| Pharmacy Policy Bulletin: J-0942 Katerzia (amlodipine benzoate) and Norliqva (amlodipine) – Commercial and Healthcare Reform | |
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| **Number:** J-0942 | **Category:** Prior Authorization |
| **Line(s) of Business:**<br>☒ Commercial<br>☒ Healthcare Reform<br>☐ Medicare | **Benefit(s):**<br>**Commercial:**<br>**Prior Authorization (1.)**<br>**1.** Other Managed Drugs = Yes w/ Prior Authorization<br><br>**Healthcare Reform:** Not Applicable |
| **Region(s):**<br>☒ All<br>☐ Delaware<br>☐ New York<br>☐ Pennsylvania<br>☐ West Virginia | **Additional Restriction(s):**<br>None |
| **Version:** J-0942-009 | **Original Date:** 08/07/2019 |
| **Effective Date: 04/25/2025** | **Review Date:** 04/09/2025 |

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| **Drugs Product(s):** | • Katerzia (amlodipine benzoate) oral suspension<br>• Norliqva (amlodipine) oral solution |
| **FDA-Approved Indication(s):** | • May be used alone or in combination with other antihypertensive and antianginal agents for the treatment of:<br>  ○ Hypertension:<br>  ▪ In adults and children 6 years and older to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.<br>  ○ Coronary Artery Disease (CAD):<br>  ▪ For the symptomatic treatment of chronic stable angina<br>  ▪ For the treatment of confirmed or suspected vasospastic angina (Prinzmetal's or Variant Angina)<br>  ▪ To reduce hospitalization for angina and reduce the risk of a coronary revascularization procedure in angiographically documented CAD in patients without heart failure or an ejection fraction < 40% |

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| **Background:** | • Katerzia and Norliqva are long acting dihydropyridine calcium channel blockers (CCBs) that inhibit the flow of calcium into cardiac and vascular smooth muscles. By inhibiting calcium influx, the muscles have decreased ability to contract, leading to decreased peripheral vascular resistance and decreased blood pressure.<br>• Amlodipine besylate tablets can be crushed or dissolved in water for administration, benefiting patients with dysphagia. It has also been shown that amlodipine besylate tablets easily disintegrate in apple sauce. Advise the patient to swallow it straight away without chewing.<br>• Prescribing Considerations:<br>  ○ Starting doses should be lower for the elderly, pediatric, and patients with hepatic impairment, as they could be at increased risk of side effects from antihypertensive agents. |

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| | ○ Doses greater than 5 mg daily have not been studied in pediatric patients.<br>○ If using concurrent Katerzia or Norliqva plus simvastatin, the dose of simvastatin should not exceed 20 mg daily.<br>○ Continual monitoring of immunosuppressant blood levels and dose adjustments may be needed when used in combination with Katerzia or Norliqva.<br>○ Katerzia and Norliqva have warnings and precautions for symptomatic hypotension and worsening angina and acute myocardial infarction after starting or increase the dose. |

## Approval Criteria

**I. Initial Authorization**

When a benefit, coverage of Katerzia or Norliqva may be approved when all of the following criteria are met **(A., B., and C.)**:

**A.** The member meets one (1) of the following criteria **(1. or 2.)**:
  **1.** The member meets all of the following criteria **(a. and b.)**:
    **a.** The member is 6 years of age or older.
    **b.** The member has a diagnosis of hypertension (ICD-10: I10).
  **2.** The member meets all of the following criteria **(a. and b.)**:
    **a.** The member is 18 years of age or older.
    **b.** The member has a diagnosis of coronary artery disease (ICD-10: I25).

**B.** The member has an inability to swallow tablets.

**C.** The member has experienced therapeutic failure or intolerance to plan-preferred generic amlodipine besylate tablets.

**II. Reauthorization**

When a benefit, reauthorization of Katerzia or Norliqva may be approved when all of the following criteria are met **(A. and B.)**:

**A.** The prescriber attests that the member has experienced positive clinical response to therapy.

**B.** The prescriber attests that the member continues to have an inability to swallow tablets.

**III.** An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

## Limitations of Coverage

**I.** Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

**II.** For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outline within this policy

## Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

## Automatic Approval Criteria

None

**References:**


1. Katerzia [package insert]. Greenwood Village, CO: Silvergate Pharmaceuticals, Inc: July 2019.
2. Norliqva [package insert]. Farmville, NC: CMP Inc.; February 2022.
3. Chung M, Garza D, Gaffney M, Glue P. Bioavailability of amlodipine besylate following oral administration as a tablet dispersed in applesauce. *J Clin Pharmacol*. 2005;45(6):695-8.
4. Waitemata District Health Board. Guide for Crushing Oral Medication for Residents with Swallowing Difficulties in Residential Aged Care. Available at: http://www.saferx.co.nz/assets/Documents/38af4a05e7/Crushing-table-RAC.pdf. Accessed March 7, 2022.
5. NHS North East Essex. NEEMMC Guidelines for Tablet Crushing and Administration via Enteral Feeding Tubes. Available at: https://www.stch.org.uk/wp-content/uploads/pct-version-neemmc-guidelines-for-tablet-crushing-april-2012.pdf. Accessed March 7, 2022.