BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
750 9th St NW
Washington, D.C. 20001
202.942.1000
Fax 202.942.1125

5.50.016

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Gastrointestinal agents	**Original Policy Date:**	May 18, 2018
Subject:	Doxylamine Pyridoxine	**Page:**	1 of 5

Last Review Date: June 13, 2024

Doxylamine Pyridoxine

Description

Bonjesta, Diclegis (doxylamine-pyridoxine)

Background
Nausea and vomiting of pregnancy (NVP) is a common problem that afflicts approximately 44 – 89% of pregnant women during their pregnancies. NVP generally starts around 4-6 weeks of pregnancy, peaks around 8 – 12 weeks, and then tapers off after around 20 weeks (however recent evidence suggests many women may experience NVP throughout pregnancy, even into late pregnancy). Conservative measures are often recommended before medications. Conservative measures involve dietary and lifestyle changes, which include: eating smaller and more frequent meals, staying adequately hydrated, and resting appropriately. Once conservative measures have failed, medications are used. The pregnancy category A medication(s) of choice include pyridoxine hydrochloride (Vitamin B_6) and doxylamine succinate (Unisom®) which are available separately over the counter. Legend medications, Diclegis and Bonjesta, include both of these agents in one tablet and are available with a prescription (1-5).

Regulatory Status
FDA-approved indications: Bonjesta and Diclegis are fixed dose combination drug products of doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, a Vitamin B6 analog, indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management (4-5).

Diclegis contains 10 mg of doxylamine succinate and 10 mg of pyridoxine hydrochloride in a delayed release dosage form. Bonjesta consist of an enteric-coated core containing 10 mg

doxylamine succinate and 10 mg pyridoxine hydrochloride, and an immediate release coating of 10 mg doxylamine succinate and 10 mg pyridoxine hydrochloride. These medications are intended to be taken on a daily basis and not as needed for nausea (physician must reassess patient throughout pregnancy to determine if continued use is needed) (4-5).

The safety and effectiveness of Bonjesta and Diclegis in pediatric patients have not been established (4-5).

Related policies
5HT3 Antagonists, Cannabinoids, NK-1 Antagonists

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Bonjesta and Diclegis may be considered **medically necessary** if the conditions indicated below are met.

Bonjesta and Diclegis may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Nausea and/or vomiting of pregnancy (NVP)

AND ALL of the following:

1. Patient has failed conservative measurements (Appendix 1)
2. Inadequate treatment response, or intolerance to doxylamine (e.g., Unisom®) and pyridoxine (Vitamin B_6) separately.

3. Prescriber agrees to monitor the patient during pregnancy to determine whether continued use of the medication is needed.

Prior–Approval *Renewal* Requirements

None

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity

Drug	Quantity
Diclegis	360 tablets per 90 days **OR**
Bonjesta	180 tablets per 90 days

Duration 9 months – Only 1 Prior Authorization allowed per pregnancy

Prior–Approval *Renewal* Limits

None

Rationale

Summary

Nausea and vomiting of pregnancy (NVP) is a common problem that afflicts approximately 44 – 89% of pregnant women during their pregnancies. Conservative measures are often recommended before medications. The pregnancy category A medication(s) of choice include pyridoxine hydrochloride (Vitamin B_6) and doxylamine succinate (Unisom®) which are available separately over the counter. Bonjesta and Diclegis are fixed dose combination drug products of doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, a Vitamin B6 analog, indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management (1-5).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Bonjesta and Diclegis while maintaining optimal therapeutic outcomes.

References

1. Briggs GG, Freeman RK, Towers CV, Forinash AB. Drugs in Pregnancy and Lactation. 11th ed. Philadelphia, PA: Wolters Kluwer, 2017.
2. Niebyl, JR and Briggs GG. The Pharmacologic Management of Nausea and Vomiting of Pregnancy. Supplement to The Journal of Family Practice. Vol 63 (2), S31; February 2014.
3. Einarson TR, Piwko C, Koren G. Prevalence of nausea and vomiting of pregancy in the USA: a meta analysis. J Popul Ther Clin Pharmacol. 2013;20(2):e163-e170.
4. Bonjesta [package insert]. Bryn Mawr, PA: Dushesnay USA, Inc.; October 2022.
5. Diclegis [package insert]. Bryn Mawr, PA: Dushesnay USA, Inc.; June 2018.

Policy History

Date	Action
May 2018	Addition to PA
June 2018	Annual review
March 2019	Annual review and reference update
March 2020	Annual review
March 2021	Annual review
March 2022	Annual review
March 2023	Annual review and reference update. Changed policy number to 5.50.016
June 2023	Annual review
March 2024	Annual review
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.

Appendix 1

Conservative Measures for NVP [1,2,3]
Maintain adequate hydration (2 liters of water daily)
Eat small, frequent meals, avoiding a full or empty stomach
Eat bland foods, avoid spicy and odorous foods
Take frequent naps
Consume ice chips or very cold beverages
Eat simple dry carbohydrates (like crackers) prior to getting out of bed in the morning