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Clinical Guideline

Oscar Clinical Guideline: Doxylamine/Pyridoxine (Bonjesta, Diclegis) (PG096, Ver. 5)

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 during 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 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 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. 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 an antihistamine such as dimenhydrinate, diphenhydramine, prochlorperazine, or promethazine. Both

pyridoxine and doxylamine are available over-the-counter (OTC). Both drugs, taken alone or together, have been found to be safe during pregnancy with no known harmful effects to 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.

Definitions

"Conservative management" refers to changes to 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/or 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***; 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***; 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***; AND***

5. The requested medication is being prescribed for use within Food and Drug Administration (FDA) approved dosing (*See Table 1 for FDA-approved dosing*) or as supported by evidence-based literature***; AND***
6. Medical records and supporting lab work are provided for review to validate 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	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 tablet in the morning and one tablet at bedtime.	The maximum recommended dose is two tablets per day, one in the morning and one at bedtime.
Diclegis	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 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

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Clinical Guideline Revision / History Information

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