

## 5.50.16

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2021
<b>Subsection:</b>	Gastrointestinal agents	<b>Original Policy Date:</b>	May 18, 2018
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**Last Review Date:** March 12, 2021

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## Doxylamine Pyridoxine

### Description

#### Bonjesta, Diclegis (doxylamine-pyridoxine)

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#### 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<sub>6</sub>) 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 indication: Bonjesta and Diclegis are fixed dose combination drug products of doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, a Vitamin B<sub>6</sub> 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

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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).

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## 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 are **medically necessary** for pregnant women 18 years of age and older experiencing nausea and vomiting of pregnancy (NVP) and if the conditions indicated below are met.

Bonjesta and Diclegis are **investigational** for people under 18 years of age and 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)

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2. Inadequate treatment response, or intolerance to doxylamine (e.g. Unisom®) and pyridoxine (Vitamin B<sub>6</sub>) separately.
3. Prescriber agrees to monitor the patient during pregnancy to determine whether continued use of the medication is needed.

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## Prior-Approval *Renewal* Requirements

None

### Policy Guidelines

## Pre-PA Allowance

None

## Prior-Approval Limits

### Quantity

Drug	Quantity
Diclegis	360 tablets per 90 days <b>OR</b>
Bonjesta	180 tablets per 90 days

**Duration** 9 months – Only 1 Prior Authorization allowed per pregnancy

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## 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<sub>6</sub>) 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 B<sub>6</sub> analog, indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management (1-5).

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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 pregnancy 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.; June 2018.
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

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.**

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## Appendix 1

<b>Conservative Measures for NVP <sup>1,2,3</sup></b>
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