Oscar Clinical Guideline: doxylamine/pyridoxine (Bonjesta, Diclegis) (PG096, Ver. 7)

Bonjesta (doxylamine/pyridoxine extended-release)
Diclegis (doxylamine/pyridoxine delayed-release)

Summary

Nausea and vomiting during pregnancy (also commonly referred to as "morning sickness") is a common condition that affects the health of a pregnant individual and their developing baby. It can diminish the pregnant individual's quality of life and significantly contribute to health care costs and time lost from work. Modifications in diet and medications to prevent or reduce nausea and vomiting in pregnancy are beneficial to prevent hyperemesis gravidarum. Treatment in the early stages may prevent more serious complications, including hospitalization. Safe and effective treatments are available for more severe cases, and mild cases of nausea and vomiting of pregnancy may be resolved with lifestyle (e.g., avoiding triggers such as heat, humidity, odors, noises or motion, use of acupressure wristbands) and dietary changes (e.g., small, frequent meals, substituting triggering foods for bland, salty, low-fat, protein-dominant, and/or dry foods). Nausea and vomiting of pregnancy should be distinguished from nausea and vomiting related to other causes, as the mechanism of nausea/vomiting is distinctly unique in this circumstance.

Pyridoxine, vitamin B6, is recommended as a first line treatment for pregnant individuals who have mild nausea and infrequent vomiting. Individuals who have nausea with frequent vomiting, or have inadequate relief from dietary changes, avoidance of triggering factors, and pyridoxine may benefit from the addition of medications with antihistamine properties such as doxylamine (Unisom), dimenhydrinate (Dramamine), diphenhydramine (Benadryl), prochlorperazine (Compazine), or promethazine (Phenergan). Both pyridoxine and doxylamine are available over-the-counter (OTC) as individual products. Both drugs, taken alone or together, have been found to be safe during pregnancy with no known harmful effects to the developing baby.

Bonjesta (doxylamine/pyridoxine extended release) and Diclegis (doxylamine/pyridoxine delayed release) are fixed dose combinations of doxylamine and pyridoxine approved by the Food and Drug Administration (FDA) for the treatment of pregnancy-related nausea and vomiting in those who have not responded to conservative management.

- Diclegis (doxylamine/pyridoxine delayed release) contains 10 mg doxylamine succinate and 10 mg pyridoxine hydrochloride.
- Bonjesta (doxylamine/pyridoxine extended release) contains 20 mg doxylamine succinate and 20 mg pyridoxine hydrochloride.

Definitions

"Conservative management" refers to changes to diet and lifestyle that might help an individual feel better. Examples include taking vitamins, adjusting meal times or changing the types of foods eaten.

"Hyperemesis gravidarum" (HG) refers to the most severe form of nausea and vomiting of pregnancy. HG may be diagnosed with the loss of 5 percent (%) of their pre-pregnancy weight and/or has other problems related to dehydration or loss of body fluids. Those with hyperemesis gravidarum often need acute treatment in a hospital setting to stop the vomiting and restore body fluids.

"Nausea" refers to an uneasy feeling in one's stomach that might indicate the need to vomit. Other symptoms that can accompany nausea include weakness, sweating, or dizziness.

"Vomiting" refers to the act of ejecting stomach contents from the mouth in an uncontrolled manner. Vomiting is a common action associated with "morning sickness" during the early stages of pregnancy.

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

Pregnancy-Related Nausea and Vomiting

The Plan considers Bonjesta or Diclegis (doxylamine/pyridoxine) medically necessary when ALL of the following criteria are met:

1. The member is 18 years of age or older*; AND*
2. The member has a diagnosis of pregnancy-related nausea and vomiting, confirmed by laboratory work and/or medical records*; AND*
3. The prescribing provider submits documentation or attestation stating that the member is unable to use, or has inadequate relief from lifestyle modifications such as dietary changes or avoidance of triggers[s]*; AND*
4. The member is unable to use, or has not benefited from, the individual components (OTC doxylamine and pyridoxine) taken concomitantly as separate products[s]*; AND*
5. The requested medication is being prescribed at a dose and frequency that is within FDA approved labeling (*See Table 1 for FDA-approved dosing*) OR is supported by compendia or evidence-based published dosing guidelines for the requested indication..

If the above prior authorization criteria are met, the requested product will be approved for up to 9 months (or the duration of the pregnancy).[s]

Table 1: Dosage Information

Product	Initial dose	Maximum dose
Bonjesta (doxylamine/pyridoxine extended release)	Initially, take one Bonjesta extended-release tablet orally at bedtime (Day 1). If this dose adequately controls symptoms the next day, continue taking one tablet daily at bedtime only. However, if symptoms persist on Day 2, increase the daily dose to one	The maximum recommended dose is two tablets per day, one in the morning and one at bedtime.

Product	Initial dose	Maximum dose
	tablet in the morning and one tablet at bedtime.	
Diclegis (doxylamine/pyridoxine delayed release)	Initially, take two Diclegis delayed-release tablets orally at bedtime (Day 1). If this dose adequately controls symptoms the next day, continue taking two tablets daily at bedtime. However, if symptoms persist into the afternoon of Day 2, take the usual dose of two tablets at bedtime that night then take three tablets starting on Day 3 (one tablet in the morning and two tablets at bedtime). If these three tablets adequately control symptoms on Day 4, continue taking three tablets daily. Otherwise take four tablets starting on Day 4 (one tablet in the morning, one tablet mid-afternoon and two tablets at bedtime).	The maximum recommended dose is four tablets (one in the morning, one in the mid-afternoon and two at bedtime) daily.

Experimental / Investigational, unproven[s]

Bonjesta or Diclegis (doxylamine/pyridoxine) for any other use is considered experimental, investigational, or unproven.

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