Drug Coverage Policy

Effective Date 11/1/2025
Coverage Policy Number.....IP0595
Policy Title.....Lodoco

Cardiology – Lodoco

- Lodoco® (colchicine 0.5 mg tablets – Agepha)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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.

Colchicine is also available generically in a 0.6 mg dose strength; these products are not interchangeable.

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; $P < 0.001$).

The COLCOT trial, a randomized, double-blind trial, also evaluated the use of Lodoco as secondary prevention in patients with a history of acute coronary syndrome (ACS).[5] A total of 4,745 patients were recruited within 30 days after an MI; they received either Lodoco 0.5 mg once daily or placebo. The mean patients age was 61 years; about 20% of patients were female and the majority (73%) were White. Most patients were receiving other standard of care therapy, which included aspirin (99%), other antiplatelet agent (98%), statin (99%), or beta-blocker (89%). Most patients (93%) had undergone percutaneous coronary intervention for MI. Patients were followed for a median of 22.6 months. The primary endpoint event (composite of CV death, resuscitated cardiac arrest, MI, stroke, or ugent hospitalization for angina leading to coronary revascularization) occurred in 5.5% of patients randomized to Lodoco vs. 7.1% of those in the placebo group (hazard ratio 0.77; $P = 0.02$).

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]

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POLICY STATEMENT
Prior Authorization is required for benefit coverage of Lodoco. All approvals are provided for the duration noted below.

Lodoco is considered medically necessary when the following are met:

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, ticagrelor), 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. Preferred product criteria is met for the products listed in the below table(s)

Employer Plans:

Product	Criteria
Lodoco (colchicine 0.5 mg capsule)	Patient has tried colchicine 0.6 mg tablets or capsules [may require prior authorization]

Individual and Family Plans:

Product	Criteria
Lodoco (colchicine 0.5 mg capsule)	Patient has tried colchicine 0.6 mg tablets or capsules [may require prior authorization]

Conditions Not Covered

Lodoco for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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]

Receipt of sample product does not satisfy any criteria requirements for coverage.

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;82(9):833-955.
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.
5. Tardif JC, Kouz S, Water DD, et al. Efficacy and safety of low-dose colchicine after myocardial infarction. *N Engl J Med*. 2019;381(26): 2497-2505.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria changes.	12/15/2024
Annual Revision	**Policy Title.** **Updated title from** "Lodoco (colchine tablets) **to** "Cardiology – Lodoco" **Atherosclerotic Disease**: Brilinta was removed from the Note of examples of background regimens for atherosclerotic disease as generic ticagrelor tablets are now available. The criterion about kidney function was removed; previously, the requirement was creatinine clearance is equal to or greater than 50 mL/min. **Removed** documentation requirements in Atherosclerotic Disease criteria and preferred product table	11/1/2025

The policy effective date is in force until updated or retired.