



## PRIOR AUTHORIZATION POLICY

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

**REVIEW DATE:** 08/30/2023

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### **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.

## **CIGNA NATIONAL FORMULARY COVERAGE:**

### **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.<sup>1</sup> 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.<sup>1,2</sup> The mean patient age was 66 years; only 15% of patients were female. Patients had an estimated glomerular filtration rate  $\geq$  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  $\geq$  risk}; Level of Evidence: randomized).<sup>3</sup>

## POLICY STATEMENT

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

- **Lodoco® (colchicine 0.5 mg tablets ( Agepha)**

**is(are) covered as medically necessary when the following criteria is(are) met for fda-approved indication(s) or other uses with supportive evidence (if applicable):**

### 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  $\geq$  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  $\geq$  50 mL/min.

## CONDITIONS NOT COVERED

- **Lodoco® (colchicine 0.5 mg tablets ( Agepha)**

**is(are) considered experimental, investigational or unproven for ANY other use(s) 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.<sup>4</sup> 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.<sup>2</sup>

## 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

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