Clinical Policy: Colchicine (Colcrys)

Reference Number: CP.PMN.123
Effective Date: 05.01.11
Last Review Date: 02.22
Line of Business: Commercial, HIM, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Colchicine (Colcrys®) is an alkaloid.

FDA Approved Indication(s)

Colcrys 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

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 Colcrys 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 ≥ 4 years;
3. Dose does not exceed 2.4 mg (4 tablets) per day.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 12 months or duration of request, whichever is less

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

1. Diagnosis of acute gout attack;
2. Age ≥ 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, b, c, d, or e):
   a. Heart failure or uncontrolled hypertension;
   b. Current use of an anticoagulant (e.g., aspirin, warfarin, low molecular weight heparin, direct thrombin inhibitors, factor Xa inhibitors, clopidogrel);
   c. Active duodenal or gastric ulcer (not gastroesophageal reflux disease [GERD]);
   d. Current use of corticosteroid;
   e. Chronic kidney disease with CrCl < 60 mL/min per 1.73 m^2;

4. Dose does not exceed 1.8 mg for the initial dose (3 tablets) followed by 1.2 mg (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 (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 is prescribed concurrently with an NSAID or glucocorticoid;
4. Dose does not exceed 1.2 mg (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.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and 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 as evidenced by, including but not limited to, improvement in any of the following parameters:
   a. Reduction/normalization of C-reactive protein (CRP) or serum amyloid A (SAA) levels;
   b. Reduction of flare frequency, symptom severity, or duration;
3. If request is for a dose increase, new dose does not exceed 2.4 mg (4 tablets) per day.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 12 months or duration of request, whichever is less

B. Treatment of Acute Gout Attack

1. Re-authorization is not permitted. Member must meet the initial approval criteria.

Approval duration: Not applicable

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 responding positively to therapy;
3. Member is currently taking a urate-lowering therapy (e.g., allopurinol, probenecid) at up to maximally indicated doses, unless contraindicated;
4. If request is for a dose increase, new dose does not exceed 1.2 mg (2 tablets) per day.

Approval duration: 6 months

D. Pericarditis (off-label) (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. At least 4 weeks has passed since the last request for colchicine;
4. Colchicine is prescribed concurrently with an NSAID or glucocorticoid;
5. If request is for a dose increase, new dose does not exceed 1.2 mg (2 tablets) per day.

Approval duration: 6 months

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

1. 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
2. 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.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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

A. 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.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

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

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 PO every 8 hours	Naproxen: 1,500 mg/day Naproxen sodium: up to 1,650 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
indomethacin (Indocin®)	50 mg PO TID	200 mg/day (IR capsules); 150 mg/day (SR capsules)
sulindac (Clinoril®)	200 mg PO BID	400 mg/day
allopurinol (Zyloprim®)	100 mg PO QD	800 mg/day
probenecid	250 to 500 mg PO BID	2 g/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: Contraindication/Boxed Warnings

- Contraindication(s): Patients with renal or hepatic impairment should not be given Colcrys in conjunction with P-gp or strong CYP3A4 inhibitors. In these patients, life-threatening and fatal colchicine toxicity has been reported with colchicine taken in therapeutic doses.
- Boxed warning(s): none reported

Appendix D: 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%.
- Acute pericarditis is defined as 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	*Age 4-6 years*: 0.3 mg to 1.8 mg daily *Age 6-12 years*: 0.9 mg to 1.8 mg daily *Age ≥ 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)	*Weight < 70 kg*: 0.5 mg daily* *Weight ≥ 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. References

1. Colcrys Prescribing Information. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; May 2020. Available at: www.colcrys.com. Accessed September 13, 2021.
2. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. Arthritis Care & Research. June 2020; 0 (0): 1-17.

3. 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.
4. Chiabrando JG, Bonaventura A, Vecchié A, et al. Management of Acute and Recurrent Pericarditis. J Am Coll Cardiol 2020;75:76-92
5. 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.
6. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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
1Q 2019 annual review: added commercial line of business; revised approval duration for FMF to length of benefit; no significant changes; references reviewed and updated.	10.30.18	02.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	10.29.19	02.20
1Q 2021 annual review: added HIM line of business; modified FMF approval duration to 12 months for Medicaid/HIM; for FMF indication added examples of positive response included in Appendix D to section II; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	11.16.20	02.21
For pericarditis, added the option to use colchicine in combination with glucocorticoids.	04.15.21	08.21
1Q 2022 annual review: changed commercial approval duration from Length of Benefit to 12 months or duration of request, whichever is less; references reviewed and updated.	09.30.21	02.22

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

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.