QUANTITY LIMIT PRIOR AUTHORIZATION CRITERIA

DRUG CLASS OPIOID CONTAINING COUGH AND COLD PRODUCTS (RX AND OTC)

BRAND NAME (generic)

CAPCOF

(codeine/phenylephrine/chlorpheniramine syrup)

CODITUSSIN AC

(codeine/guaifenesin syrup)

CODITUSSIN DAC

(codeine/guaifenesin/pseudoephedrine syrup)

HISTEX AC

(codeine/phenylephrine/triprolidine syrup)

(hydrocodone/chlorpheniramine extended-release suspension)

(hydrocodone/homatropine tablet)

HYDROMET

(hydrocodone/homatropine solution)

MAR-COF BP

(codeine/pseudoephedrine/brompheniramine syrup)

MAR-COF CG

(codeine/guaifenesin syrup)

MAXI-TUSS AC

(codeine/guaifenesin liquid)

MAXI-TUSS CD

(codeine/phenylephrine/chlorpheniramine liquid)

M-CLEAR WC

(codeine/guaifenesin liquid)

M-END PE

(codeine/phenylephrine/brompheniramine liquid)

NINJACOF-XG

(codeine/guaifenesin liquid)

POLY-TUSSIN AC

(codeine/phenylephrine/brompheniramine liquid)

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(promethazine/codeine)

(promethazine/codeine/phenylephrine)

PRO-RED AC

(codeine/dexchlorpheniramine/phenylephrine syrup)

RYDEX

(codeine/pseudoephedrine/brompheniramine liquid)

TUSNEL C

(codeine/guaifenesin/pseudoephedrine liquid)

TUSSICAPS

(hydrocodone/chlorpheniramine extended-release capsule)

TUXARIN ER

(codeine/chlorpheniramine extended-release tablet)

TUZISTRA XR

(codeine/chlorpheniramine extended-release suspension)

VIRTUSSIN DAC

(codeine/guaifenesin/pseudoephedrine liquid)

Status: CVS Caremark Criteria

Type: Quantity Limit; Post Limit Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Hydrocodone and homatropine solution, tablets

Hydrocodone and homatropine is indicated for the symptomatic relief of cough in patients 18 years of age and older.

Limitations of Use:

- Not indicated for pediatric patients under 18 years of age.
- Contraindicated in pediatric patients less than 6 years of age.
- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve
 hydrocodone and homatropine for use in adult patients for whom the benefits of cough suppression are expected
 to outweigh the risks, and in whom an adequate assessment of the etiology of the cough has been made.

Hydrocodone Polistirex and Chlorpheniramine Polistirex Suspension, Extended-Release

Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Oral Suspension is indicated for the temporary relief of cough and upper respiratory symptoms associated with allergy or the common cold in patients 18 years of age or older.

Important Limitations of Use

Not indicated for pediatric patients under 18 years of age.

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- Contraindicated in pediatric patients less than 6 years of age.
- Because of the risks of addiction, abuse and misuse with opioids, even at recommended doses, reserve
 Hydrocodone Polistirex and Chlorpheniramine Polistirex for use in adult patients for whom the benefits of cough
 suppression are expected to outweigh the risk, and in whom an adequate assessment of the etiology of the cough
 has been made.

Promethazine with codeine oral solution

Promethazine with codeine oral solution is indicated for the temporary relief of coughs and upper respiratory symptoms associated with allergy or the common cold in patients 18 years of age and older.

Limitations of Use:

- Not indicated for pediatric patients under 18 years of age.
- Contraindicated in pediatric patients under 12 years of age.
- Contraindicated in pediatric patients 12 to 18 years of age after tonsillectomy and/or adenoidectomy.
- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve
 promethazine with codeine oral solution for use in adult patients for whom the benefits of cough suppression are
 expected to outweigh the risks, and in whom an adequate assessment of the etiology of the cough has been
 made.

Promethazine, codeine, phenylephrine oral solution

Promethazine, codeine, phenylephrine Oral Solution is indicated for the temporary relief of coughs and upper respiratory symptoms, including nasal congestion, associated with allergy or the common cold in patients 18 years of age and older.

Limitations of Use:

- Not indicated for pediatric patients under 18 years of age.
- Contraindicated in pediatric patients under 12 years of age.
- Contraindicated in pediatric patients 12 to 18 years of age after tonsillectomy or adenoidectomy.
- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve
 promethazine, codeine, phenylephrine oral solution for use in adult patients for whom the benefits of cough
 suppression are expected to outweigh the risks, and in whom an adequate assessment of the etiology of the
 cough has been made.

TussiCaps

TussiCaps (hydrocodone polistirex and chlorpheniramine polistirex) extended-release capsules are indicated for relief of cough and upper respiratory symptoms associated with allergy or a cold in adults and children 6 years of age and older.

Tuxarin ER

Tuxarin ER is indicated for the relief of cough and symptoms associated with upper respiratory allergies or a common cold in adults 18 years of age and older.

Limitations of Use:

Not indicated for pediatric patients under 18 years of age.

Tuzistra XR

Tuzistra XR is indicated 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.

Limitations of Use:

- Not indicated for pediatric patients under 18 years of age.
- Contraindicated in pediatric patients under 12 years of age.
- Contraindicated in pediatric patients 12 to 18 years of age after tonsillectomy or adenoidectomy.
- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve Tuzistra
 XR for use in adult patients for whom the benefits of cough suppression are expected to outweigh the risks, and in
 whom an adequate assessment of the etiology of the cough has been made.

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OVER-THE-COUNTER PRODUCT USES

CapCof

Temporarily relieves these symptoms due to common cold, hay fever (allergic rhinitis), or other upper respiratory allergies:

- Runny nose
- Sneezing
- Itching of the nose or throat
- Itchy, watery eyes
- Cough due to minor throat and bronchial irritation
- Nasal congestion
- · Reduces swelling of nasal passages

Coditussin AC

Temporarily relieves these symptoms due to common cold, hay fever (allergic rhinitis), or other upper respiratory allergies:

- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive

Coditussin DAC

Temporarily relieves these symptoms due to common cold, hay fever (allergic rhinitis), or other upper respiratory allergies:

- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- reduces swelling of nasal passages

Histex AC

Temporarily relieves these symptoms due to common cold, hay fever (allergic rhinitis), or other upper respiratory allergies:

- Runny nose
- Sneezing
- Itching of the nose or throat
- Itchy, watery eyes
- Cough due to minor throat and bronchial irritation
- Nasal congestion
- Reduces swelling of nasal passages

Mar-cof BP

Temporarily relieves these symptoms due to cold, hay fever or other respiratory allergies:

- runny nose, sneezing, itching of the nose or throat, and itchy watery eyes
- cough due to minor throat and bronchial irritation
- nasal congestion

Mar-cof CG

Temporarily relieves:

- cough due to minor throat and bronchial irritations as may occur with a cold or inhaled irritants
- your cough to help you sleep
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and makes cough more productive

Maxi-Tuss AC

Temporarily relieves:

- cough due to minor throat and bronchial irritations as may occur with a cold or inhaled irritants
- · your cough to help you sleep
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and makes cough more productive

Maxi-Tuss CD

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Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- cough due to minor throat and bronchial irritation
- runny nose
- sneezing
- · itching of the nose or throat
- · itchy, watery eyes
- nasal congestion
- reduces swelling of nasal passages
- calms the cough control center and relieves coughing

M-Clear WC

Temporarily relieves these symptoms due to the common cold:

- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive

M-END PE

Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- cough due to minor throat and bronchial irritation
- nasal congestion
- itching of nose or throat
- runny nose
- itchy, watery eyes
- sneezing
- reduces swelling of nasal passages

Ninjacof-XG

Temporarily relieves:

- cough due to minor throat and bronchial irritations
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive

Poly-Tussin AC

Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis), or other upper respiratory allergies:

- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- cough due to minor throat and bronchial irritation
- nasal congestion
- reduces swelling of the nasal passages

Pro-Red AC

Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis), or other upper respiratory allergies:

- cough due to minor throat and bronchial irritation
- nasal congestion
- reduces swelling of nasal passages
- runny nose
- sneezing
- itching of nose or throat
- itchy, watery eyes

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Rydex

Temporarily relieves these symptoms due to the common cold, hay fever or other upper respiratory allergies (allergic rhinitis):

- cough due to minor throat and bronchial irritation
- nasal congestion
- reduces swelling of the nasal passages
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes

Tusnel C

Uses:

- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily relieves: nasal congestion due to the common cold, hay fever or other upper respiratory allergies and nasal congestion associated with sinusitis, cough due to minor bronchial irritation as may occur with the common cold
- temporarily restores freer breathing through the nose
- · calms the cough control center and relieves coughing

Virtussin DAC

Uses:

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- temporarily relieves nasal congestion due to the common cold
- · temporarily restores freer breathing through the nose
- · helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- calms the cough control center and relieves coughing

QUANTITY LIMIT**

LIMIT CRITERIA This limit is coded for daily dose.	
Drug	Daily Limit
CapCof (codeine/phenylephrine/chlorpheniramine [10 mg-5 mg-2 mg/5 mL] syrup)	60 mL/day
Coditussin AC (codeine/guaifenesin [10 mg-200 mg/5 mL] syrup)	60 mL/day
Coditussin DAC (codeine/guaifenesin/pseudoephedrine [10 mg-200 mg-30 mg/5 mL] syrup)	40 mL/day
Histex AC (codeine/phenylephrine/triprolidine [10 mg-10 mg-2.5 mg/5 mL] syrup)	20 mL/day
(hydrocodone and homatropine [5 mg-1.5 mg/5 mL] solution)	30 mL/day
(hydrocodone and homatropine [5 mg-1.5 mg] tablets)	6 tablets/day
(hydrocodone polistirex and chlorpheniramine polistirex [10 mg – 8 mg/5 mL] suspension, extended-release)	10 mL/day
Mar-cof BP (codeine/pseudoephedrine/brompheniramine [7.5 mg-30 mg-2 mg/5 mL] syrup)	60 mL/day
Mar-cof CG (codeine/guaifenesin [7.5 mg-225 mg/5 mL] syrup)	45 mL/day
Maxi-Tuss AC (codeine/guaifenesin [10 mg-100 mg/5 mL] liquid)	60 mL/day

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Maxi-Tuss CD (codeine/phenylephrine/chlorpheniramine [10 mg-10 mg-4 mg/5 mL] liquid)	30 mL/day
M-Clear WC (codeine/guaifenesin [6.33 mg-100 mg/5 mL] liquid)	90 mL/day
M-END PE (codeine/phenylephrine/brompheniramine [6.33 mg-3.33 mg-1.33 mg/5 mL] liquid)	90 mL/day
Ninjacof-XG (codeine/guaifenesin [8 mg-200 mg/5 mL] liquid)	60 mL/day
Poly-Tussin AC (codeine/phenylephrine/brompheniramine [10 mg-10 mg-4 mg/5 mL] liquid)	30 mL/day
(promethazine with codeine [6.25 mg-10 mg/5 mL] oral solution)	30 mL/day
(promethazine, codeine, phenylephrine [6.25 mg-10 mg-5 mg/5 mL] oral solution)	30 mL/day
Pro-RED AC (codeine/dexchlorpheniramine/phenylephrine [9 mg-1 mg-5 mg/5 mL] syrup)	60 mL/day
Rydex (codeine/pseudoephedrine/brompheniramine [6.33 mg-10 mg-1.33 mg/5 mL] liquid)	90 mL/day
Tusnel C (codeine/guaifenesin/pseudoephedrine liquid [10 mg-100 mg-30 mg/5 mL])	40 mL/day
TussiCaps (hydrocodone/chlorpheniramine extended-release [10 mg-8 mg] capsule)	2 capsules/day
Tuxarin ER (codeine/chlorpheniramine extended-release [54.3 mg-8 mg] tablet)	2 tablets/day
Tuzistra XR (codeine/chlorpheniramine [14.7 mg-2.8 mg/5 mL] extended-release suspension)	20 mL/day
Virtussin DAC (codeine/guaifenesin/pseudoephedrine [10 mg-100 mg-30 mg/5 mL] liquid)	40 mL/day

^{**}If the patient is requesting more than the initial quantity limit, then the claim will reject with a message indicating that the daily dose has been exceeded. No PA allowed to exceed daily dose limit.

DURATION LIMIT*

Drug	Duration Limit (per month)
ALL TARGET DRUGS	7-day supply

^{*}If the patient is requesting more than a 7-day supply within the past month, then the claim will reject with a message indicating that the patient can receive a 7-day supply or submit a prior authorization (PA): "MAX 7 DS per 30 days. PA reg call 800-XXX-XXXX." [Note: Benefits coding to populate correct PA phone number.]

The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

• The patient has a persistent cough requiring treatment beyond 7 days

AND

• The patient has been reevaluated for the cause of the cough to address any underlying pathology, such as foreign body or lower respiratory tract disease

AND

• The need for continued use of the requested drug has been assessed considering the relative incidence of adverse reactions, and the development of addiction, abuse, or misuse

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