DRUG QUANTITY MANAGEMENT POLICY – PER RX AND PER DAYS

POLICY: Antiemetics – Doxylamine and Pyridoxine Combination Products Drug Quantity Management Policy – Per Rx and Per Days
- Bonjesta® (doxylamine succinate and pyridoxine hydrochloride tablets – Duchesnay)
- Diclegis® (doxylamine succinate and pyridoxine hydrochloride delayed-release tablets – Duchesnay, generic)

REVIEW DATE: 04/09/2025

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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]

POLICY STATEMENT

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 combination 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. All approvals are provided for 1 year in duration, unless otherwise noted below.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity	Home Delivery Maximum Quantity
Bonjesta® (doxylamine succinate and pyridoxine hydrochloride tablets)	20/20 mg tablets	360 tablets per 365 days‡	
		60 tablets per Rx	180 tablets per Rx
Diclegis® (doxylamine succinate and pyridoxine hydrochloride delayed-release tablets, generic)	10/10 mg tablets	720 tablets per 365 days‡	
		120 tablets per Rx	360 tablets per Rx

‡ This is enough drug for patients to complete 6 months of therapy. For coverage of additional quantities (for example, 9 months of therapy), a coverage review is required.

Antiemetics – Doxylamine and Pyridoxine Combination Products Drug Quantity Management Policy – Per Rx and Per Days **product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.**

CRITERIA

Bonjesta 20 mg/20 mg tablets "Per Rx" Limit
No overrides recommended.

Bonjesta 20 mg/20 mg tablets "Per Days" Limit

1. If the patient has continued nausea and vomiting of pregnancy beyond 6 months, approve a total of 540 tablets per 365 days at retail or home delivery.

Doxylamine succinate and pyridoxine hydrochloride 10 mg/10 mg tablets (Diclegis, generic) "Per Rx" Limit
No overrides recommended.

Doxylamine succinate and pyridoxine hydrochloride 10 mg/10 mg tablets (Diclegis, generic) "Per Days" Limit

1. If the patient has continued nausea and vomiting of pregnancy beyond 6 months, approve a total of 1,080 tablets per 365 days at retail or home delivery.

REFERENCES

1. Bonjesta® tablets [prescribing information]. Princeton, PA: Duchesnay; February 2025.
2. Diclegis® tablets [prescribing information]. Princeton, PA: Duchesnay; December 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. No criteria changes.	04/19/2023
Annual Revision	No criteria changes.	04/22/2024
Annual Revision	The title of the policy was updated to "Antiemetics – Doxylamine and Pyridoxine Combination Products Drug Quantity Management Policy – Per Rx and Per Days". Previously, the policy name was "Antiemetics – Doxylamine and Pyridoxine Combination Products Drug Quantity Management Policy – Per Days". **Bonjesta 20 mg/20 mg tablets:** "Per Rx" quantity limits were updated to 60 tablets per dispensing at retail and 180 tablets per dispensing at home delivery. Previously, the "Per Rx" quantity limit was 60 tablets per dispensing at retail or home delivery. No override criteria apply to the "Per Rx" quantity limits. "Per Days" quantity limits did not change. "Per Days" override criteria were updated to approve a total of 540 tablets per 365 days if the patient has continued nausea and vomiting of pregnancy beyond 6 months. Previously, this criteria approved 60 tablets per 30 days for three fills. **Doxylamine succinate and pyridoxine hydrochloride 10 mg/10 mg tablets (Diclegis, generic):** "Per Rx" quantity limits were updated to 120 tablets per dispensing at retail and 360 tablets per dispensing at home delivery. Previously, the "Per Rx" quantity	04/09/2025

	limit was 120 tablets per dispensing at retail or home delivery. No override criteria apply to the "Per Rx" quantity limits. "Per Days" quantity limits did not change. "Per Days" override criteria were updated to approve a total of 1,080 tablets per 365 days if the patient has continued nausea and vomiting of pregnancy beyond 6 months. Previously, this criteria approved 120 tablets per 30 days for three fills.	