BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/16/17
LAST REVIEW DATE: 5/16/19
LAST CRITERIA REVISION DATE: 5/16/19
ARCHIVE DATE:

BONJESTA® (doxylamine-pyridoxine) oral tablet extended release 20-20 mg
DICLEGIS® (doxylamine-pyridoxine) oral tablet delayed release 10-10 mg

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.**

BONJESTA® (doxylamine-pyridoxine) oral tablet extended release 20-20 mg DICLEGIS® (doxylamine-pyridoxine) oral tablet delayed release 10-10 mg (cont.)

Criteria:

- **Criteria for initial therapy:** Bonjesta and Diclegis are 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 nausea and vomiting of pregnancy
  3. Individual has failure, contraindication or intolerance to simultaneous use of generic **doxylamine** and generic **pyridoxine** (Vitamin B6)
  4. **Additional criteria for Bonjesta**: Individual has failure, contraindication or intolerance to Diclegis
  5. Bonjesta and Diclegis will not be used concurrently with each other
  6. There are **NO** contraindications.
     - Contraindications include:
       - Known hypersensitivity to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride or any inactive ingredient in the formulation
       - Monoamine oxidase (MAO) inhibitors intensify and prolong the adverse central nervous system effects of Diclegis

  Initial approval duration: 9 months

Description:

Bonjesta and Diclegis are fixed dose combination drug products of doxylamine succinate and pyridoxine hydrochloride, indicated for the treatment of nausea and vomiting of pregnancy (NVP) in women who do not respond to conservative management. These agents have not been studied in woman with hyperemesis gravidarum. The mechanism of action of Diclegis and Bonjesta are unknown, however, doxylamine is known to compete with histamine for H1-receptor sites and block the chemoreceptor trigger zone thereby decreasing nausea and vomiting.

Diclegis is formulated as a delayed release (enteric coated) tablet containing 10 mg of doxylamine and 10 mg of pyridoxine. Bonjesta is formulated as an extended release tablet containing an enteric coated core of 10 mg doxylamine and 10 mg of pyridoxine and an immediate release coating containing 10 mg of doxycycline and 10 mg of pyridoxine.

Both Diclegis and Bonjesta are considered safe to use during pregnancy. However women should not breastfeed while using doxylamine succinate/pydridoxine HCl.

BONJESTA® (doxylamine-pyridoxine) oral tablet extended release 20-20 mg DICLEGIS® (doxylamine-pyridoxine) oral tablet delayed release 10-10 mg (cont.)

The active ingredients of Bonjesta and Diclegis are available over-the-counter (OTC) as separate products. OTC products that contain doxylamine succinate are Unisom®, Nitetime Sleep-Aid, and Sleep Aid. OTC products that contain pyridoxine hydrochloride are pyridoxine and Vitamin B-6.

During pregnancy, 70-85% of women experience nausea and vomiting, commonly known as morning sickness. The most severe form, hyperemesis gravidarum, occurs in 0.5-2% of pregnancies, causes weight loss, and is the second most common cause of hospitalization during pregnancy. Early treatment of NVP may help prevent progression to hyperemesis gravidarum.

The 2015 clinical consensus guidelines for NVP from the American College of Obstetricians and Gynecologists (ACOG) recommends pyridoxine alone or in combination with doxylamine as first line pharmacologic therapy.

Resources:

Bonjesta product information accessed 04-22-19 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=dba60bb4-54ff-4e06-b8d2-acbbd3717666

Diclegis product information accessed 04-22-19 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8bde08f6-e8bd-4e90-baa7-82e01876a86a

Bonjesta. Package Insert. Revised by manufacturer 11/2017. Accessed 4/03/17.

Diclegis. Package Insert. Revised by manufacturer 9/2013. Accessed 10/13/17.

Bonjesta product information accessed 05-04-18 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=dba60bb4-54ff-4e06-b8d2-acbbd3717666

Diclegis product information accessed 05-04-18 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8bde08f6-e8bd-4e90-baa7-82e01876a86a

UpToDate: Treatment and outcome of nausea and vomiting of pregnancy. Current through Apr 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/treatment-and-outcome-of-nausea-and-vomiting-of-pregnancy?search=nausea%20and%20vomiting%20in%20pregnancy&source=search_result&selectedTitle=1~121&usage_type=default&display_rank=1

Goodwin TM and Ramin SM: Nausea and vomiting of pregnancy. Practice Bulletin No. 153. American College of Obstetricians and Gynecologists. Obstet Gynecol 2015; 126:e12-24.

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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.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.