Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 6/1/2018**
Policy Number: : PA.CP.PPA.11	**Effective Date: 01/01/2018** **Revision Date: 04/18/2018**
Policy Name: Colchicine (Colcrys)	**HC Approval Date:**

Type of Submission – Check all that apply:

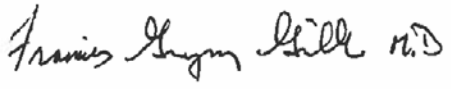
- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

This policy is being retired and replaced by the following policy:

- **PA.CP.PMN.123 Colchicine (Colcrys)**

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Colchicine (Colcrys)

Reference Number: PA.CP.PPA.11
Effective Date: 01/18
Last Review Date: 11/17
Line of Business: Medicaid

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 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 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 ≥ 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;
   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 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 with clinical evidence of disease activity indicated by at least one of the following:
   a. 1 or more tophi detected on physical examination;
   b. Recent acute gout attacks;
   c. Chronic gouty arthritis;
   d. Current (within the last 30 days) serum urate ≥ 6.0 mg/dL;
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 classified as one of the following (a or b):
   a. Acute (new onset);
   b. Recurrent (recurring after a symptom-free interval of at least 4 weeks);
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: 3 months for acute pericarditis; 6 months for recurrent pericarditis

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. FMF (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. Documentation of positive response to therapy (e.g., reduction/normalization of C-reactive protein (CRP) or serum amyloid A (SAA) levels; reduction of flare frequency, symptom severity, or duration);
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; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

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

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. Documentation of positive response to therapy;
4. 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)**:**

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. Documentation of positive response to therapy;
3. Pericarditis has recurred after a symptom-free interval of at least 4 weeks 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 per day (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: Inadequate Response to Acute Gout Treatment

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%.

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. References

1. Colcrys Prescribing Information. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; December 2015. Available at: www.colcrys.com. Accessed January 12, 2017.
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