Pharmacy Policy Bulletin: J-1187 Dartisla ODT (glycopyrrolate) – Commercial and Healthcare Reform	
Number: J-1187	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial (1., 2., or 3.)**: **1.** Rx Mgmt Performance = Deterrent/Patent Extenders **2.** Rx Mgmt Performance = Deterrent/Patent Extenders + Guideline **3.** Rx Mgmt Performance = MRXC = Yes **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1187-003	**Original Date:** 01/26/2022
Effective Date: 12/20/2024	**Review Date:** 12/04/2024

Drugs Product(s):	• Dartisla ODT (glycopyrrolate)
FDA-Approved Indication(s):	• Indicated in adults for reducing symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer.

Background:	• Dartisla ODT is an anticholinergic (antimuscarinic) agent that inhibits the action of acetylcholine on parietal cells in the stomach and decreases the volume and acidity of gastric secretions. • Peptic ulcer disease affects 4.6 million people annually in the United States. The lifetime prevalence of peptic ulcer disease is 11% to 14% in men and 8% to 11% in women. Symptoms of peptic ulcer disease include abdominal discomfort, pain, and nausea. Peptic ulcers are typically diagnosed by a gastrointestinal endoscopy. • The 2021 National Institute for Health Care Excellence (NICE) guidelines recommends *H. pylori* testing and eradication and PPI or H2RA therapy as first-line therapies for treatment of peptic ulcer disease. Most ulcers heal within 2 months and PPIs are usually prescribed for 4 to 8 weeks. • Generic glycopyrrolate tablets may be crushed. • Prescribing Considerations: ○ Dartisla ODT is not indicated as monotherapy for treatment of peptic ulcer because effectiveness in peptic ulcer healing has not been established. ○ The safety and effectiveness of Dartisla ODT for treatment of peptic ulcer disease in pediatric patients younger than 18 years of age have not been established. Use in this population is not recommended. ○ Patients receiving the 2 mg dosage strength of another oral tablet dosage form of glycopyrrolate may be switched to Dartisla ODT. Dartisla ODT is not

	recommended for patients initiating treatment or receiving maintenance treatment with a lower dosage strength such as glycopyrrolate 1 mg tablets. o The maximum recommend daily dosage of Dartisla ODT is 6.8 mg.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Dartisla ODT may be approved when all of the following criteria are met **(A. through D.)**:

- **A.** The member is 18 years of age or older.
- **B.** The member has a diagnosis of peptic ulcer disease (ICD-10: K27).
- **C.** The member will be using Dartisla ODT as an adjunct to treatment of peptic ulcer disease (e.g., PPI or H2RA therapy).
- **D.** The member has experienced therapeutic failure, or intolerance to plan-preferred generic glycopyrrolate 2 mg tablets.

II. Reauthorization

When a benefit, reauthorization of Dartisla ODT may be approved when all of the following criteria are met **(A., B., and C.)**:

- **A.** The member meets one (1) of the following criteria **(1. or. 2):**
  - **1.** The member has a recurrence of peptic ulcer disease. (ICD-10: K27)
  - **2.** The member's peptic ulcer disease has not resolved.
- **B.** The member will be using Dartisla ODT as an adjunct to treatment of peptic ulcer disease (e.g., PPI or H2RA therapy).
- **C.** The prescriber attests that the member has experienced positive clinical response to therapy to previous treatment with Dartisla ODT.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 3 month authorization may be granted.

Automatic Approval Criteria

Members who meet the criterion as outlined below **(A.)** will receive automatic authorization at the pharmacy point of service without documentation of additional information. Claims will automatically adjudicate on-line, with no prior authorization required.

- **A.** If the member is requesting Dartisla ODT, the member has at least one (1) paid claim for generic glycopyrrolate 2 mg tablets in the member's prescription drug claims history within the previous 365 days.

References:

1. Dartisla ODT [package insert]. Parsippany, NJ: Edenbridge Pharmaceuticals, LLC; October 2023.
2. John Hopkins Medicine. Peptic Ulcer Disease. Available at: https://www.hopkinsmedicine.org/health/conditions-and-diseases/peptic-ulcer-disease. Accessed October 29, 2024.
3. National Institute for Health and Care Excellence. Dyspepsia and gastro-oesophageal reflux disease overview. Available at: https://pathways.nice.org.uk/pathways/dyspepsia-and-gastro-oesophageal-reflux-disease. Accessed October 29, 2024.
4. National Health Service. Stomach Ulcer. Available at: https://www.nhs.uk/conditions/stomach-ulcer/treatment/. Accessed October 29, 2024.
5. DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics; 2024.