UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 2024-7
Program	Prior Authorization/Medical Necessity
Medication	Bonjesta (doxylamine/pyridoxine extended-release), Diclegis (doxylamine/pyridoxine)
P&T Approval Date	4/2014, 4/2015, 3/2016, 4/2017, 7/2018
Effective Date	10/1/2018; Oxford only: 10/1/2018

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 [a]:

1. Initial Authorization

a. **Bonjesta* or Diclegis*** will be approved based on **all** of the following criteria:

1. Diagnosis of nausea and vomiting associated with pregnancy

-AND-

2. Documented failure or contraindication to lifestyle modifications (e.g., diet, avoidance of triggers)

-AND-

3. Documented trial and failure or contraindication to a five day trial of over-the-counter doxylamine in combination with pyridoxine.

Authorization will be issued for 9 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

*Bonjesta and Diclegis (as of 1/1/2019) are typically excluded from coverage.

- Supply limitations may be in place.

4. References:

1. Diclegis prescribing information. Duchesnay USA, Inc. Bryn Mawr, PA. January 2017.
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 prescribing information. Duchesnay USA, Inc. Bryn Mawr, PA. November 2017.

Program	Prior Authorization/Medical Necessity – Bonjesta and Diclegis
Change Control	
4/2014	New Program
4/2015	Annual review with administrative changes.
3/2016	Increased initial authorization from 3 to 9 months and removed reauthorization criteria.
7/2016	Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
4/2017	Annual Review. Removed dosing for over-the-counter products. Removed requirement for trial of dimenhydrinate and pyridoxine. Updated references. State mandate reference language updated.
7/2018	Added Bonjesta to criteria. Updated to note Bonjesta and Diclegis are typically excluded from coverage.