PREFERRED STEP THERAPY POLICY

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

REVIEW DATE: 11/13/2024

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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

Colcrys is indicated for the following uses:[1]
- **Prophylaxis of gout flares**, in adults and adolescents > 16 years of age.
- **Treatment of gout flares**, in adults.
- **Familial Mediterranean fever**, in adults and children ≥ 4 years of age.

Mitigare is indicated for the **prophylaxis of gout flares** in adults.[2] Limitations of Use: The safety and effectiveness of Mitigare for acute treatment of gout flares during prophylaxis has not been studied. Mitigare is not an analgesic medication and should not be used to treat pain from other causes.

The safety and pharmacokinetic profiles presented in the product labeling are comparable for Colcrys and Mitigare.[1,2]

Table 1. FDA-Approved Indication(s), Dosing, and Dosage Forms[1,2]

	Indication(s)	Recommended Dosing*	Dosage Form
Colcrys® (colchicine tablets, generic)	Prophylaxis of gout flares	> 16 years of age: 0.6 mg QD or BID. *Maximum recommended dose*: 1.2 mg/day.	0.6 mg tablets
	Treatment of gout flares	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.	
	Treatment 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)	Prophylaxis of gout flares	Adults: 0.6 mg QD or BID. *Maximum recommended dose*: 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 Colcrys 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. Note: Gloperba® (colchicine oral solution) and Lodoco® (colchicine 0.5 mg tablets) are not targeted in this Policy.

Step 1: colchicine tablets (generic)

Step 2: colchicine capsules (generic), Colcrys (brand), Mitigare (brand)

***Colchicine Products Preferred Step Therapy Policy* product(s) is(are) covered as medically necessary when the following preferred step therapy criteria is(are) met. Any other exception is considered not medically necessary.**

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.

REFERENCES

1. Colcrys® tablets [prescribing information]. Deerfield, IL. Takeda; December 2023.
2. Mitigare® capsules [prescribing information]. Memphis, TN: Hikma; November 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	**Title:** "Products" was added to title. **Mitigare**: Mitigare (brand) was removed Step 1 and added to Step 2. **Policy Statement**: The following note was added: Lodoco (colchicine 0.5 mg tablets) is not targeted in this Policy.	12/13/2023
Annual Revision	No criteria changes. **Policy Statement**: Gloperba was added to the following Note: Gloperba (colchicine oral solution) and Lodoco (colchicine 0.5 mg tablets) are not targeted in this Policy.	11/13/2024