

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Doxylamine and Pyridoxine Agents

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Bonjesta (doxylamine and pyridoxine, delayed-release) Diclegis (doxylamine and pyridoxine, delayed-release)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for doxylamine and pyridoxine agents (Bonjesta, Diclegis) may be approved for individuals who meet the following criteria:

- I. Individual is a female; **AND**
- II. Individual is 18 years of age or older; **AND**
- III. Individual has nausea and vomiting of pregnancy; **AND**
- IV. Individual has had a previous trial of and inadequate response to conservative management*; **AND**
- V. Individual has had a trial of immediate-release doxylamine and pyridoxine

Doxylamine and pyridoxine agents (Bonjesta, Diclegis) may not be approved for:

- I. Hyperemesis gravidarum (defined as severe, intractable vomiting of pregnancy and associated with weight loss of greater than 5% of prepregnancy weight).

***NOTE:** Examples of conservative management include rest, avoidance of provoking stimuli, frequent and small meals, avoiding spicy or fatty foods, multivitamins taken at time of conception (for prevention), and ginger (ACOG 2018).

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Applicable	X	X	X	X	X	X	NA

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 27, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin No. 189: Nausea and Vomiting of Pregnancy. *Obstetrics and gynecology*. 2018; 131(1): e15-e30. Available from https://journals.lww.com/greenjournal/Fulltext/2018/01000/ACOG_Practice_Bulletin_No__189___Nausea_And.39.aspx. Accessed September 27, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.