Effective Date: 08/01/2018
Last P&T Approval/Version: 04/27/2022
Next Review Due By: 04/2023
Policy Number: C15190-A

Doxylamine-Pyridoxine (Bonjesta, Diclegis)

PRODUCTS AFFECTED

Diclegis (doxylamine-pyridoxine), Bonjesta (doxylamine-pyridoxine), doxylamine-pyridoxine

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:
Diagnosis of severe nausea and vomiting due to pregnancy (hyperemesis gravidarum)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. SEVERE NAUSEA AND VOMITTING DUE TO PREGNANCY:
1. Documentation of member's estimated delivery date
   AND
2. Prescriber attests to an inadequate response to ALL of the following first line treatment options unless a contraindication exists and is documented:
   (i) Conversion of prenatal vitamin to folic acid supplement only AND (ii) Dietary changes- smaller meals every few hours AND (iii) Trigger avoidance [NOTES: Prescriber attestation of member utilization of ginger capsules or P6 acupressure with wrist bands could also meet this requirement]

AND

3. Documentation of medical rationale for the utilization of the combination product instead of Vitamin B6 (pyridoxine) and doxylamine administered together as separate products.
   AND
4. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to doxylamine-pyridoxine include: concurrent utilization of Monoamine oxidase (MAO) inhibitors

CONTINUATION OF THERAPY:
N/A

DURATION OF APPROVAL:
Initial authorization: Until member's Estimated Delivery Date (no more than 9-month approval),
Continuation of Therapy: None

PRESCRIBER REQUIREMENTS:
No requirements

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
BONJESTA: up to 60 tablets/30 days
DICLEGIS: up to 120 tablets/30 days, Max Dosing: FDA-labeled dosing or per Off-Label MCP-162

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Antiemetic Combinations

FDA-APPROVED USES:
For the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:

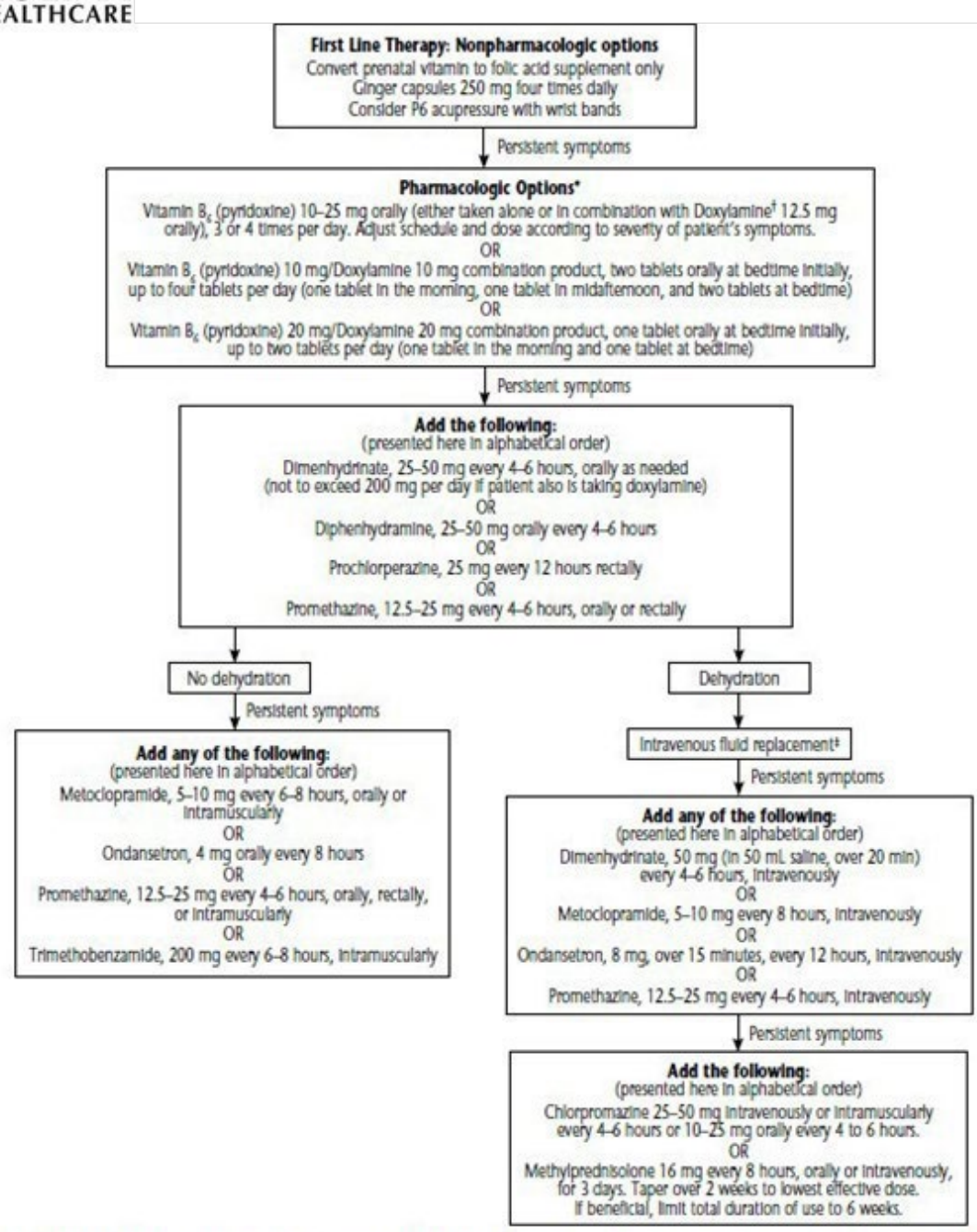

Figure 1. Algorithm of therapeutic treatment of nausea and vomiting of pregnancy (if no improvement, proceed to next step in algorithm). This algorithm assumes other causes of nausea and vomiting have been ruled out. At any step, consider enteral nutrition if dehydration or persistent weight loss is noted. *Some antiemetic medications have only been approved by the U.S. Food and Drug Administration for use in nonpregnant patients; however, off-label use is common. Obstetricians and other obstetric care providers should counsel patients and document such discussions accordingly. Care should be exercised if multiple antiemetic medications are used simultaneously. Parallel use of some medications (see text) may result in an increased risk of adverse effects. †In the United States, doxylamine is available as the active ingredient in some over-the-counter sleep aids; one half of a scored 25-mg tablet can be used to provide a 12.5-mg dose of doxylamine. ‡Thiamine, intravenously, 100 mg with the initial rehydration fluid and 100 mg daily for the next 2–3 days (followed by intravenous multivitamins), is recommended for women who require intravenous hydration and have vomited for more than 3 weeks to prevent a rare but serious maternal complication, Wernicke encephalopathy. (Modified from Levichek Z, Atanackovic G, Oepkes D, Maltepe C, Einarson A, Magee L, et al. Nausea and vomiting of pregnancy. Evidence-based treatment algorithm. Can Fam Physician 2002;48:267–8, 277.)

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Diclegis (doxylamine-pyridoxine) and Bonjesta (doxylamine-pyridoxine) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Bonjesta TBCR 20-20MG (60ct bottle), Diclegis TBEC delayed release 10-10MG (100ct bottle),Doxylamine-Pyridoxine TBEC 10-10MG (100ct bottle)

REFERENCES

1. Committee on Practice Bulletins-Obstetrics. ACOG Practice Bulletin No. 189: Nausea And Vomiting Of Pregnancy. Obstet Gynecol 2018; 131:e15. Reaffirmed 2020.
2. Bonjesta (doxylamine and pyridoxine) [prescribing information]. Bryn Mawr, PA: Duchesnay USA; June 2018.
3. Diclegis (doxylamine and pyridoxine) [prescribing information]. Bryn Mawr, PA: Duchesnay, USA. June 2018

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Age Restrictions Quantity References	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file