Select Novel Drug Formulations

Policy #  00698
Original Effective Date:  01/08/2020
Current Effective Date:  04/10/2023

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), and Aspruzo Sprinkle™‡ (ranolazine) 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), or Aspruzo Sprinkle (ranolazine) 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), or Aspruzo Sprinkle (ranolazine) when patient selection criteria are not met to be not medically necessary.**
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**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.

**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**
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**Policy History**

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<td>01/03/2020</td>
<td>Medical Policy Committee review</td>
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<td>01/08/2020</td>
<td>Medical Policy Implementation Committee approval. New policy.</td>
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Next Scheduled Review Date: 03/2024

**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;
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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.

‡ 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.