Dartisla® ODT (glycopyrrolate orally disintegrating tablets)

Policy # 00785
Original Effective Date: 05/09/2022
Current Effective Date: 05/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Dartisla®‡ ODT (glycopyrrolate orally disintegrating tablets) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Dartisla ODT (glycopyrrolate orally disintegrating tablets) will be considered when the following criteria are met:

- Requested drug is used to reduce symptoms of peptic ulcer as an adjunct to treatment of a peptic ulcer; AND
- Requested drug is NOT being used as monotherapy for the requested condition; AND
- Patient is 18 years of age or older; AND
- Patient is currently receiving the 2 mg strength oral tablet of GENERIC glycopyrrolate; AND
- There is clinical evidence or patient history that suggests the use of the GENERIC 2 mg glycopyrrolate oral tablets will be ineffective or cause an adverse reaction to the patient. *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Dartisla ODT (glycopyrrolate orally disintegrating tablets) when there is no clinical evidence or patient history that suggests the use of the GENERIC 2 mg glycopyrrolate oral tablets will be ineffective or cause an adverse reaction to the patient to be **not medically necessary.****

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Dartisla ODT (glycopyrrolate orally disintegrating tablets) when the patient selection criteria are not met (except the criterion denoted as **not medically necessary****) to be **investigational.***

Background/Overview

Dartisla ODT is indicated in adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer. Dartisla ODT is available as 1.7 mg orally disintegrating tablets containing glycopyrrolate. The package insert notes that this medication should only be started in patients who are already receiving the 2 mg dosage of other oral glycopyrrolate tablets. Dartisla ODT is not recommended for initiating treatment or receiving maintenance treatment with a lower dosage strength of another oral glycopyrrolate product (e.g., tablet strength of 1 mg). The recommended dose is 1.7 mg given two or three times daily. The maximum recommended dose is 6.8 mg daily. There were no clinical studies performed with Dartisla ODT. Kinetic analysis revealed that 1.7 mg of Dartisla ODT was comparable to an oral 2 mg glycopyrrolate tablet. Glycopyrrolate is available in generic form in 1 mg and 2 mg tablets, which carry the same indication as Dartilsa ODT. Glycopyrrolate, and subsequently Dartisla ODT, should never be given as monotherapy for the treatment of peptic ulcer disease. Given that there were no clinical studies performed with Dartisla ODT, there can be no claims of superiority made over generic glycopyrrolate tablets. The generic 1 mg and 2 mg oral tablet strengths of glycopyrrolate offer an equally efficacious and more economical option for the adjunct treatment of peptic ulcers.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Dartisla ODT is indicated in adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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The purpose of this policy is to ensure that Dartisla ODT is used for its FDA approved indication as well as to ensure that equally efficacious yet more cost effective medications are used for the condition being treated.

References

1. Dartisla ODT [package insert]. Edenbridge Pharmaceuticals, LLC. Parsippany, New Jersey. December 2021.

Policy History

Original Effective Date: 05/09/2022
Current Effective Date: 05/01/2025

04/07/2022	Medical Policy Committee review
04/13/2022	Medical Policy Implementation Committee approval. New policy.
04/06/2023	Medical Policy Committee review
04/12/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/04/2024	Medical Policy Committee review
04/10/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/03/2025	Medical Policy Committee review
04/09/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 04/2026

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.