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Commercial PA Criteria Effective: October 13, 2023

Prior Authorization: Lodoco (colchicine)

Products Affected: Lodoco (colchicine) oral tablets

<u>Medication Description</u>: Lodoco, an alkaloid, is indicated to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular (CV) death in adults with established atherosclerotic disease or with multiple risk factors for CV disease.

<u>Covered Uses</u>: Atherosclerotic occlusive disease, Established, or multiple risk factors for cardiovascular disease; reduce risk of myocardial infarction, stroke, coronary revascularization, and cardiovascular death

Exclusion Criteria:

- 1. Primary prevention of cardiovascular disease
- 2. Concomitant use of P-glycoprotein and strong CYP3A4 inhibitors in patients with renal or hepatic impairment
- 3. Patients with both renal and hepatic impairment
- 4. Patients with preexisting blood dyscrasias
- 5. Hypersensitivity to colchicine or any component of the product (tablet)

Required Medical Information:

- 1. Diagnosis
- 2. Medical History
- 3. Current laboratory values

<u>Prescriber Restriction</u>: Medication must be prescribed by, or in consultation with, a cardiologist or Internal medicine /Primary care prescriber

Age Restriction: 18 years and older

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

- 1. <u>Atherosclerotic Disease</u>. Approve if the patient meets the following (A, B, C, <u>AND</u> D):
 - A. Patient has had one of the following conditions or diagnoses (i, ii, iii, iv, v, <u>**OR**</u> vi):
 - i. A previous myocardial infarction or a history of an acute coronary syndrome; OR
 - ii. Angina (stable or unstable); OR
 - iii. A past history of stroke or transient ischemic attack; OR

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- iv. Coronary artery disease; OR
- v. Peripheral arterial disease; OR
- vi. Patient has undergone a coronary or other arterial revascularization procedure in the past; **AND** <u>Note</u>: Examples include coronary artery bypass graft surgery, percutaneous coronary intervention, angioplasty, and coronary stent procedures.
- B. Lodoco is being added onto other background regimens of other atherosclerotic disease medications according to the prescriber; **AND**

<u>Note</u>: Examples of medications recommended in guideline-directed therapy for patients with atherosclerotic disease can include aspirin, antiplatelet agents (e.g., clopidogrel, Brilinta [ticagrelor tablets]), anticoagulants, lipid-lowering agents (e.g., statins such as atorvastatin and rosuvastatin), beta blockers, angiotensin-converting enzyme inhibitors, and/or angiotensin receptor blockers.

- C. Patient does not have severe hepatic impairment according to the prescriber; AND
- D. Patient has a creatinine clearance \geq 50 mL/min.

<u>References:</u>

1. Lodoco® tablets [prescribing information]. Parsippany, NJ: Agepha; June 2023.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	10/13/2023