Cough and cold products containing opioids are not covered by Texas Medicaid for ages < 18. Prior authorization for these agents will not be accepted.
- The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

Table F	
Products Containing Acetaminophen or Ibuprofen	
Label Name	GCN
ALLERGY MULTI-SYMPTOM CAPLET	85915
ALL-NITE COLD-FLU RELIEF LIQ	30232
CHILD MUCINEX M-S COLD DAY-NTE	37876
CHILD MUCINEX NIGHTTIME LIQ	35755
CHILDS MUCINEX COLD-CGH-SORE	30579
CHILDS MUCINEX COLD-FEVER LIQ	30579
DAYTIME COLD-FLU RELIEF LIQUID	97129
DAYTIME COLD-FLU RELIEF SFTGL	25093
DAY MULTI-SYMP FLU-SEVERE COLD	44033
DURAFLU 325-20-200-60 MG TAB	39986
FLU HBP 325-2-10 MG CAPLET	46697
MAPAP COLD FORMULA CAPLET	27135
MUCINEX COLD-FLU-SORETHROAT LQ	30577
MUCINEX FAST-MAX COLD-SINUS TB	26743
MUCINEX FAST-MAX DAY-NITE COLD	36522
MUCINEX FAST-MAX DAY-NITE CONG	37839
MUCINEX FAST-MAX NITE COLD-FLU	35755
MUCINEX FAST-MAX SEV COLD LIQ	30577
NIGHT SEVERE COLD-COUGH PKT	14359
NIGHTTIME COLD AND FLU LIQUID	30232
NIGHTTIME COLD-FLU LIQUID	30232

Table F		
Products Containing Acetaminophen or Ibuprofen		
Label Name	GCN	
NIGHTTIME COLD-FLU RLF SFTGL	25094	
NIGHTTIME SEVERE COLD-FLU LIQ	97134	
SEVERE COLD-FLU CAPLET	26742	
SINUS CONGESTION-PAIN CAPLET	25468	
SINUS CONGST-PAIN 325-200-5 MG	26743	
SINUS PRESSURE-PAIN CAPLET	25468	
SINUS-HEADACHE 5-325 MG CAPLET	25468	



### **Cough and Cold Medications**

#### **Clinical Criteria References**

- 1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2022. Available at **www.clinicalpharmacology.com**. Accessed on August 5, 2022.
- 2. Micromedex [online database]. Available at **www.micromedexsolutions.com**. Accessed on August 5, 2022.
- 3. Facts and Comparisons [online database]. Available at **www.online.factsandcomparisons.com**. Accessed on August 5, 2022.
- 4. 2022 ICD-10-CM Diagnosis Codes, Volume 1. 2022. Available at www.icd10data.com. Accessed on August 5, 2022.
- 5. Srinivasan A, Budnitz D, Shehab N, Cohen A. CDC. (2007, January 12). Infant Deaths Associated with Cough and Cold Medications. Retrieved October 14, 2014, from www.cdc.gov.
- 6. CDC Study Estimates 7,000 Pediatric Emergency Departments Visits Linked to Cough and Cold Medication. (2008, January 28). Retrieved October 16, 2014, from www.cdc.gov.
- 7. COMMITTEE ON DRUGS, 1996 TO 1997, C. (1997, June 1). Use of Codeine- and Dextromethorphan-Containing Cough Remedies in Children. Retrieved October 13, 2014, from www.pediatrics.aappublication.org.
- 8. Cold and Cough Medicines: Information for Parents. (2009, January 14). Retrieved October 14, 2014, from **www.cdc.gov**.
- 9. Cough and Cold Medications Over-The-Counter (OTC). (2009, February 1). Retrieved October 17, 2014, from **www.nationwidechildrens.org**.
- 10.Fashner J, Ericson K, Werner S. (2012, July 15). Treatment of the Common Cold in Children and Adults. Retrieved October 14, 2014, from www.aafp.org.
- 11.Guirguis-Blake, J. (2008, July 8). Over-the-Counter Medications for Acute Cough Symptoms. Retrieved October 13, 2014, from **www.aafp.org**.
- 12.Hampton L, Nguyen D, Edwards J, Budnitz D. (2013, November 11). Cough and Cold Medication Adverse Events After Market Withdrawal and Labeling Revision. Retrieved October 13, 2014, from www.pediatrics.aappublications.org.
- 13.Mazer-Amirshahi M, Reid N, van den Anker J, Litovitz J. (2013, June 14). Effect of cough and cold medication restriction and label changes on pediatric

- ingestions reported to United States poison centers. Retrieved October 14, 2014, from www.ncbi.nlm.nih.gov.
- 14.Mazer-Amirshahi M. (2014, December 1). Warnings have little impact on use of OTC cold medicines. Retrieved December 11, 2014, from www.aapnews.aappublications.org.
- 15.OTC Cough and Cold Products: Not For Infants and Children Under 2 Years of Age. (2008, January 17). Retrieved October 14, 2014, from www.fda.gov.
- 16.Preidt R. (2014, November 26). Steer Clear of Cold Meds for Babies, FDA Advises. Retrieved December 9, 2014, from www.consumer.healthday.com.
- 17.Revised Product Labels for Pediatric Over-the-Counter Cough and Cold Medicines. (2008, October 21). Retrieved October 14, 2014, from **www.cdc.gov**.
- 18.Schaefer M, Shehab N, Cohen A, Budnitz D. (2008, April 1). Adverse Events From Cough and Cold Medications in Children. Retrieved October 14, 2014, from www.pediatrics.aappublications.org.
- 19.Shehab N, Schaefer M, Kegler S, Budnitz D. (2010, November 22). Adverse Events From Cough and Cold Medications After a Market Withdrawal of Products Labeled for Infants. Retrieved October 13, 2014, from www.pediatrics.aappublications.org.
- 20. Withdrawal of Cold Medicines: Addressing Parent Concerns. (n.d.). Retrieved October 14, 2014, from **www.aap.org**.
- 21.2013 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 31st Annual Report.
- 22.Use of codeine- and dextromethorphan-containing cough remedies in children. American Academy of Pediatrics. Committee on Drugs. Pediatrics 1997; 99:918.
- 23.Mazer-Amirshahi M, Rasooly I, Brooks G, Pines J, May L, van den Anker J. The impact of pediatric labeling changes on prescribing patterns of cough and cold medications. J Pediatr 2014; 165:1024-8.
- 24.Dart RC, Paul IM, Bond GR, et al. Pediatric fatalities associated with over the counter (nonprescription) cough and cold medications. Ann Emerg Med. 2009;53:411-417.
- 25. Shields MD, Bush A, Everard ML, et al. BTS guidelines: recommendations for the assessment and management of cough in children. Thorax 2008;63(Suppl 3): iii1e15
- 26.Yang M, So TY. Revisiting the safety of over-the-counter cough and cold medications in the pediatric population. Clin Pediatr (Phila) 2014;53:326-30.
- 27. Codeine. Poisindex. (Micromedex)

- 28. Fashner J., Ericson K., Werner S. (2012). Treatment of the common cold in children and adults. Am. Fam. Phys. 86 153–159
- 29.Texas Poison Center Network. Reported cough/cold product ingestions among patient 0-6 years. (Non-exposures and calls from outside of Texas have been excluded.)
- 30.Linn KA, Long MT, Pagel PS. "Robo-Tripping": Dextromethorphan Abuse and its Anesthetic Implications. Anesth Pain Med. 2014 December; 4(5):e20990.
- 31. Guidelines for Evaluating Chronic Cough in Pediatrics: ACCP Evidence-Based Clinical Practice Guidelines. Chest. 2006;129(1\_suppl):260S-283S.
- 32.U.S. Food and Drug Administration (FDA). Drug Safety Communication. FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women. Available at **www.fda.gov**. April 20, 2017.
- 33.U.S. Food and Drug Administration (FDA). Drug Safety Podcasts. FDA requires labeling changes for prescription opioid cough and cold medicines to limit their use to adults 18 years and older. Available at **www.fda.gov**. January 11, 2018.



### **Cough and Cold Medications**

#### **Publication History**

### **Publication History**

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
07/23/2015	Presented to DUR Board
08/06/2015	Initial publication and posting to website
11/03/2015	Drugs Requiring PA – lists updated
01/20/2017	GCNs for Cough Syrup and Deconex IR added to Table A GCN for J-Tan D PD Drops updated in Table A GCNs for Alahist DM and Deconex DM added to Table B GCN for Mucinex Fast-Max Congest-Cough updated in Table B GCNs for Flowtuss and Hycofenix added to Table D
08/03/2017	Added statement "Products containing codeine are not covered by Texas Medicaid for ages < 12" to notes sections of document Biannual review of cough and cold agents Updated references
02/12/2018	Biannual review of cough and cold agents Removed cough and cold agents containing hydrocodone that are no longer recommended for use in children less than 18 years of age. Updated statement to read: Claims for cough and cold products containing acetaminophen or ibuprofen are not covered by Texas Medicaid for ages ≥ 2 to < 6 years of age. Products containing opioids are not covered by Texas Medicaid for ages < 18. (Removed the statement about use of codeine in <12 years of age).Prior authorization for these agents will not be accepted. Added GCNs for Alahist CF tablet, Poly Hist Forte tablet, Vanatab AC caplet and Vanatab DM caplet Removed GCNs for J-max syrup, J-tan PD drops and Rezira solution Reviewed dosing guidelines Updated references
03/26/2019	Updated to include formulary statement (The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.) on each 'Drug Requiring PA' table
09/26/2019	Added GCNs for Deconex DMX and Poly Hist Forte to drug table B

Publication Date	Notes
12/30/2019	Added GCN for Polytussin DM to drug table B
03/10/2020	Added GCNs for Children's Dayclear allergy cough and Vanacof DMX to Table B
04/15/2021	Annual review by staff Added GCNs for child cold-allergy liquid (27207); child Mucinex chest packet (97123) to Table A Added GCNs for Child Mucinex cough pack (99068); doxylamine-PE 7.5-10 (35587); Endacof-DM (26808) to Table B Updated references
01/13/2022	Reviewed drug tables Added tables for opioid containing cough and cold medications and for products containing acetaminophen or ibuprofen
10/20/2022	Annual review by staff Updated references
11/18/2022	Added GCN for Nighttime Cough Liquid (26684) ) and Sinus Relief 1% Nasal Spray (34124) to Table D Added GCN for Day Multi-Symptom Flu-Severe Cold (44033) to Table F
02/28/2023	Added GCN for Robafen DM liquid (45903) to Table D