

### Clinical Pharmacy Program Guidelines for Bonjesta and Diclegis

Program	Prior Authorization
Medication	Diclegis (doxylamine/pyridoxine delayed-release), Bonjesta (doxylamine/pyridoxine extended-release)
Markets in Scope	Arizona, Hawaii, Florida-CHIP, Maryland, New Jersey, New York, New York EPP, Ohio, Pennsylvania- CHIP, Rhode Island, California, Nevada
Issue Date	12/2013
Pharmacy and Therapeutics Approval Date	10/2020
Effective Date	12/2020

**1. Background:**

Bonjesta and Diclegis are fixed dose combinations of doxylamine and pyridoxine approved by the Food and Drug Administration (FDA) for the treatment of nausea and vomiting of pregnancy in women who have not responded to conservative management.

**2. Coverage Criteria:**

<p><b>1. <u>Authorization</u></b></p> <p><b>a. Bonjesta or Diclegis</b> will be approved based on all of the following criteria:</p> <ol style="list-style-type: none"> <li>1) Diagnosis of nausea and vomiting associated with pregnancy</li> </ol> <p style="text-align: center;"><b>-AND-</b></p> <ol style="list-style-type: none"> <li>2) Documented failure or contraindication to lifestyle modifications (e.g., diet, avoidance of triggers)</li> </ol> <p style="text-align: center;"><b>-AND-</b></p> <ol style="list-style-type: none"> <li>3) Documented trial and failure or contraindication to a five day trial of over-the-counter doxylamine taken together with pyridoxine (i.e., not a combined dosage form, but separate formulations taken concomitantly).</li> </ol> <p><b>Authorization will be issued for 9 months.</b></p>
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**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes

(ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place.

#### 4. References:

1. Diclegis [package insert]. . Bryn Mawr, PA: Duchesnay USA, Inc.; June 2018.
2. ACOG (American College of Obstetrics and Gynecology) Practice Bulletin: Nausea and vomiting of pregnancy." Obstetrics and gynecology 2018; 131(1) e15-e30.
3. Herrell HE. Nausea and vomiting of pregnancy. Am Fam Physician 2014 Jun 15;89(12):965-970.
4. Bonjesta [package insert]. Bryn Mawr, PA: Duchesnay USA, Inc.; June 2018.

Program	Prior Authorization
<b>Change Control</b>	
12/2013	New Non-Preferred Drug Guideline
12/2015	Annual Review
3/2016	Criteria rewritten to align Diclegis clinical policies across multiple UHC business segments
4/2017	Annual Review. Removed dosing for over-the-counter products. Removed requirement for trial of dimenhydrinate and pyridoxine. Updated references.
7/2018	Added Bonjesta to criteria. Updated background and references.
9/2019	Annual review. Updated references and clarified trial/failure language with separate dosage forms.
10/2020	Annual review. Updated reference, clarified Diclegis dosage form. Added Additional Clinical Rules.