oscar

Clinical Guideline

Guideline Number: PG096, Ver. 2

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

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Nausea and vomiting of pregnancy is a common condition that affects the health of a pregnant woman and her developing baby. It can diminish a woman's quality of life and also significantly contributes to health care costs and time lost from work. Once nausea and vomiting of pregnancy progresses, it can become more difficult to control symptoms. 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 and dietary changes. Nausea and vomiting of pregnancy should be distinguished from nausea and vomiting related to other causes.

Pyridoxine is recommended as a first line treatment for pregnant women who have mild nausea and infrequent vomiting. For individuals who have nausea with frequent vomiting or for those who require additional treatment on top of dietary changes, trigger avoidance, and/or pyridoxine, antihistamines (doxylamine, diphenhydramine, meclizine, dimenhydrinate) are recommended as first line. Both pyridoxine and doxylamine are available over the counter. Both drugs, taken alone or together, have been found to be safe to take during pregnancy and have no harmful effects on the developing baby.

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.

Note: The Plan may require that preferred medications be used first.

Definitions

"Conservative management" refers to changes to your diet and lifestyle that might help a patient 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 when a woman has lost 5 percent of her pre-pregnancy weight and has other problems related to dehydration or loss of body fluids. Women 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

Medical Necessity Criteria for Initial Authorization

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;
2. The member has a diagnosis of nausea and vomiting associated with pregnancy as evidenced by lab work and/or chart documentation;
3. The requesting provider submits documentation or attestation indicating that the member has a documented failure or contraindication to lifestyle modifications (such as diet, avoidance of triggers);
4. The member meets ONE of the following conditions:
    a. The member has a documented trial and failure of the individual components (over-the-counter (OTC) doxylamine taken together with pyridoxine) used as separate formulations taken concomitantly; OR
    b. The member has a contraindication or medical reason why the individual components cannot be used or tried to treat the condition.
5. The requested medication will be dosed within FDA approved limits or as recommended by case studies or clinical guidelines. See Table 1 for dosing information.
    a. If dosing outside normal limits, reviewers may consult with Medical Directors or other clinical resources to confirm appropriate dosing.
6. Chart documentation and supporting labwork are provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, Bonjesta or Diclegis [doxylamine/pyridoxine] will be approved for 9 months.

Table 1: Dosage Information

Product	Initial dose	Maximum dose
Bonjesta	On Day 1, take one tablet at bedtime. On Day 2, if symptoms are not adequately controlled, the dose can be increased to one tablet in the morning and one tablet at bedtime.	The maximum recommended dose is two tablets daily.
Diclegis	Take two tablets daily at bedtime. If symptoms are not adequately controlled, the dose can be increased to a maximum recommended dose of four tablets daily (one in the morning, one mid-afternoon and two at bedtime).	The maximum recommended dose is four tablets daily.

Experimental or Investigational / Not Medically Necessary*:*

Bonjesta or Diclegis [doxylamine/pyridoxine] for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

1. Bonjesta [package insert]. Bryn Mawr, PA: Duchesnay USA, Inc.; June 2018.
2. Diclegis [package insert]. Bryn Mawr, PA: Duchesnay USA, Inc.; June 2018.
3. ACOG (American College of Obstetrics and Gynecology) Practice Bulletin: Nausea and Vomiting of Pregnancy." Obstetrics and gynecology 2018; 131(1) e15-e30. Available at: https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/01/nausea-and-vomiting-of-pregnancy
4. ACOG (American College of Obstetrics and Gynecology): Nausea and Vomiting of Pregnancy FAQs. Available at: https://www.acog.org/womens-health/faqs/morning-sickness-nausea-and-vomiting-of-pregnancy
5. Herrell HE. Nausea and vomiting of pregnancy. Am Fam Physician 2014 Jun 15;89(12):965-970.
6. Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed August 16, 2021.

Clinical Guideline Revision / History Information

Original Date: 10/14/2021 Reviewed/Revised: 12/01/2021