Commercial/Healthcare Exchange PA Criteria
Effective: June 3rd, 2019

Prior Authorization: glycopyrrolate

Products Affected: Dartisla ODT 1.7 mg

Covered Uses: Adjunctive therapy in the treatment of peptic ulcer

Exclusion Criteria:
- Patients at risk for anticholinergic toxicity due to various underlying medical conditions.
- Hypersensitivity to glycopyrrolate or the inactive ingredients.

Required Medical Information:
1. Diagnosis
2. Past medication trials

Age Restrictions: Age 18 years old and older

Prescriber Restrictions: N/A

Coverage Duration: 1 year

Other Criteria: Approve if patient meets ALL the following criteria:

A. Patient must have a diagnosis of peptic ulcer disease; **AND**
B. Patient is not initiating treatment or receiving maintenance treatment with a lower dosage strength of another oral glycopyrrolate product **AND**
C. Patient must have a previous trial and failure or intolerance to generic glycopyrrolate 2 mg tablets in addition to two other generic medications used to treat peptic ulcer disease (including but not limited to: lansoprazole, omeprazole, pantoprazole, famotidine, and ranitidine); **AND**
D. Dartisla ODT 1.7 mg tablets will not be covered for any other non-FDA approved indication, including sialorrhea (excessive drooling) and hyperhidrosis (excessive sweating).

References:

1. Dartisla ODT. Package insert. Edenbridge Pharmaceuticals, LLC; 2021. Accessed February 1, 2022. http://www.dartisla.com/downloads/Dartisla-pi.pdf

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	6/3/2019
2	Update	Age Restrictions	Age Restrictions	03/04/2020
	Policy Update	Removed Glycopyrrolate 1.5mg [discontinued] and added Dartisla ODT 1.7mg Added exclusion criteria for Dartisla Updated criteria to include Dartisla ODT 1.7mg Removed Quantity limit .	Products Affected Exclusion Criteria Other Criteria Other Criteria	2/2/2022

Last Rev. Feb, 2022

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