Pharmacy Policy Bulletin

Title:	Glycopyrrolate (Dartisla ODT™)
Policy #:	Rx.01.264

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **Glycopyrrolate (Dartisla ODT™)** as provided under the member's prescription drug benefit.

Description:

Peptic ulcer disease (PUD) involves the development of mucosal defect(s) in the gastric or duodenal wall that typically extend through the muscularis mucosa (innermost layer of mucosa) into deeper layers of the wall (submucosa or muscularis propria). Most peptic ulcers are caused by Helicobacter pylori infection or nonsteroidal anti-inflammatory drugs (NSAIDs), including aspirin.

Many patients with PUD remain asymptomatic but may present with nonspecific intermittent symptoms of epigastric pain, early satiety, and/or bloating. Bleeding is the most frequent and severe complication of PUD. Other complications include perforation, penetration, and development of scarring with gastric outlet obstruction. For patients on chronic NSAIDs, consider primary ulcer prophylaxis with proton pump inhibitor (PPI) if there are risk factors for peptic ulcer disease, such as age > 50 years and concomitant use of aspirin, anticoagulants, or corticosteroids.

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.

Dartisla ODT is indicated in adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer. Limitations of Use: Dartisla ODT is not indicated as monotherapy for treatment of peptic ulcer because effectiveness in peptic ulcer healing has not been established.

Policy:

INITIAL CRITERIA Glycopyrrolate (Dartisla ODT™) is approved when ALL of the following are met:

1. Diagnosis of peptic ulcer as confirmed by endoscopy; and
2. One of the following:
    a. Member is on concomitant therapy with a proton-pump inhibitor (PPI) (e.g., lansoprazole, omeprazole); or
    b. Member has inadequate response or inability to tolerate PPI and is receiving concomitant treatment with an H2-receptor antagonist (e.g., famotidine, nizatidine); and
3. One of the following:
    a. Inadequate response or inability to tolerate generic glycopyrrolate tablets; or
    b. Member is unable to swallow tablets; and
4. Prescribed by or in consultation with a gastroenterologist; and
5. Member is 18 years of age or older

Initial authorization duration: 3 months

REAUTHORIZATION CRITERIA Glycopyrrolate (Dartisla ODT™) is reapproved when ALL of the following are met:

1. One of the following:
    a. Member's peptic ulcer has not healed as confirmed by endoscopy; or
    b. Member has a new peptic ulcer as confirmed by endoscopy; and
2. One of the following:
    a. Member is on concomitant therapy with a proton-pump inhibitor (PPI) (e.g., lansoprazole, omeprazole); or
    b. Member has inadequate response or inability to tolerate PPI and is receiving concomitant treatment with an H2-receptor antagonist (e.g., famotidine, nizatidine); and
3. Member experienced a reduction in peptic ulcer symptoms while on Dartisla ODT™ therapy; and
4. Prescribed by or in consultation with a gastroenterologist

Reauthorization duration: 3 months

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

DynaMed. Peptic Ulcer Disease. EBSCO Information Services. Accessed January 04, 2023. https://www.dynamed.com/condition/peptic-ulcer-disease

Dartisla ODT (glycopyrrolate) [prescribing information]. Parsippany, NJ: Edenbridge Pharmaceuticals, LLC; December 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215019s000lbl.pdf. Accessed January 04, 2023..

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Dartisla ODT	Glycopyrrolate

Cross References:

Rx.01.33 Off Label Use

Policy Version Number:	2.00
P&T Approval Date:	December 08, 2022
Policy Effective Date:	April 01, 2023
Next Required Review Date:	December 08, 2023

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.