BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.50.033

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Gastrointestinal Agents	**Original Policy Date:**	January 28, 2022
Subject:	Dartisla ODT	**Page:**	1 of 5

Last Review Date: March 7, 2025

Dartisla ODT

Description

Dartisla ODT (glycopyrrolate)

Background

Dartisla ODT (glycopyrrolate), an anticholinergic (antimuscarinic) agent, inhibits the action of acetylcholine on parietal cells in the stomach and decreases the volume and acidity of gastric secretions (1).

Regulatory Status

FDA-approved indication: Dartisla ODT is an anticholinergic indicated in adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer (1).

Limitations of Use:
Not indicated as monotherapy for treatment of peptic ulcer because effectiveness in peptic ulcer healing has not been established (1).

Dartisla ODT is contraindicated in patients at risk for anticholinergic toxicity due to an underlying medical condition, including: (1)

- Glaucoma
- Obstructive uropathies including prostatic hypertrophy
- Mechanical obstructive diseases of gastrointestinal tract (e.g., pyloroduodenal stenosis, strictures)
- Gastrointestinal motility disorders (e.g., achalasia, paralytic ileus, intestinal atony)
- Bleeding gastrointestinal ulcer

- Active inflammatory or infectious colitis which can lead to toxic megacolon
- History of or current toxic megacolon
- Myasthenia gravis

Dartisla ODT has warnings regarding the following: precipitation of acute glaucoma, partial or complete mechanical intestinal obstruction, gastrointestinal adverse reactions due to decreased gastrointestinal motility, cognitive and visual adverse reactions, heat prostration at high environmental temperatures, other conditions exacerbated by anticholinergic adverse reactions, and increased risk of anticholinergic adverse reactions in geriatric patients (1).

Dartisla ODT is not recommended for patients in whom a lower dosage strength of another oral glycopyrrolate product (e.g., tablet strength of 1 mg) is appropriate for initial or maintenance treatment because the dosage strength of Dartisla ODT may exceed the recommended initial and maintenance dosage of other oral glycopyrrolate products. Use the lowest effective dosage to control symptoms, switch patients who can be titrated to a lower dosage strength to another oral tablet dosage form of glycopyrrolate. Patients receiving the 2 mg dosage strength of another oral tablet dosage form of glycopyrrolate may be switched to the 1.7 mg dosage strength of Dartisla ODT (1).

The safety and effectiveness of Dartisla ODT in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Dartisla ODT may be considered **medically necessary** if the conditions indicated below are met.

Dartisla ODT may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Peptic ulcer

AND ALL of the following:

1. Used as an adjunct to treatment of peptic ulcer
2. Inadequate treatment response, intolerance, or contraindication to **ONE** of the following:
    a. Proton pump inhibitor (PPI)
    b. Histamine-2 (H2) receptor antagonist
3. Inadequate treatment response to a lower dosage strength of an oral glycopyrrolate product (e.g., glycopyrrolate 1 mg tablet) **OR** patient is receiving the 2 mg dosage strength of another oral tablet dosage form of glycopyrrolate
4. Prescriber agrees to titrate the patient to a lower dosage strength of another oral dosage form of glycopyrrolate, if clinically appropriate

AND NONE of the following:

1. Glaucoma
2. Obstructive uropathies including prostatic hypertrophy
3. Mechanical obstructive diseases of gastrointestinal tract (e.g., pyloroduodenal stenosis, strictures)
4. Gastrointestinal motility disorders (e.g., achalasia, paralytic ileus, intestinal atony)
5. Bleeding gastrointestinal ulcer
6. Active inflammatory or infectious colitis which can lead to toxic megacolon
7. History of or current toxic megacolon
8. Myasthenia gravis

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Peptic ulcer

AND ALL of the following:

1. Improvement in peptic ulcer symptoms
2. Patient **cannot** be switched to another oral dosage form of glycopyrrolate

AND NONE of the following:

1. Glaucoma
2. Obstructive uropathies including prostatic hypertrophy
3. Mechanical obstructive diseases of gastrointestinal tract (e.g., pyloroduodenal stenosis, strictures)
4. Gastrointestinal motility disorders (e.g., achalasia, paralytic ileus, intestinal atony)
5. Bleeding gastrointestinal ulcer
6. Active inflammatory or infectious colitis which can lead to toxic megacolon
7. History of or current toxic megacolon
8. Myasthenia gravis

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 240 tablets

Duration 2 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Dartisla ODT is an anticholinergic used to treat the symptoms of peptic ulcer in combination with peptic ulcer treatment. This medication should not be used in patients at risk of anticholinergic toxicity due to various underlying medical conditions. The safety and effectiveness of Dartisla ODT in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Dartisla ODT while maintaining optimal therapeutic outcomes.

References

1. Dartisla ODT [package insert]. Parsippany, NJ: Edenbridge Pharmaceuticals, LLC; December 2021.

Policy History

Date	Action
January 2022	Addition to PA
March 2022	Annual review
June 2022	Annual review. Per SME, addition of requirement to t/f a PPI or a H2 antagonist
March 2023	Annual review. Changed policy number to 5.50.033
June 2023	Annual review
March 2024	Annual review
March 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.