
Title: Doxylamine/ pyridoxine (Diclegis®, Bonjesta®)

Policy #: Rx.01.188

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **doxylamine/ pyridoxine (Diclegis®, Bonjesta®)** as provided under the member's prescription drug benefit.

Description:

Nausea and vomiting of pregnancy is a common condition affecting approximately 50-80% of pregnancies. The etiology of nausea and vomiting in pregnancy is unknown, but various theories exist including psychologic predisposition, evolutionary adaption, and hormonal stimulus. While mortality from nausea and vomiting of pregnancy is rare, significant morbidity, including hospital admissions, has been observed.

Initiating prenatal vitamins three months prior to conception may reduce the incidence and severity of nausea and vomiting of pregnancy. Treatment with pyridoxine or pyridoxine and doxylamine is effective and considered first line pharmacologic therapy. Ginger and acupressure have also shown beneficial effects in the treatment of nausea and vomiting of pregnancy.

Doxylamine/ pyridoxine (Diclegis®, Bonjesta®) is a fixed dose combination drug product 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. The mechanism of action of doxylamine/ pyridoxine for the treatment of nausea and vomiting of pregnancy is unknown. Diclegis® contains 10mg doxylamine and 10mg pyridoxine. Bonjesta® contains 20mg doxylamine and 20mg pyridoxine.

Policy:

Doxylamine/pyridoxine (Diclegis®, Bonjesta®) is approved when ALL of the following are met:

- A. Diagnosis of nausea and vomiting of pregnancy; AND
- B. Inadequate response to conservative management (e.g., change in dietary habits, ginger, acupressure, etc.); AND
- C. Inadequate response or inability to tolerate generic doxylamine and generic pyridoxine (Vitamin B6) taken together.

Authorization duration: 9 months

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Bonjesta (doxylamine/pyridoxine) [package insert]. Bryn Mawr, PA. Duchesnay USA, Inc. June 2018. Available at: <https://files.duchesnay.com/duchesnay-usa/bonjesta/bonjesta-prescribing-information.pdf>. Accessed March 30, 2021.

Diclegis (doxylamine/ pyridoxine) [package insert]. Bryn Mawr, PA. Duchesnay USA, Inc. June 2018. Available at: <https://files.duchesnay.com/duchesnay-usa/diclegis/diclegis-prescribing-information.pdf>. Accessed March 30, 2021.

The American College of Obstetricians and Gynecologists. Practice Bulletin No. 153: Nausea and Vomiting of Pregnancy. Obstet Gynecol. 2015;126:e12-24.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand name

Diclegis
Bonjesta

Generic name

doxylamine/ pyridoxine
doxylamine/ pyridoxine

Cross References:

Off-Label Use Rx.01.33

Policy Version Number:	6.00
P&T Approval Date:	March 18, 2021
Policy Effective Date:	July 01, 2021
Next Required Review Date:	March 18, 2022

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

