Diclegis® (doxylamine/pyridoxine)

**OVERVIEW**

**FDA-APPROVED INDICATIONS**

Diclegis® is indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.

**PHARMACY COVERAGE GUIDELINES**

Tufts Health Plan – Network Health may authorize coverage of Diclegis® (doxylamine/pyridoxine) for members when all the following criteria for a particular regimen are met and limitations do not apply:

- The member is diagnosed with nausea and vomiting associated with pregnancy **AND**
- The member tried and failed concurrent therapy with over-the-counter doxylamine and pyridoxine, or the provider indicates clinical inappropriateness of treatment with the concurrent use of over-the-counter doxylamine and pyridoxine.

**LIMITATIONS**

Coverage of Diclegis® will be limited to a 9-month approval.

**CODES**

None

**REFERENCES**

APPROVAL HISTORY

- 8/12/14: Reviewed by the Pharmacy and Therapeutics Committee
- 12/12/13: Reviewed by the Pharmacy and Therapeutics Committee

BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medical Necessity Guidelines apply to all fully insured Tufts Health Plan – Network Health offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable product formulary in the Pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines, when applicable, and adherence to plan policies and procedures and claims editing logic.