

Clinical Policy: Colchicine (Colcrlys)

Reference Number: CP.PMN.123

Effective Date: 05.01.11

Last Review Date: 05.18

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Colchicine (Colcrlys[®]) is an alkaloid.

FDA Approved Indication(s)

Colcrlys is indicated:

- For the prophylaxis and treatment of gout flares in adults
- For the treatment of familial Mediterranean fever (FMF) in adults and children 4 years or older

Limitation of use: Colcrlys is not an analgesic medication and should not be used to treat pain from other causes.

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 Colcrlys is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Familial Mediterranean Fever (must meet all):

1. Diagnosis of FMF;
2. Age \geq 4 years;
3. Dose does not exceed 2.4 mg per day (4 tablets per day).

Approval duration: 12 months

B. Gout - Treatment of Acute Attack (must meet all):

1. Diagnosis of acute gout attack;
2. Age \geq 16 years;
3. Failure of a nonsteroidal anti-inflammatory drug (NSAID) (e.g., naproxen, indomethacin, sulindac) within the last 30 days unless member has one of the following contraindications:
 - a. Heart failure or uncontrolled hypertension;
 - b. Current use of an anticoagulant (aspirin, warfarin, low molecular weight heparin, direct thrombin inhibitors, factor Xa inhibitors, and clopidogrel);
 - c. Active duodenal or gastric ulcer (not gastroesophageal reflux disease [GERD]);
 - d. Current use of corticosteroid;

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- e. Chronic kidney disease with CrCl < 60 mL/min per 1.73 m²;
4. Dose does not exceed 1.8 mg for the initial dose (3 tablets) followed by 1.2 mg per day (2 tablets per day) thereafter.

Approval duration: 2 weeks (no more than 30 tablets)

C. Gout - Anti-Inflammatory Prophylaxis (must meet all):

1. Diagnosis of gout;
2. Age ≥ 16 years;
3. Member is currently taking or will be initiating a urate-lowering therapy (e.g., allopurinol, probenecid) within the next 6 months, unless contraindicated;
4. Dose does not exceed 1.2 mg per day (2 tablets per day).

Approval duration: 6 months

D. Pericarditis (off-label) (must meet all):

1. Diagnosis of pericarditis;
2. Prescribed by or in consultation with a cardiologist;
3. Colchicine will be used concurrently with an NSAID;
4. Dose does not exceed 1.2 mg per day (2 tablets per day).

Approval duration: 6 months

E. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy**A. Familial Mediterranean Fever (must meet all):**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 2.4 mg per day (4 tablets per day).

Approval duration: 12 months

B. Gout - Treatment of Acute Attack (must meet all):

1. Member meets all initial approval criteria.

Approval duration: 2 weeks (no more than 30 tablets)

C. Gout - Anti-Inflammatory Prophylaxis (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is currently taking a urate-lowering therapy (e.g., allopurinol, probenecid) at up to maximally indicated doses, unless contraindicated;
3. Member is responding positively to therapy;

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- If request is for a dose increase, new dose does not exceed 1.2 mg per day (2 tablets per day).

Approval duration: 6 months

D. Pericarditis (off-label) (must meet all):

- Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
- Member is responding positively to therapy;
- At least 4 weeks since the last request for colchicine;
- Colchicine will be used concurrently with an NSAID;
- If request is for a dose increase, new dose does not exceed 1.2 mg per day (2 tablets per day).

Approval duration: 6 months

E. Other diagnoses/indications (must meet 1 or 2):

- Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 12 months (whichever is less); or
- Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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

- 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.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CrCl: creatinine clearance	GERD: gastroesophageal reflux disease
FDA: Food and Drug Administration	NSAID: nonsteroidal anti-inflammatory drug
FMF: familial Mediterranean fever	

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
naproxen (Naprosyn [®])	250 mg every 8 hours	Naproxen 1500 mg/day Naproxen sodium up to 1650 mg/day
indomethacin (Indocin [®])	50 mg three times daily	200 mg/day IR capsules 150 mg/day SR capsules

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
sulindac (Clinoril [®])	200 mg twice daily	400 mg per day
allopurinol (Zyloprim [®])	100 mg once daily	800 mg per day
probenecid	250 to 500 mg twice daily	2 g per day

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: General Information

- Per the American College of Rheumatology 2012 guidelines for the management of gout, an inadequate response to therapy is defined as < 20% improvement in pain score within 24 hours or < 50% improvement in pain score at ≥ 50%.
- Examples of positive response to therapy for FMF are: reduction/normalization of C-reactive protein (CRP) or serum amyloid A (SAA) levels; reduction of flare frequency, symptom severity, or duration.
- Acute pericarditis is defined as or new onset. Recurrent pericarditis is defined as recurring after a symptom-free interval of at least 4 weeks.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
FMF	4-6 years: 0.3 mg to 1.8 mg daily 6-12 years: 0.9 mg to 1.8 mg daily ≥ 12 years: 1.2 mg to 2.4 mg daily	2.4 mg/day
Prophylaxis of gout flares	0.6 mg once or twice daily	1.2 mg/day
Treatment of gout flares	1.2 mg at first sign of flare, followed by 0.6 mg one hour later	1.8 mg/treatment
Pericarditis (off-label)	< 70 kg: 0.5 mg daily* ≥ 70 kg: 0.5 mg twice daily*	1 mg/day*

** This is the recommended dosing per the European Society of Cardiology guidelines. Note that the 0.5 mg dosage form is not available in the US.*

VI. Product Availability

Tablet: 0.6 mg

VII. Workflow Document

N/A

VIII. References

1. Colcrys Prescribing Information. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; December 2015. Available at: www.colcrys.com. Accessed February 2, 2018.
2. Khanna D, Fitzgerald JD, Khanna PJ, et al. 2012 American College of Rheumatology guidelines for management of gout. Part 1: systemic nonpharmacologic and pharmacologic approaches to hyperuricemia. *Arthritis Care & Research*. 2012; 64(10): 1431-1446.

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3. Khanna D, Khanna PJ, Fitzgerald JD, et al. 2012 American College of Rheumatology guidelines for management of gout. Part 2: therapy and antiinflammatory prophylaxis of acute gouty arthritis. *Arthritis Care & Research*. 2012; 64(10): 1447-1461.
4. Ozen S, Demirkaya E, Erer B, et al. EULAR recommendations for the management of familial Mediterranean fever. *Ann Rheum Dis*. 2016; 75(4): 644-651.
5. Lilly LS. Clinician update: treatment of acute and recurrent idiopathic pericarditis. *Circulation*. 2013; 127: 1723-1726.
6. Adler Y, Charron P, Imazio M, et al. 2015 ESC guidelines for the diagnosis and management of pericardial diseases: the Task Force for the Diagnosis and Management of Pericardial Diseases of the European Society of Cardiology (ESC). *Eur Heart J*. 2015; 36(42): 2921-2964.
7. Bach DS. Latest in cardiology: 2015 ESC guidelines for pericardial disease. American College of Cardiology. Published October 30, 2015. Available at: <http://www.acc.org/latest-in-cardiology/ten-points-to-remember/2015/10/30/12/01/2015-esc-guidelines-for-the-diagnosis-and-management-of-pericardial-diseases>. Accessed February 6, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
<p>Special instruction: Added “hepatic disease; renal impairment/disease contraindications” and “Dosage adjustments are needed in patients with normal renal and hepatic function taking interacting medications”</p> <p>Criteria for approval: Added “Concomitant use upon initiation of allopurinol therapy” for gout prophylaxis and noted “3 months with initiation of allopurinol therapy” in the initial approval.</p> <p>Criteria for approval: Added “Baseline CBC and Alkaline phosphatase” to information needed for approval because colchicine has been associated with decreased blood count and hepatic enzyme elevation. Added: “severe adverse reaction and contraindication” to the definition of trial and failure.</p> <p>Note: Added “and adolescents”</p> <p>Description: Rewording and added that “Colchicine is not effective for other types of pain. It is not an analgesic and does not affect uric acid clearance.”</p> <p>Updated references</p>	05.13	05.13
Updated references	05.15	05.15
Converted to new template; Modified criteria specify required time frame for allopurinol use to be considered a failure; Modified criteria to require use of colchicine/probenecid in patients who cannot use allopurinol, added a specified time frame for use to be considered a failure; Added criteria for treatment of acute gout attack with quantity limit	08.15	08.15
Modify the criteria for chronic use of gout to allow for gout prophylaxis in members with hyperuricemia , initiating therapy with a urate lowering medication and changed approval duration to 6 months;	05.16	05.16

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Specified the maximum allowable dose for FMF and gout; Modify renewal criteria to identify the diagnoses for which continued treatment may be approved. References updated		
Treatment of gout: added option for failure of NSAID (per ACR guidelines: those with inadequate response to initial therapy should be switched to alternate monotherapy); Prophylaxis of gout: Removed diagnosis of hyperuricemia as colchicine is indicated for gout and does not alter urate levels, Added requirement for evidence of active gout and modified serum urate level from 6.5 mg/dL to 6 mg/dL per ACR guideline minimum target, Removed requirement for trial/failure of urate lowering therapies (per ACR guidelines: colchicine is 1 st line for anti-inflammatory prophylaxis and should be used with or just prior to initiating ULT), Continuation: added requirement for use of ULT; modified approval duration to 6 months; Pericarditis: developed criteria set for this off-label indication (per ESC guidelines, which were supported by ACC, and per AHA clinician update: colchicine is a 1 st line agent that can be added to conventional NSAID therapy to improve response to therapy, increase remission, and reduce recurrence) <i>Note: the maximum dose enforced in this criteria reflects the available 0.6 mg dosage form and allows up to 2 tablets per day;</i> Converted to new template; Removed age restriction for FMF per updated template; age restriction is maintained for gout indications per package insert and per age edits currently in place; Added quantity limit for gout treatment (max 30 tablets); Continuation: separated into individual criteria sets; added requirement for documentation of positive response for FMF and anti-inflammatory prophylaxis of gout; Updated references	03.17	05.17
2Q 2018 annual review: no significant changes, reference number changed from PPA to PMN; removed classification of pericarditis indication; removed requirement of clinical evidence of gout; added age limit to FMF; references reviewed and updated.	02.13.18	05.18

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

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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.

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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.

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