Pharmacy Policy Bulletin: J-0522 Diclegis and Bonjesta (doxylamine succinate and pyridoxine hydrochloride) – Commercial and Healthcare Reform	
Number: J-0522	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Other Managed Prior Authorization = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0522-011	**Original Date:** 12/07/2016
Effective Date: 12/20/2024	**Review Date:** 12/04/2024

Drugs Product(s):	• Diclegis (doxylamine succinate and pyridoxine hydrochloride) delayed-release • Bonjesta (doxylamine succinate and pyridoxine hydrochloride) extended-release
FDA-Approved Indication(s):	• Treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.

Background:	• Diclegis and Bonjesta are fixed-dose combinations of doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, a vitamin B6 analog. The mechanism of action of doxylamine and pyridoxine in the treatment of pregnancy-induced nausea and vomiting is currently unknown.
	• Doxylamine and pyridoxine are individually available as over-the-counter (OTC) products.
	• The American College of Obstetricians and Gynecologists (ACOG) recommends either pyridoxine (vitamin B6) alone or in combination with doxylamine as first-line pharmacologic treatment of nausea and vomiting of pregnancy.
	• This policy outlines the criteria under which coverage for prescription products for the treatment of pregnancy induced nausea and vomiting will be considered.
	• Prescribing considerations:
	  ○ Pregnant patients experiencing nausea and vomiting should first attempt lifestyle modifications such as diet changes and avoidance of triggers to relieve symptoms.
	  ○ Diclegis contains 10 mg of doxylamine and 10 mg of pyridoxine, while Bonjesta contains 20 mg of doxylamine and 20 mg of pyridoxine.
	  ○ The maximum recommended dose of both Diclegis and Bonjesta is 40 mg daily.
	  ▪ Diclegis can be taken as 1 tablet in the morning, 1 tablet mid-afternoon, and 2 tablets at bedtime.
	  ▪ Bonjesta can be taken as 1 tablet in the morning and 1 tablet at bedtime.

Approval Criteria

I. Approval Criteria

When a benefit, coverage of Diclegis (doxylamine succinate and pyridoxine hydrochloride) or Bonjesta may be approved when all of the following criteria are met **(A. and B.)**:

A. The member has a diagnosis of nausea and vomiting in pregnancy (ICD-10: O21).

B. The member has experienced therapeutic failure or intolerance to the individual products of OTC doxylamine succinate and OTC pyridoxine hydrochloride (vitamin B6), available separately yet taken together.

II. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 9 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Diclegis [package insert]. Bryn Mawr, PA: Duchesnay USA Inc.; March 2022 .
2. Bonjesta [package insert]. Bryn Mawr, PA: Duchesnay USA Inc.; March 2022 .
3. American College of Obstetricians and Gynecologists (ACOG) Committee on Obstetric Practice. ACOG Practice Bulletin No. 189: Nausea and Vomiting of Pregnancy. *Obstet Gynecol*. 2018; 131(1):e15-e30.