



# Louisiana

## Select Novel Drug Formulations

Policy # 00698

Original Effective Date: 01/08/2020

Current Effective Date: 08/09/2021

*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 the following Food and Drug Administration (FDA) approved novel dosage forms for previously available drugs: Katerzia<sup>TM</sup>† (amlodipine) and Gloperba<sup>®</sup>‡ (colchicine) to be **eligible for coverage\*\*** when the patient selection criteria are met.

### Patient Selection Criteria

Coverage eligibility for Katerzia (amlodipine) or Gloperba (colchicine) will be considered when the following patient selection criteria are met:

- Patient has a gastrostomy tube (G-tube) or is otherwise unable to swallow tablets and/or capsules; AND
- Patient is not currently taking any medication in tablet or capsule form.

## When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Katerzia (amlodipine) or Gloperba (colchicine) when patient selection criteria are not met to be **not medically necessary.\*\***

## Background/Overview

The drugs included in this policy represent FDA approved novel formulations of drugs that were previously only available in tablet or capsule form. These formulations are often developed to assist in drug administration to patients with gastrostomy tubes (G-tubes) or who are otherwise unable to swallow tablets or capsules.

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### **Rationale/Source**

The patient selection criteria presented in this policy take into consideration whether or not the patient is able to take medications in tablet or capsule form. Based on a review of the available data, if the above mentioned criteria are not met there is no advantage to the use of these products over the traditional dosage forms.

### **References**

1. Katerzia [package insert]. Silvergate Pharmaceuticals, Inc. Greenwood Village, CO. Updated July 2019.
2. Gloperba [package insert]. Avion Pharmaceuticals, LLC. Alpharetta, Georgia. Updated July 2019.

### **Policy History**

Original Effective Date: 01/08/2020

Current Effective Date: 08/09/2021

01/03/2020 Medical Policy Committee review

01/08/2020 Medical Policy Implementation Committee approval. New policy.

07/02/2020 Medical Policy Committee review

07/08/2020 Medical Policy Implementation Committee approval. Added a new product, Gloperba, to the policy.

07/01/2021 Medical Policy Committee review

07/14/2021 Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 07/2022

\*\*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

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- 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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**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.

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