

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1189-3
Program	Prior Authorization/Excluded Drug
Medication	Colchicine Tablet (Colcrlys authorized generic)
P&T Approval Date	5/2016, 5/2017, 6/2018
Effective Date	9/1/2018; Oxford only: 9/1/2018

1. Background:

Mitigare (colchicine capsule) and the Mitigare authorized generic are indicated for the prophylaxis of acute gout flares. Colcrlys (colchicine tablet) and the Colcrlys authorized generic are indicated for prophylaxis and the treatment of gout flares and the treatment of familial Mediterranean fever (FMF). The recommended dose for the prophylaxis of gout flares is 0.6 mg once to twice daily up to a maximum dose of 1.2 mg per day. The recommended dose for the treatment of gout flares is 1.2 mg followed by 0.6 mg one hour later. For FMF, the recommended dose is 1.2 to 2.4 mg daily, titrated by 0.3 mg increments to manage side effects. Patients with severe renal or hepatic impairment and patients taking concomitant CYP3A4 inhibitors, P-glycoprotein inhibitors, or protease inhibitors may require a reduced dose of 0.3 mg.

2. Coverage Criteria:

A. Initial Authorization

1. Colchicine tablet (Colcrlys authorized generic) is currently excluded.

However, it will be approved based on the following criterion:

a. Patient requires a reduced dose of 0.3 mg (half of a 0.6 mg tablet) due to **one** of the following criteria:

- (1) Severe renal impairment (e.g. estimated creatinine clearance less than 30 mL/min)
- (2) Severe hepatic impairment (e.g. Child-Pugh score of B or C)
- (3) Concomitant use of a CYP3A4 inhibitor (e.g. clarithromycin, itraconazole), P-glycoprotein inhibitor (e.g. cyclosporine), or a protease inhibitor (e.g. Reyataz)
- (4) The treatment of familial Mediterranean fever
- (5) Intolerable side effects that cannot be managed by extending the dosing interval

Authorization will be issued for 12 months

3. Additional Clinical Rules:

- N/A

4. References:

1. Colcrys Prescribing Information. Takeda Pharmaceuticals America, Inc. Deerfield, IL. Dec. 2015.
2. Mitigare Prescribing Information. Hikma Americas, Inc. Memphis, TN. Nov. 2015.

Program	Prior Authorization/Excluded Drug – Colcrys
Change Control	
Date	Change
5/2016	New program.
5/2017	Annual review. Removed medical record requirement.
6/2018	Annual review. No changes.