



**STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES**



**Office of Pharmacy Service
Prior Authorization Criteria**

**Diclegis® (doxylamine and pyroxidine)
Effective 10/01/2019**

Prior Authorization Request Form

DICLEGIS is a fixed dose combination drug product of doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, a Vitamin B6 analog, indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.

Prior authorization requests for Diclegis may be approved if the following criteria are met:

1. Diagnosis of nausea and vomiting associated with pregnancy; **AND**
2. Failure of conservative therapy for nausea and vomiting* (please document all previous therapies);
*An algorithm containing recommended alternative management strategies for nausea and vomiting of pregnancy (NVP) may be found at the end of this document.
AND
3. Failure of a seven (7) day trial of combination therapy consisting of doxylamine 12.5 mg taken twice daily with pyridoxine 25 mg taken qid. Although available OTC, Medicaid provides coverage for both of these products, therefore this trial must be verifiable by review of pharmacy claims or purchase history.

Initial approval of Diclegis will be for seven (7) days at a dose of up to four (4) tablets daily.

Additional therapy shall only be authorized with documentation that the member has experienced satisfactory efficacy within the initial approval period. Clinical studies have shown that efficacy of Diclegis should be assessable in most patients within 4 days, therefore extensions will not be granted if the patient has not experienced relief within the initial prior authorization period.

References

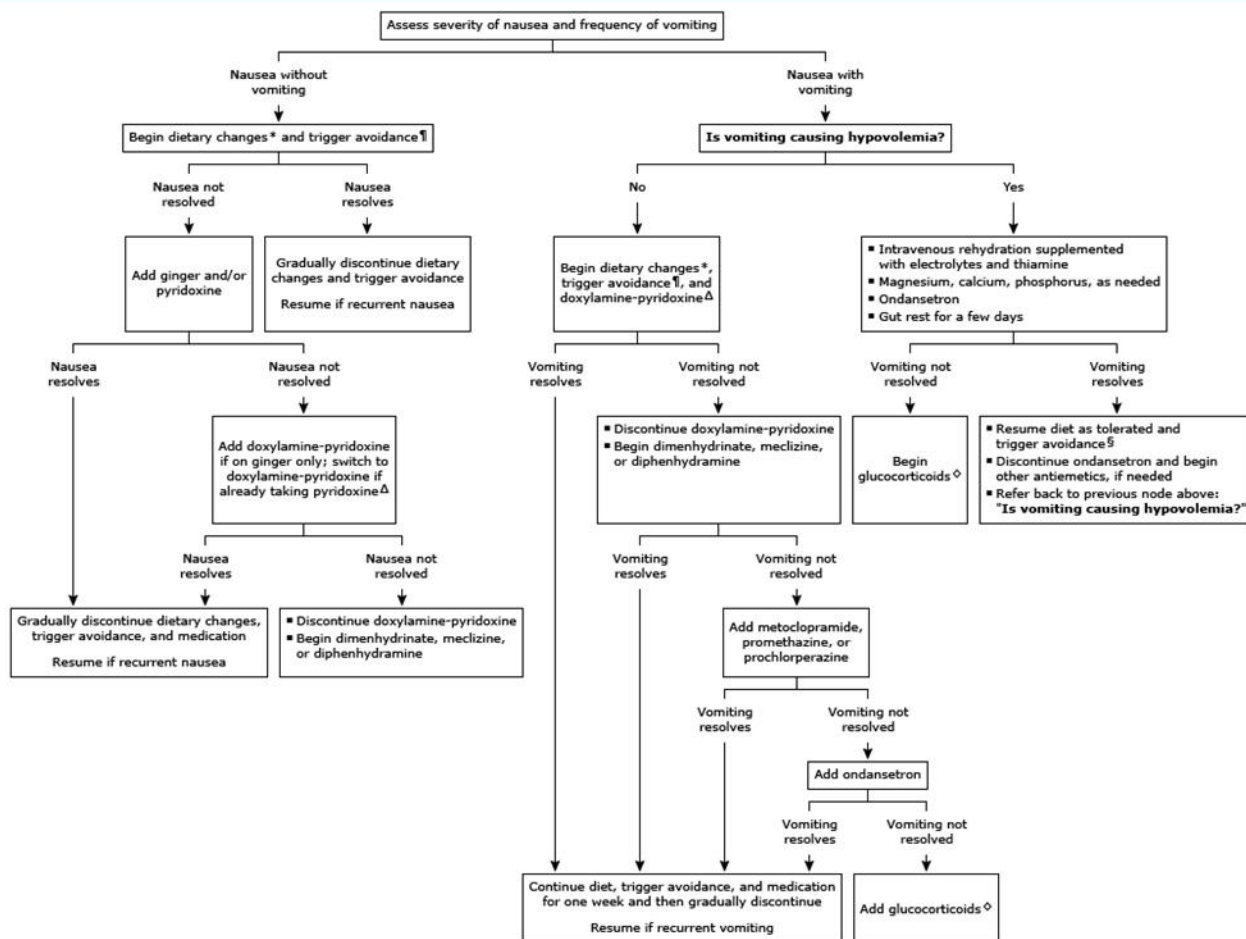
- 1.) <https://www.ncbi.nlm.nih.gov/pubmed/27881103>
- 2.) UptoDate – Treatment and Outcome of Nausea and Vomiting in Pregnancy (9/06/2019)
- 3.) Diclegis Package Insert (6/2018)
- 4.) LexiComp monograph on Diclegis (reviewed 9/06/2019)



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Management algorithm for treatment of nausea and vomiting of pregnancy (NVP)



Women with mild symptoms may benefit from acupuncture, acupressure, or hypnosis. Women with heartburn/acid reflux may benefit from acid-reducing medications as adjunctive therapy anytime during the course of illness. Antacids containing aluminum or calcium are preferred. Preferred H2 blockers are ranitidine or cimetidine. There is less experience using proton pump inhibitors (eg, lansoprazole or esomeprazole).

* Eat small amounts of food every one to two hours to avoid an empty or full stomach. It can be helpful to eliminate spicy, odorous, high-fat, acidic, and very sweet foods, and substitute protein-dominant, salty, low-fat, bland, and/or dry foods. Fluids should be consumed at least 30 minutes before or after solid food to minimize the effect of a full stomach. Fluids are better tolerated if cold, clear, and carbonated or sour. Avoid lying down after eating.

† Examples of some triggers include stuffy rooms, odors, heat, humidity, noise, visual or physical motion, and gastric irritants (eg, coffee, iron supplements).

Δ Doxylamine succinate 10 mg and pyridoxine 10 mg may be given separately or as a combination pill. We begin with 20 mg of each drug at bedtime. If ineffective, we give an additional 10 mg of each drug in the morning and in the afternoon.

◊ We generally treat refractory cases with a short course of glucocorticoids but may begin with chlorpromazine in selected patients, such as those in whom the side effects of glucocorticoids may be more serious.

§ We usually begin with a diet consisting of bananas, rice, applesauce, and toast (BRAT diet) and then advance as tolerated to usual diet suggested for women with nausea and vomiting of pregnancy.

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