MEDICAL MUTUAL®

Drug Policy

Policy:	**Amlodipine Products Preferred Step Therapy**	**Annual Review Date:** **05/18/2023**
Impacted Drugs:	**Conjupri (levamlodipine) tablets** **Katerzia (amlodipine) suspension** **Norvasc (amlodipine) tablets** **Norliqva (amlodipine) oral solution**	**Last Revised Date:** **05/18/2023**

OVERVIEW

Conjupri, Katerzia, Norvasc are calcium channel blockers which lower blood pressure and reduce the risk of fatal and nonfatal cardiovascular events. Each of these calcium channel blockers are branded amlodipine products which may be used alone or in combination with other antihypertensive and antianginal agents for the treatment of hypertension and coronary artery disease in adults and children 6 years and older. Katerzia is the first amlodipine product that is available as an oral suspension (1 mg/mL). Norliqva is an amlodipine oral solution.

POLICY STATEMENT

A step therapy program has been developed to encourage use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: Patients with a history of one preferred drug within the 130-day look-back period are excluded from step therapy.

Preferred Medications

- Generic amlodipine

Non-Preferred Medications

- Conjupri
- Katerzia
- Norvasc
- Norliqva

PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried a preferred medication, then authorization for a non-preferred medication may be given.
2. If the patient cannot swallow or has difficulty swallowing capsules or tablets, authorization may be given for Katerzia or Norliqva.

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Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days
B) *Extended Approval:* 365 days

Preferred Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list specific diagnosis and/or specific patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the specific contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following (1 or 2):
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or

performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Katerzia suspension [prescribing information]. Greenwood Village, CO: Silvergate Pharmaceuticals, Inc.; July 2019.
2. Norvasc tablets [prescribing information]. New York, NY: Pfizer Laboratories Div of Pfizer Inc.; March 2019.
3. amlodipine. In: DRUGDEX [online database]. Truven Health Analytics. Greenwood Village, CO. Last updated 13 August 2019. Accessed 05 September 2019.
4. Conjupri tablets [prescribing information]. Princeton, NJ: CSPC Ouyi Pharmaceutical Co., Ltd; December 2019.
5. Norliqva oral solution [prescribing information]. Farmville, NC: CMP Pharma, Inc. February 2022