Drug Quantity Management – Per Days
Antiemetics – Doxylamine and Pyridoxine Combination Products

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Product Identifier(s)

Effective 1/1/23 to 2/6/23: 108030

Effective 2/7/23: 60889

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

Drugs Affected

- Bonjesta® (doxylamine succinate and pyridoxine hydrochloride tablets)
- Diclegis® (doxylamine succinate and pyridoxine hydrochloride delayed-release tablets – generic)

This Drug Quantity Management program has been developed to prevent stockpiling, misuse and/or overuse while providing a sufficient quantity for the indications of doxylamine and pyridoxine products. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below.

Drug Quantity Limits

Product	Strength and Form	Maximum Quantity per 365 Days‡
Bonjesta® (doxylamine succinate and pyridoxine hydrochloride tablets)	20/20 mg tablets	360 tablets†
Diclegis® (doxylamine succinate and pyridoxine hydrochloride delayed-release tablets, generic)	10/10 mg tablets	720 tablets*

‡ This is enough drug for individuals to complete 6 months of therapy. For coverage of additional quantities (for example, 9 months of therapy), a coverage review is required. † A quantity of 360 Bonjesta tablets per 365 days (six fills of 60 tablets/30 days) will be covered without prior authorization. * A quantity of 720 Diclegis tablets per 365 days (six fills of 120 tablets/30 days) will be covered without prior authorization.

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

Bonjesta

1. If the individual has continued nausea and vomiting of pregnancy beyond 6 months, approve 60 tablets per 30 days for three fills to allow for a total treatment duration of 9 months.

Diclegis (generic)

1. If the individual has continued nausea and vomiting of pregnancy beyond 6 months, approve 120 tablets per 30 days for three fills to allow for a total treatment duration of 9 months.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Bonjesta and Diclegis are fixed dose combination drug products of doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, a Vitamin B6 analog.[1,2] Diclegis and Bonjesta are indicated for the treatment of **nausea and vomiting of pregnancy** in women who do not respond to conservative management.

Dosing

On Day 1, the dose of Bonjesta is one tablet at bedtime.[1] If this dose adequately controls symptoms on Day 2, the patient continues to take one tablet at bedtime. However, if symptoms persist on Day 2, the dose is increased to two tablets daily (one tablet in the morning and one tablet at bedtime). The maximum recommended dose is two tablets per day.

On Day 1, the dose of Diclegis is two tablets at bedtime.[2] If this dose adequately controls symptoms on Day 2, the patient continues to take two tablets at bedtime. However, if symptoms persist into the afternoon of Day 2, the dose is increased to three tablets daily on Day 3 (one tablet in the morning and two tablets at bedtime). If three tablets adequately control symptoms on Day 4, the dose is continued. If symptoms persist, the dose on Day 4 is four tablets daily (one tablet in the morning, one tablet mid-afternoon, and two tablets at bedtime). The maximum recommended dose is four tablets per day.

For both Bonjesta and Diclegis, the tablets must be swallowed whole.[1,2] Tablets should not be crushed, chewed or split.

Availability
Bonjesta is available as tablets containing 20 mg of doxylamine succinate and 20 mg of pyridoxine hydrochloride in bottles of 60 tablets.[1] Diclegis (generic) is available as delayed-release tablets containing 10 mg of doxylamine succinate and 10 mg of pyridoxine hydrochloride in bottles of 100 tablets.[2]

References

1. Bonjesta® tablets [prescribing information] Bryn Mawr, PA: Duchesnay USA; February 2022.
2. Diclegis® tablets [prescribing information] Bryn Mawr, PA: Duchesnay USA; June 2018.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No change to criteria.	04/19/2022