UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 2024-14
Program	Prior Authorization/Medical Necessity
Medication	Bonjesta®* (doxylamine/pyridoxine extended-release), Diclegis®* (doxylamine/pyridoxine delayed-release)
P&T Approval Date	4/2014, 4/2015, 3/2016, 4/2017, 7/2018, 9/2019, 10/2020, 11/2021, 12/2022, 1/2024, 3/2025, 32026
Effective Date	6/1/2026

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 taken together with pyridoxine (i.e., not a combined dosage form, but separate formulations taken concomitantly).

   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.

*Bonjesta and Diclegis are typically excluded from coverage. Please refer to plan specifics to determine exclusion status.

3. Additional Clinical Rules:

- Supply limitations may be in place.
- 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.

4. References:

1. Diclegis [package insert]. Princeton, NJ: Duchesnay USA, Inc.; June 2023.
2. American College of Obstetricians and Gynecologists. (2018). Practice Bulletin No. 189: Nausea and vomiting of pregnancy [Reaffirmed 2024]. Obstetrics & Gynecology, 131(1), e15–e30.Herrell HE. Nausea and vomiting of pregnancy. Am Fam Physician 2014 Jun 15;89(12):965-970.
3. Bonjesta [package insert]. Princeton, NJ: Duchesnay USA, Inc.; October 2022.

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.
9/2019	Annual review. Updated references, added automation language, and clarified trial/failure language with separate dosage forms.
10/2020	Annual review. Updated reference, clarified Diclegis dosage form.
11/2021	Annual review with no changes.
12/2022	Annual review with no changes.
1/2024	Annual review with no changes.
3/2025	Annual review with no changes.
3/2026	Annual review. Updated references.