Effective Date **3/1/2024**
Next Review Date… **3/1/2025**
Coverage Policy Number **IP0595**

Lodoco (colchicine capsule)

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Related Coverage Resources

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. 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

This policy supports medical necessity review for colchicine 0.5 mg capsule (**Lodoco**®).

Additional criteria that support the review for medical necessity exceptions of non-covered products are located in the Non-Covered Product Table by the respective plan type and drug list where applicable.

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

Medical Necessity Criteria

Colchicine 0.5 mg capsule (Lodoco) is considered medically necessary when the following are met:

Atherosclerotic Disease. Individual meets **ALL** of the following criteria:
- A. Age 18 years or older
- B. Documentation of one of the following conditions or diagnoses
  - 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 (for example, coronary artery bypass graft surgery, percutaneous coronary intervention, angioplasty, and coronary stent procedures) in the past

C. Lodoco is being added onto other background regimens of other atherosclerotic disease medications (for example, aspirin, antiplatelet agents [clopidogrel, Brilinta], anticoagulants, lipid-lowering agents [statins such as atorvastatin and rosuvastatin], beta blockers, angiotensin-converting enzyme inhibitors, and/or angiotensin receptor blockers)
D. Attestation the individual does not have severe hepatic impairment
E. Creatinine clearance equal to, or greater than, 50 mL/min
F. Preferred product criteria is met for the products listed in the below table(s)

Employer Group Plans Products and Criteria:

Product	Criteria
Lodoco (colchicine 0.5 mg capsule)	Documentation of intolerance to colchicine 0.6 mg tablet

Individual and Family Plans Products and Criteria:

Product	Criteria
Lodoco (colchicine 0.5 mg capsule)	Documentation of intolerance to colchicine 0.6 mg tablet

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When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of Lodoco (colchicine 0.5 mg capsule) is considered medically necessary for Atherosclerotic Disease when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

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]

Background

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]

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.