Select Novel Drug Formulations

Policy # 00698
Original Effective Date: 01/08/2020
Current Effective Date: 04/01/2025

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 the following Food and Drug Administration (FDA) approved novel dosage forms for previously available drugs: Katerzia™‡ (amlodipine), Norliqva®‡ (amlodipine), Gloperba®‡ (colchicine), chlorpromazine oral concentrate, valsartan oral solution, Zonisade™‡ (zonisamide), Aspruzyo Sprinkle™‡ (ranolazine), and Likmez™‡ (metronidazole suspension) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Katerzia (amlodipine), Norliqva (amlodipine), Gloperba (colchicine), chlorpromazine oral concentrate, valsartan oral solution, Zonisade (zonisamide), Aspruzyo Sprinkle (ranolazine), or Likmez (metronidazole suspension) 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), Norliqva (amlodipine), Gloperba (colchicine), chlorpromazine oral concentrate, valsartan oral solution, Zonisade (zonisamide), Aspruzyo Sprinkle (ranolazine), or Likmez (metronidazole suspension) 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

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.

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.
3. chlorpromazine oral concentrate [package insert]. Arbor Pharmaceuticals. Atlanta, Georgia. Updated June 2021.
4. valsartan oral solution [package insert]. Lifsa Drugs LLC. New Brunswick, NJ. Updated April 2022.
5. Aspruzyo Sprinkle [package insert]. Sun Pharmaceuticals, Inc. Cranbury, New Jersey. Updated February 2022.
6. Norliqva [package insert]. CMP Pharma, Inc. Farmville, NC. Updated February 2022.
7. Zonisade [package insert]. Azurity Pharmaceuticals, Inc. Wilmington, MA. Updated. July 2022.
8. Likmez [package insert]. Saptalis Pharmaceuticals, LLC. Hauppauge, NY. Updated September 2023.

Policy History

Original Effective Date: 01/08/2020
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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.
04/07/2022	Medical Policy Committee review

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04/13/2022	Medical Policy Implementation Committee approval. Added a new product, chlorpromazine oral concentrate, to the policy.
08/04/2022	Medical Policy Committee review
08/10/2022	Medical Policy Implementation Committee approval. Added a new product, valsartan oral solution, to the policy.
11/03/2022	Medical Policy Committee review
11/09/2022	Medical Policy Implementation Committee approval. Added a new product, Aspruzyo Sprinkle, to the policy.
01/05/2023	Medical Policy Committee review
01/11/2023	Medical Policy Implementation Committee approval. Added a new product, Norliqva, to the policy.
03/02/2023	Medical Policy Committee review
03/08/2023	Medical Policy Implementation Committee approval. Added a new product, Zonisade, to the policy.
03/07/2024	Medical Policy Committee review
03/13/2024	Medical Policy Implementation Committee approval. Added a new product, Likmez, to the policy.
03/06/2025	Medical Policy Committee review
03/12/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2026

**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.