BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 11/17/16**
SECTION: DRUGS	**LAST REVIEW DATE: 11/16/17**
	LAST CRITERIA REVISION DATE: 11/16/17
	ARCHIVE DATE:

FLOWTUSS™ (hydrocodone bitartrate and guaifenesin) oral solution
OBREDON™ (hydrocodone bitartrate and guaifenesin) oral solution

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

FLOWTUSS™ (hydrocodone bitartrate and guaifenesin) oral solution
OBREDON™ (hydrocodone bitartrate and guaifenesin) oral solution (cont.)

Description:

Flowtuss (hydrocodone bitartrate and guaifenesin) and Obredon (hydrocodone bitartrate and guaifenesin) are a combination of an antitussive and an expectorant indicated for the symptomatic relief of cough and to loosen mucus associated with the common cold. Flowtuss (hydrocodone bitartrate and guaifenesin) and Obredon (hydrocodone bitartrate and guaifenesin) are not indicated for pediatric patients under 18 years of age. There is no clinical evidence that any one product is safer or more effective than any other product. There are many low-cost prescription and over-the-counter (OTC; non-prescription) options available, which will meet the needs of most patients.

The common cold is a benign, self-limiting disease. Symptoms usually last for about 7-10 days. Symptomatic therapy is the mainstay treatment of the common cold. The goal of therapy is to control symptoms with medications such as antihistamines, antitussives, expectorants, and/or decongestants. The choice of which combination product is often dependent upon symptoms present.

Hydrocodone is a semisynthetic narcotic antitussive and analgesic with multiple actions qualitatively similar to those of codeine. The precise mechanism of action of hydrocodone and other opiates is not known; however, hydrocodone is believed to act directly on the cough center. Codeine also provides symptomatic cough relief and is available in combination with an expectorant.

Other antitussive agents include benzonatate, available through a prescription, and dextromethorphan, that is found in many OTC products. Benzonatate, suppresses cough through a peripheral action, anesthetizing the stretch or cough receptors of vagal afferent fibers, which are located in the respiratory passages, lungs, and pleura. It may also, may suppress transmission of the cough reflex by a central mechanism, at the level of the medulla. Dextromethorphan decreases the sensitivity of cough receptors and interrupts cough impulse transmission by depressing the medullar cough center. It is structurally related to codeine.

Guaifenesin is an expectorant which promotes or facilitates the removal of secretions from the respiratory tract. The precise mechanism of action of guaifenesin is not known; however, it is thought to act as an expectorant by increasing the volume and reducing the viscosity of secretions in the trachea and bronchi. In turn, this may increase the efficiency of the cough reflex and facilitate removal of the secretions. Adhesiveness and surface tension of respiratory tract fluid is reduced with enhanced removal of viscous mucus. It is available in numerous OTC preparations.

Flowtuss (hydrocodone bitartrate/guaifenesin) solution
Obredon (hydrocodone bitartrate/guaifenesin) solution

Medication class:
Antitussive/Expectorant

FDA-approved indication(s):
- Symptomatic relief of cough and to loosen mucus associated with the common cold in adults.

Recommended Dose:
- Hydrocodone 5 mg/guaifenesin 400 mg (10 mL) every 4 to 6 hours.

Maximum dosage
- Hydrocodone 30 mg/guaifenesin 2,400 mg (60 mL) per 24 hours.

Available Dosage Forms:
- Hydrocodone 2.5 mg/guaifenesin 200 mg per 5 mL

Limitations of use:
- Not indicated for pediatric patients under 18 years of age.

Warnings and Precautions:
- Concurrent use of opioid with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death
- Avoid use with opioids, antihistamines, antipsychotics, anti-anxiety agents, or other CNS depressants (including alcohol)
- Avoid use in individuals with head injury, intracranial lesions or increased intracranial pressure
- Do not use with MAO inhibitors or tricyclic antidepressants
- Use anticholinergic agents with caution in order to avoid paralytic ileus
- Should not be used in patients with diabetes, thyroid disease, Addison's disease, prostatic hypertrophy, or urethral stricture, or asthma
- Should not be used in patients with a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or where the cough is accompanied by excessive mucus production
- Woman who is breast feeding an infant or child should stop breast feeding

FLOWTUSS™ (hydrocodone bitartrate and guaifenesin) oral solution
OBREDON™ (hydrocodone bitartrate and guaifenesin) oral solution (cont.)

Criteria:

- **Criteria for initial therapy:** Flowtuss (hydrocodone bitartrate and guaifenesin) and Obredon (hydrocodone bitartrate and guaifenesin) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual is 18 years of age or older

2. A confirmed diagnosis of cough associated with the common cold

3. Individual has failure, contraindication, and intolerance to **ALL** of the following:
   - Preferred agents include:
     - Benzonatate oral capsule and simultaneous use with guaifenesin oral
     - Guaifenesin-codeine oral solution or syrup
     - Dextromethorphan and guaifenesin product

4. Individual has failure, contraindication, or intolerance to hydrocodone suspension

5. There are **NO** contraindications:
   - Contraindications include:
     1. Individuals with known hypersensitivity to hydrocodone bitartrate, guaifenesin, or any of the inactive ingredients of Flowtuss
     2. Individuals receiving monoamine oxidase inhibitor (MAOI) therapy or within 14 days of stopping such therapy

Initial approval duration: One time for Quantity of 480ml or less and less than 7 days

Resources:

Flowtuss. Package Insert. Revised by manufacturer 9/2015. Accessed 9/16/16.

Obredon. Package Insert. Revised by manufacturer 6/2015. Accessed 01/24/17.

UpToDate: Treatment of subacute and chronic cough in adults. Current through Sep 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/treatment-of-subacute-and-chronic-cough-in-adults?source=search_result&search=cough%20suppressant%20adult&selectedTitle=1~121#H19

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:		Dosage Form:
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

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