Clinical Policy: Colchicine (Colcrys)

Reference Number: PA.CP.PMN.123
Effective Date: 01/18
Last Review Date: 01/19

Coding Implications
Revision Log

Description
Colchicine (Colcrys®) is an alkaloid.

FDA approved indication
Colcrys is indicated:

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

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

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness ® that Colcrys is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Familial Mediterranean Fever (FMF) (must meet all)**:**

1. Diagnosis of familial Mediterranean fever (FMF);
2. Dose does not exceed 2.4 mg (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 ≥ 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 will be used concurrently with an NSAID;
4. Dose does not exceed 1.2 mg (2 tablets) per day.

Approval duration: 6 months

E. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 2.4 mg (4 tablets) per day.

Approval duration: Length of Benefit

B. Treatment of Acute Gout Attack:

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

Approval duration: Not Applicable

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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;
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 Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. At least 4 weeks have passed since the last request for colchicine;

4. Colchicine will be used concurrently with an NSAID;
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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

Approval duration: 12 months or duration of request (whichever is less)

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 policy – PA.CP.PMN.53 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
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%.
- 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	*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.; December 2015. Available at: www.colcrys.com. Accessed October 30, 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.
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
2Q 2018 annual review: reference number changed from PPA to PMN; removed classification of pericarditis indication; removed requirement of clinical evidence of gout; references reviewed and updated.	02.13.18	
1Q 2019 annual review: revised approval duration for FMF to length of benefit; references reviewed and updated.	01.19	