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Last P&T Approval/Version: 10/29/2025
Next Review Due By: 10/2026
Policy Number: C4205-A

Colcrys, Mitigare, Gloperba (colchicine)

PRODUCTS AFFECTED

Colcrys (colchicine), Gloperba (colchicine) oral solution, Mitigare (colchicine)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Treatment and prevention of acute gout flares, Familial Mediterranean Fever (FMF), Behcet's syndrome, Amyloidosis, Pericarditis (acute and prophylaxis of recurrent) including post-pericardiotomy syndrome

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. ALL INDICATIONS:
1. (a) Documented diagnosis of gout AND EITHER of the following (i) FOR ACUTE treatment: Documentation of a trial (2 weeks) and failure or FDA labeled contraindication to ONE formulary/preferred glucocorticoids AND ONE formulary/preferred NSAIDs OR (ii) FOR

PROPHYLAXIS: Documentation of a trial, failure or contraindication to formulary allopurinol [failure at maximal therapeutic doses (600mg/day), failure defined as non- resolution of tophi or at least 4 gout attacks (joint flares) per year with demonstrated medication adherence]
OR
(b) Documented diagnosis of familial Mediterranean fever
OR
(c) Documented diagnosis of Behcet's syndrome
OR
(d) Documented diagnosis of pericarditis
OR
(e) Documented diagnosis of amyloidosis
AND

2. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Colcrys (colchicine), Mitigare (colchicine), Gloperba (colchicine oral solution) include: Concomitant use of drugs that are both P-glycoprotein and CYP3A4 inhibitors in patients with renal or hepatic impairment]
   AND
3. Documentation of trial (2 weeks) and therapeutic failure of generic preferred formulary product of colchicine
   AND
4. Prescriber attests that Gloperba (colchicine) oral solution or Mitigare (colchicine capsules) will NOT be used for acute treatment of gout flares during prophylaxis.

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:

1. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:

Initial authorization 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

No requirement

AGE RESTRICTIONS:

Gout acute treatment, Pericarditis, Behcet's syndrome: 18 years of age and older
Gout Prophylaxis: 16 years of age and older
Familial Mediterranean fever: 4 years of age and older
Amyloidosis: 5 years and older

QUANTITY:

Familial Mediterranean fever: 2.4 mg per day
Prophylaxis of gout: 1.2 mg per day, acute gout flares: 10 tabs/caps per 30 days
Pericarditis: maximum dose 1.2 mg per day
Behcet's syndrome: maximum of 1.8 mg per day
Amyloidosis: 2.4 mg per day

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Gout Agents

FDA-APPROVED USES:
Mitigare (colchicine capsules) is indicated for prophylaxis of gout flares in adults
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.

Gloperba (colchicine) oral solution is indicated for prophylaxis of gout flares in adults
Limitations of use: The safety and effectiveness of GLOPERBA for acute treatment of gout flares during prophylaxis has not been studied. GLOPERBA is not an analgesic medication and should not be used to treat pain from other causes.

Colcrys (colchicine tablets) is indicated for prophylaxis and treatment of gout flares in adults and Familial Mediterranean fever (FMF) in adults and children 4 years or older. Colcrys is not an analgesic medication and should not be used to treat pain from other causes.

COMPENDIAL APPROVED OFF-LABELED USES:
Acute pericarditis, Pericarditis with multiple recurrences, Prophylaxis of post-pericardiotomy syndrome, Behcet's syndrome, Amyloidosis

APPENDIX

APPENDIX:

CYP3A4 Inhibitors and Inducers

Strong Inhibitors	Moderate Inhibitors	Strong Inducers	Moderate Inducers
Atazanavir	Amiodarone	Apalutamide	Bexarotene
Clarithromycin	Amprenavir	Carbamazepine	Bosentan
Darunavir	Conivaptan	Enzalutamide	Dabrafenib
Indinavir	Delavirdine	Fosphenytoin	Dexamethasone
Itraconazole	Diltiazem	Lumacaftor	Efavirenz
Ketoconazole	Erythromycin	Mitotane	Eslicarbazepine
Lopinavir	Fluconazole	Phenobarbital	Etravirine
Nefazodone	Fosamprenavir	Phenytoin	Lorlatinib
Nelfinavir	Miconazole	Primidone	Modafinil
Ritonavir and ritonavir containing coformulations	Verapamil	Rifampin (rifampicin)	Nafcillin
Saquinavir			Rifabutin
Telithromycin			Rifapentine
Tipranavir			St. John's Wort

Inhibitors and inducers of P-glycoprotein (P-gp) drug efflux pump (P-gp multidrug resistance transporter)

Inhibitors of P-gp	Inducers of P-gp
Amiodarone	Apalutamide
Azithromycin (systemic)	Carbamazepine
Carvedilol	Fosphenytoin
Clarithromycin	Phenobarbital
Cobicistat	Phenytoin
Cyclosporine	Rifampin (rifampicin)
Daclatasivir	St. John's Wort
Dronedarone	
Elagolix	
Eliglustat	
Erythromycin	
Flibanserin	
Fostamatinib	
Glecaprevir-pibrentasvir	
Itraconazole	
Ivacaftor	
Ketoconazole	
Lapatinib	

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Mitigare (colchicine capsule) and the Mitigare authorized generic are indicated for the prophylaxis of acute gout flares. Colcrys (colchicine tablet) and the Colcrys authorized generic are indicated for prophylaxis and the treatment of gout flares and the treatment of familial Mediterranean fever (FMF). The recommended dose for the prophylaxis of gout flares is 0.6 mg once to twice daily up to a maximum dose of 1.2 mg per day. The recommended dose for the treatment of gout flares is 1.2 mg followed by 0.6 mg one hour later. For FMF, the recommended dose is 1.2 to 2.4 mg daily, titrated by 0.3 mg increments to manage side effects. Members with severe renal or hepatic impairment and members taking concomitant CYP3A4 inhibitors, P-glycoprotein inhibitors, or protease inhibitors may require a reduced dose of 0.3 mg.

Colchicine should be administered in a total dose on day 1 not to exceed 1.8 mg, either taken as 0.6 mg three times on the first day or taken as 1.2 mg for the first dose followed by 0.6 mg an hour later. Most member s will not achieve complete resolution of pain within 24 hours but will respond further over several days of continued dosing at 0.6 mg once or twice daily, as tolerated, with stepwise reduction in the dose as the flare gradually resolves. Colchicine flare treatment can be discontinued within two to three days of flare resolution.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of colchicine are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to colchicine include: Concomitant use of p-glycoprotein or CYP3A4 inhibitors, including all protease inhibitors except fosamprenavir, in patients with hepatic or renal impairment (life-threatening and fatal colchicine toxicity has been reported), patients with both renal and hepatic impairment.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device*

code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Colchicine CAPS 0.6MG
Colchicine TABS 0.6MG
Colcrys TABS 0.6MG
Gloperba SOLN 0.6MG/5ML (150ml) bottle
Mitigare CAPS 0.6MG

REFERENCES

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2. Gloperba (colchicine USP) Oral Solution [prescribing information]. Palo Alto, CA: Scilex Holding Company; August 2024.
3. Colcrys (colchicine , USP) tablets, for oral use [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; July 2025.
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5. FitzGerald, J., Dalbeth, N., Mikuls, T., Brignardello-Petersen, R., Guyatt, G., & Abeles, A. et al. (2020). 2020 American College of Rheumatology Guideline for the Management of Gout. Arthritis Care & Research, 72(6), 744-760. doi: 10.1002/acr.24180
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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Continuation of Therapy References	Q4 2025
REVISION- Notable revisions: Coding/Billing Information Template Update ANNUAL REVIEW COMPLETED- No coverage criteria	Q4 2024

changes with this annual review.	
REVISION- Notable revisions: Continuation of Therapy Quantity FDA-Approved Uses References	Q4 2023
REVISION- Notable revisions: Required Medical Information FDA-Approved Uses Appendix Contraindications/Exclusions/Discontinuation References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file