PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

LODOCO
(colchicine)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization with Quantity Limit ***Ref # 6039-C***

**Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

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.

COVERAGE CRITERIA

Myocardial Infarction (MI), Stroke, Coronary Revascularization, and Cardiovascular Death
Authorization may be granted when the requested drug is being prescribed to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death when ALL of the following criteria are met:

- The patient is currently receiving guideline-directed management and therapy (GDMT) for chronic coronary disease (e.g., antiplatelet or anticoagulant, lipid-lowering agent, beta-blocker, renin-angiotensin inhibitor, etc.)
- The patient meets ONE of the following:
  - The patient has established atherosclerotic disease [Note: Clinical atherosclerotic disease includes acute coronary syndromes, history of MI, angina, coronary or other arterial revascularization, stroke, transient ischemic attack (TIA), or peripheral arterial disease (PAD).]
  - The patient has multiple risk factors for cardiovascular disease (e.g., family history of premature atherosclerotic cardiovascular disease (ASCVD), primary hypercholesteremia, metabolic syndrome, chronic kidney disease (CKD), etc.)

QUANTITY LIMITS APPLY

30 tablets per 25 days*, 90 tablets per 75 days*
**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

DURATION OF APPROVAL (DOA)

- 6039-C: DOA: 12 months

REFERENCES

1. Lodoco [package insert]. Parsippany, NJ: AGEPHA Pharma USA, LLC; June 2023.
2. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed March 6, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: *03/06/2024*).
4. Nidorf SM, Fiolet ATL, Mosterd A, et al. Colchicine in Patients with Chronic Coronary Disease. *N Engl J Med*. 2020;383:1838-1847.
5. 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;140: e596–e646.

6. 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. *Circulation*. 2023;148:e9-e119.

Written by: UM Development (DRS)
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External Review: 08/2023, 09/2024

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death? [If Yes, then go to 2. If No, then no further questions.]	Yes	No
2	Does the patient have established atherosclerotic disease? [NOTE: Clinical atherosclerotic disease includes acute coronary syndromes, history of myocardial infarction (MI), angina, coronary or other arterial revascularization, stroke, transient ischemic attack (TIA), or peripheral arterial disease (PAD).] [If Yes, then go to 4. If No, then go to 3.]	Yes	No
3	Does the patient have multiple risk factors for cardiovascular disease (e.g., family history of premature atherosclerotic cardiovascular disease (ASCVD), primary hypercholesteremia, metabolic syndrome, chronic kidney disease (CKD), etc.)? [If Yes, then go to 4. If No, then no further questions.]	Yes	No
4	Is the patient currently receiving guideline-directed management and therapy (GDMT) for chronic coronary disease (e.g., antiplatelet or anticoagulant, lipid-lowering agent, beta-blocker, renin-angiotensin inhibitor, etc.)? [If Yes, then go to 5. If No, then no further questions.]	Yes	No
5	Does the patient require MORE than the plan allowance of 30 tablets per month? [No further questions] RPh Note: If yes, then deny and enter a partial approve for 30 tablets / 25 days or 90 tablets / 75 days of Lodoco.	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for decreasing the risk of heart attack, stroke, heart surgery and dying from heart issues. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]

2.	Go to 4	Go to 3	
3.	Go to 4	Deny	Your plan only covers this drug if you have heart disease or if you have several risk factors for heart disease. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Severity]
4.	Go to 5	Deny	Your plan only covers this drug if you will be taking it with other drugs. We have denied your request because: A) You are not (or will not be) taking it with other drugs for heart disease (for example, antiplatelet or anticoagulant drugs, cholesterol drugs, beta-blockers, or renin-angiotensin inhibitors), and B) You do not have a medical reason not to take them. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review [Short Description: No concurrent therapy]
5.	Deny	[PA Approved for 12 months. Approve 30 tablets per 25 days* or 90 tablets per 75 days*.]. Approve, 12 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (30 tablets per month). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review [Short Description: Quantity, Exceeds max limit, Partial denial]