UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Diclegis

Program	Prior Authorization
Medication	Diclegis (doxylamine/pyridoxine)
Issue Date	12/2013
Pharmacy and Therapeutics Approval Date	4/2017
Effective Date	6/2017

1. Background:

Diclegis is a fixed dose combination 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.

Diclegis was previously sold in the United States under the brand name Bendectin between 1956 and 1983, but it was voluntarily pulled from the market because of litigation about birth defects that were eventually shown to be false.

2. Coverage Criteria:

1. Initial Authorization

a. 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.

3. References:

1. Diclegis prescribing information. Duchesnay USA, Inc. Bryn Mawr, PA. May 2016.

2. ACOG (American College of Obstetrics and Gynecology) Practice Bulletin: Nausea and vomiting of pregnancy." Obstetrics and gynecology 2015; 126:e12-24.
3. Herrell HE. Nausea and vomiting of pregnancy. Am Fam Physician 2014 Jun 15;89(12):965-970.

Program	Prior Authorization - Diclegis (doxylamine/pyridoxine)
Change Control	
December 2013	New Non-Preferred Drug Guideline
December 2015	Annual Review
March 2016	Criteria rewritten to align Diclegis clinical policies across multiple UHC business segments
April 2017	Annual Review. Removed dosing for over-the-counter products. Removed requirement for trial of dimenhydrinate and pyridoxine. Updated references.