VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Cardiology – Lodoco Prior Authorization Policy
- Lodoco® (colchicine 0.5 mg tablets – Agepha)

REVIEW DATE: 08/30/2023

OVERVIEW

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.[1] The safety and effectiveness have not been established in pediatric patients.

Clinical Efficacy

The efficacy of Lodoco was evaluated in one, double-blind, placebo-controlled, event-driven, investigator-initiated, pivotal study called LoDoCo2 involving 5,522 adults with chronic stable coronary disease who received Lodoco 0.5 mg once daily or matching placebo.[1,2] The mean patient age was 66 years; only 15% of patients were female. Patients had an estimated glomerular filtration rate ≥ 50 mL/min. An acute coronary syndrome event had occurred previously in 84% of patients. Most patients were also receiving standard of care therapy for secondary prevention of CV events. Examples of medications utilized for chronic coronary disease included antiplatelet agents or an anticoagulant (99.7%), a lipid-lowering agent (96.6% [mostly statins]), a renin-angiotensin system inhibitor (71.7%), and beta-blockers (62.1%). The median time on study medication was 28.6 months. A primary endpoint event (a composite of CV death, MI, ischemic stroke, or ischemia-driven coronary revascularization) occurred in 6.8% of patients randomized to Lodoco vs. 9.6% of patients receiving placebo (hazard ratio 0.69; $P < 0.001$).

Guidelines

Guidelines for the management of patients with chronic coronary disease from the American Heart Association and the American College of Cardiology (2023) state that in patients with chronic coronary disease, the addition of colchicine for secondary prevention may be considered to reduce recurrent atherosclerotic cardiovascular disease events (Class of Recommendation: 2b [weak] {benefit ≥ risk}; Level of Evidence: randomized).[3]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Lodoco. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Lodoco is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Atherosclerotic Disease.** Approve for 1 year if the patient meets the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has had one of the following conditions or diagnoses (i, ii, iii, iv, v, or 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
     - **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
       Note: Examples include coronary artery bypass graft surgery, percutaneous coronary intervention, angioplasty, and coronary stent procedures.
   - **C)** Lodoco is being added onto other background regimens of other atherosclerotic disease medications according to the prescriber; AND
     Note: 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.
   - **D)** Patient does not have severe hepatic impairment according to the prescriber; AND
   - **E)** Patient has a creatinine clearance ≥ 50 mL/min.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Lodoco is not recommended in the following situations:

1. **Primary Prevention of Cardiovascular Events.** Guidelines for the primary prevention of cardiovascular disease do not currently address Lodoco.[4] Most patients in the pivotal trial with Lodoco had past cardiovascular events or had undergone a coronary or other arterial revascularization procedure in the past.[2]

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Lodoco® tablets [prescribing information]. Parsippany, NJ: Agepha; June 2023.
2. Nidorf SM, Fiolet ATL, Mosterd A, et al, for the LoDoCo2 trial investigators. Colchicine in patients with chronic coronary disease. *N Engl J Med*. 2020;383(19):1838-1847.
3. Virani SS, Newby LK, Arnold SV, et al. 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA guideline for the management of patients with chronic coronary disease: a report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2023 July 14. [Online ahead of print].
4. Arnett DK, Blumenthal RS, Albert MA, et al. 2019 ACC/AHA guideline on the primary prevention of cardiovascular disease. *J Am Coll Cardiol*. 2019;74(10):e177-e232.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/30/2023