

PREFERRED STEP THERAPY POLICY

- POLICY:** Colchicine Preferred Step Therapy Policy
- Colcryst™ (colchicine tablets – Takeda, generic)
 - Mitigare® (colchicine capsules – Hikma, generic)

REVIEW DATE: 05/04/2022

OVERVIEW

Colcryst is indicated for the following uses:¹

- **Prophylaxis of gout flares**, in adults.
- **Treatment of gout flares**, in adults.
- **Familial Mediterranean fever (FMF)**, in adults and children aged ≥ 4 years.

Mitigare is indicated for the **prophylaxis of gout flares** in adults.² The safety and effectiveness of Mitigare for acute treatment of gout flares during prophylaxis has not been studied.

The safety and pharmacokinetic profiles presented in the product labeling are comparable for Colcryst and Mitigare.^{1,2}

Table 1. FDA-Approved Indications, Dosing, and Dosage Forms.^{1,2}

	Indications	Recommended Dosing*	Dosage Form(s)
Colcryst™ (colchicine tablets, generic)	<u>Prophylaxis</u> of gout flares in adults	> 16 years of age: 0.6 mg QD or BID. <i>Maximum recommended dose:</i> 1.2 mg/day.	0.6 mg tablets
	<u>Treatment</u> of gout flares in adults	Adults: 1.2 mg at the first sign of a gout flare, followed by 0.6 mg 1 hour later (maximum of 1.8 mg per 1-hour period). Wait 12 hours to resume prophylactic dosing.	
	<u>Treatment</u> of Familial Mediterranean fever	Daily doses may be given in one or two divided doses. Titrate to maximum recommended doses as needed. > 12 years of age: 1.2 mg to 2.4 mg/day. 6 to 12 years of age: 0.9 mg to 1.8 mg/day. 4 to 6 years of age: 0.3 mg to 1.8 mg/day.	
Mitigare® (colchicine capsules, generic)	<u>Prophylaxis</u> of gout flares in adults	Adults: 0.6 mg QD or BID. <i>Maximum recommended dose:</i> 1.2 mg/day.	0.6 mg capsules

* Specific dose adjustment recommendations for patients with drug interactions or renal dysfunction are provided in the prescribing information for Colcryst and colchicine tablets; QD – Once daily; BID – Twice daily.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Preferred Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Preferred Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: colchicine tablets (generic), Mitigare capsules

Step 2: colchicine capsules (generic), Colcrys tablets

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

Note: Colcrys with DAW 9 (indicating that substitution is allowed by the prescriber but the Plan requests brand) will also count as a Step 1 Product.

2. No other exceptions are recommended.

REFERENCES

1. Colcrys™ tablets [prescribing information]. Deerfield, IL: Takeda; April 2021.
2. Mitigare® capsules [prescribing information]. Memphis, TN: Hikma; June 2020.