MEDICAL MUTUAL®

Drug Policy

Policy:	**Diclegis (doxylamine succinate/pyridoxine HCl) and Bonjesta (doxylamine succinate/pyridoxine HCl) and doxylamine succinate/pyridoxine HCl 10mg/10mg**	**Annual Review Date:** **04/20/2023** **Last Revised Date:** **04/20/2023**

OVERVIEW

Diclegis and Bonjesta are fixed-dose combination drug products of doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, a Vitamin B6 analog. Both are indicated for the treatment of nausea and vomiting of pregnancy (NVP) in women who do not respond to conservative management. Diclegis has not been studied in women with hyperemesis gravidarum. Diclegis is available as a delayed-release tablet containing 10 mg of doxylamine succinate and 10 mg of pyridoxine hydrochloride. Bonjesta contains 20 mg of doxylamine succinate and 20 mg of pyridoxine hydrochloride in the form of an extended release tablet.

POLICY STATEMENT

This policy involves the use of Diclegis and Bonjesta. Prior authorization is recommended for pharmacy benefit coverage of Diclegis and Bonjesta. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of doxylamine succinate/pyridoxine HCl 10mg/10mg, Diclegis and Bonjesta is recommended in those who meet the following criteria:

1. **Nausea and vomiting of pregnancy in patients who do not respond to conservative management**
   Criteria. *Approve if the patient meets the following criteria* (A AND B)*:*
   - **A.** The patient has tried and failed or was intolerant to generic doxylamine succinate and pyridoxine HCl single ingredient tablets [documentation required] AND
   - **B.** The patient meets one of the following (i, ii, or iii):
     - **i.** If requesting brand Bonjesta, the patient must have failed or is intolerant to brand or generic Diclegis [documentation required]
     - **ii.** If requesting brand Diclegis, approve using DAW 9

iii. If requesting generic doxylamine succinate/pyridoxine HCl, approve for Diclegis using DAW9

Initial Approval/ Extended Approval.
A) *Initial Approval:* 180 days
B) *Extended Approval:* 180 days

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Diclegis and Bonjesta has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Declegis® delayed-release tablets [prescribing information]. Bryn Mawr, PA: Duchesnay USA, Inc.; September 2013.
2. Bonjesta doxylamine succinate and pyridoxine hydrochloride tablet, extended release. Bryn Mawr, PA: Duchesnay USA, Inc. November 2017.
3. Doxylamine succinate/Pyridoxine hydrochloride. In: DRUGDEX (online database). Truven Health Analytics; Greenwood Village, CO. Last updated on 10 April 2019. Accessed on 16 April 2019.
4. American College of Obstetricians and Gynecologists (ACOG). Nausea and vomiting of pregnancy. ACOG Practice Bulletin Number 153. *Obstet Gynecol*. 2015;126(3):e12-e24.
5. Niebyl JR. Nausea and vomiting in pregnancy. *N Eng J Med*. 2010;363(16):1544-1550.