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## **DARTISLA ODT (glycopyrrolate)**

### **RATIONALE FOR INCLUSION IN PA PROGRAM**

#### **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).



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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).

### **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.