# Clinical Policy: Colchicine (Lodoco)

Reference Number: CP.PMN.123
Effective Date: 05.01.11
Last Review Date: 02.26
Line of Business: Commercial, HIM, Medicaid Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## Description

Colchicine (Lodoco®) is an alkaloid.

## FDA Approved Indication(s)

Lodoco is indicated to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death in adult patients with established atherosclerotic disease or with multiple risk factors for cardiovascular disease.

## Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Lodoco is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Cardiovascular Event Prophylaxis** (must meet all)**:**

1. Member meets one of the following (a, b, c, d, e, or f, *see Appendix D*):
   a. History of myocardial infarction or acute coronary syndrome;
   b. History of stroke;
   c. History of coronary revascularization;
   d. Has multiple risk factors for cardiovascular disease;
   e. Diagnosis of stable coronary artery disease;
   f. Peripheral arterial disease;
2. Prescribed by or in consultation with a cardiologist;
3. Age ≥ 18 years;
4. Documentation that member has been clinically stable for at least 6 months (*see Appendix D*);
5. Prescriber attestation that member is concurrently receiving standard of care for one of the following (a or b, *see Appendix D*):
   a. Treatment for atherosclerotic disease (e.g., beta-blockers, antiplatelet therapy, statins, angiotensin converting enzyme inhibitors, aldosterone antagonist, nitrates, antithrombotic therapy, antihypertensive therapy, calcium channel blockers);
   b. Treatment for stable coronary artery disease;
6. Dose does not exceed 0.5 mg (1 tablet) per day.

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2):
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## II. Continued Therapy

**A. Cardiovascular Event Prophylaxis** (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy (e.g. *no drug-related adverse events such as myotoxicity, rhabdomyolysis, abdominal pain, acute renal impairment*);
3. If request is for a dose increase, new dose does not exceed 0.5 mg (1 tablet) per day.

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 2 above does not apply, refer to the off-label use policy for the relevant line

of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

ACC: American College of Cardiology
AHA: American Heart Association
ASCVD: atherosclerotic cardiovascular disease risk assessment
CVD: cardiovascular disease
FDA: Food and Drug Administration
MI: myocardial infarction

*Appendix B: Therapeutic Alternatives*

Not Applicable

*Appendix C: Contraindication/Boxed Warnings*

- Contraindication(s): concurrent use of strong CYP3A4 inhibitors of P-gp inhibitors, including in patients with hepatic or renal impairment; patients with pre-existing blood dyscrasias, renal failure, and severe hepatic impairment
- Boxed warning(s): none reported

*Appendix D: General Information*

- The Lodoco2 study inclusion criteria included patients that were clinically stable, defined as no cardiovascular related hospital admission in the prior 6 months.
- Non-acute management of MI may include beta-blockers, long-term dual antiplatelet therapy with aspirin and a $P2Y_{12}$ receptor blocker, high intensity statins, angiotensin converting enzyme inhibitors, aldosterone antagonist, and/or nitroglycerin.
- Secondary prevention therapies for ischemic stroke may include antithrombotic therapy, antihypertensive therapy, and/or statins.
- Chronic coronary syndrome treatment therapies include beta-blockers, calcium channel blockers, short-acting nitrates, and/or antiplatelet therapies.
- Per American College of Cardiology (ACC) and American Heart Association (AHA), risk factors for cardiovascular disease include:
  - Overweight/obesity or metabolic syndrome
  - Hypertension
  - Dyslipidemia or familial hypercholesterolemia
  - Hyperglycemia
  - Family history of premature ASCVD (males, age < 55 years; females, age <65 years)
  - Diabetes
  - Chronic kidney disease
  - Cigarette smoking/ tobacco use

- Dietary factors (diets with high glycemic index, low consumption of fruits and vegetables, high consumption of trans fatty acids, low consumption of fiber)
- Chronic inflammatory conditions (e.g. psoriasis, RA, lupus, HIV/AIDS)
- Pregnancy-related complications (e.g., intrauterine growth retardation, hypertensive disorders of pregnancy, gestational diabetes)

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Cardiovascular event prophylaxis | 0.5 mg PO once daily | 0.5 mg/day |

## VI. Product Availability

Tablet: 0.5 mg

## VII. References

1. Lodoco Prescribing Information. Parsippany, NJ: Agepha Pharma USA, LLC.; June 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215727s000lbl.pdf. Accessed: November 6, 2025.
2. Nidorf SM, Fiolet ATL, Mosterd A, et al. LoDoCo2 Trial Investigators. Colchicine in patients with chronic coronary disease. N Engl J Med. 2020 Nov 5;383(19):1838-1847. doi: 10.1056/NEJMoa2021372.
3. Nidorft SM, Fiolet ATL, Mosterd A, et al. Colchicine in patients with chronic coronary disease supplementary appendix. N Engl J Med. 2020 Nov 5;383(19):1838-1847. doi: 10.1056/NEJMoa2021372.
4. Kofler T, Kurmann R, Lehnick D, et al. Colchicine in patients with coronary artery disease: A systematic review and meta-analysis of randomized trials. J Am Heart Assoc. 2021 Aug 17;10(16):e021198. doi: 10.1161/JAHA.121.021198.
5. Anzctr.org.au. The LoDoCo2 Trial: A randomized controlled trial on the effect of low dose Colchicine for secondary prevention of cardiovascular disease in patients with established, stable coronary artery disease. March 22, 2021. Available at: https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12614000093684. Accessed November 6, 2025.
6. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2024. Available at: https://www.clinicalkey.com/pharmacology/. Accessed November 24, 2025.
7. Arnett DK, Blumenthal RS, Albert MA, et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2019 Sep 10;140(11):e596-e646. doi: 10.1161/CIR.0000000000000678.
8. Virani SS, Newby LK, Arnold SV, et al.; Peer Review Committee Members. 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. Circulation. 2023 Aug 29;148(9):e9-e119. doi: 10.1161/CIR.0000000000001168.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 1Q 2022 annual review: changed commercial approval duration from Length of Benefit to 12 months or duration of request, whichever is less; references reviewed and updated. | 09.30.21 | 02.22 |
| Removed Commercial and HIM lines of business per formulary statuses; added that member must use generic tablet formulations; added that health plan-approved quantity limits also applies. | 05.23.22 | 08.22 |
| Template changes applied to other diagnoses/indications and continued therapy section. | 10.03.22 | |
| 1Q 2023 annual review: no significant changes; updated dosing in Appendix B; updated template language for continued therapy and other diagnoses/indication sections; references reviewed and updated. | 09.30.22 | 02.23 |
| Added Lodoco to the policy (CP.PHAR.640 to be retired); for FMF, treatment of acute gout attack, gout anti-inflammatory prophylaxis, and pericarditis indications, added "request is not for Lodoco"; added generic redirection for CV prophylaxis; added Commercial and HIM lines of business. | 10.03.23 | 11.23 |
| 1Q 2024 annual review: for Gout Anti-Inflammatory Prophylaxis, updated "unless contraindicated" to "unless contraindicated or clinically significant adverse effects are experienced"; references reviewed and updated. | 11.12.23 | 02.24 |
| Removed generic redirection to colchicine 0.6 mg tablet for CV prophylaxis; updated Appendix B with indications for respective therapeutic alternatives. | 05.07.24 | 06.24 |
| Removed product-specification for CV prophylaxis in continued therapy section. | 07.08.24 | |
| 1Q 2025 annual review: for cardiovascular event prophylaxis, added options of peripheral arterial disease and acute coronary syndrome per competitor analysis and FDA approved indication of atherosclerotic disease and updated the criteria "secondary prevention regimen for MI or stroke" to "treatment for atherosclerotic disease" with examples of standard of care therapy; updated cardiovascular risk factor examples in Appendix D; references reviewed and updated. | 10.29.24 | 02.25 |
| 1Q 2026 annual review: removed brand Colcrys from policy due to product discontinuation and its corresponding indications [familial mediterranean fever, treatment of acute gout attack, gout anti-inflammatory prophylaxis, pericarditis (off-label)]; references reviewed and updated. | 11.06.25 | 02.26 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted

standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.



**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.