Effective Date **1/15/2024**
Next Review Date… **1/15/2025**
Coverage Policy Number **IP0388**

Glycopyrrolate

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Related Coverage Resources

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.

Overview

This policy supports medical necessity review for formulary exceptions for the following glycopyrrolate oral products:

- **Dartisla ODT** (glycopyrrolate disintegrating tablet)
- **Glycopyrrolate** 1.5 mg tablet
- **Robinul®** (glycopyrrolate tablet)
- **Robinul® Forte** (glycopyrrolate tablet)

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for products **in below table:**

Product Name	Criteria
Dartisla ODT (glycopyrrolate 1.7 mg disintegrating tablet)	**Dartisla ODT is considered medically necessary when the individual meets the following:** **Adjunct to treatment of peptic ulcer. BOTH** of the following criteria are met: A. Age 18 years or older B. Documentation of an inability to swallow glycopyrrolate 2mg tablets
Glycopyrrolate 1.5 mg tablet	**Glycopyrrolate 1.5 mg tablet is considered medically necessary when the individual meets the following:** **Adjunct to treatment of peptic ulcer. BOTH** of the following criteria are met: A. Age 18 years or older B. Documentation of failure, contraindication, or intolerance to **ONE** of the following: i. glycopyrrolate 1mg tablet ii. glycopyrrolate 2mg tablet
Robinul (glycopyrrolate 1 mg tablet)	**Robinul is considered medically necessary when the individual meets the following:** **Adjunct to treatment of peptic ulcer. BOTH** of the following criteria are met: A. Age 18 years or older B. Documented trial of **glycopyrrolate 1 mg tablet** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
Robinul Forte (glycopyrrolate 2 mg tablet)	**Robinul Forte is considered medically necessary when the individual meets the following:** **Adjunct to treatment of peptic ulcer. BOTH** of the following criteria are met: A. Age 18 years or older B. Documented trial of **glycopyrrolate 2 mg tablet** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of glycopyrrolate oral products (Dartisla ODT, glycopyrrolate 1.5mg tablet, Robinul, or Robinul Forte) is considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW
Glycopyrrolate oral products are synthetic anticholinergics indicated in adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer.[1,2]

References

1. Edenbridge Pharmaceuticals, LLC. Dartisla ODT [product information]. Parsippany, NJ: Edenbridge Pharmaceuticals, LLC. December 2021.
2. Casper Pharma LLC. Robinul/Robinul Forte tablets [product information]. East Brunswick, NJ: Casper Pharma LLC. September 2022.