Clinical Policy: Analgesic Agents: Gout

Reference Number: OH.PHAR.PPA.22
Effective Date: 01.2020
Last Review Date: 11.2021
Line of Business: Medicaid

Coding Implications
remove if no codes added
Revision Log

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

Description

The following are Analgesic Agents for the treatment of Gout requiring prior authorization:

ANALGESIC AGENTS: GOUT – Agents to Reduce Hyperuricemia

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ALLOPURINOL (generic of Zyloprim®) PROBENECID (generic for Benemid®)	ULORIC® (febuxostat)

ANALGESIC AGENTS: GOUT – Analgesic Agents*

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
COLCHICINE tablets (generic of Colcrys®) PROBENECID-COLCHICINE	GLOPERBA® solution (colchicine) COLCHICINE capsules (generic of Mitigare®) COLCHICINE capsules

Colchicine quantity limit 6/claim for acute gout, 60/30 days for chronic gout after trial on xanthine oxidase inhibitor, 120/30 days for FMF

* Gloperba quantity limit is 1.2 mg per day

FDA Approved Indication(s)

- Familial Mediterranean fever
- Gout
- Gouty arthritis
- Hyperuricemia

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 Buckeye Health Plan, an affiliate of Centene Corporation® that Uloric, and colchicine (generic Colcrys or Mitagare) are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria - prescribed drug is colchicine

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: 6 months

B. Acute Gout (must meet all)**:**

1. Diagnosis of Acute Gout
2. Age ≥ 16 years
3. Trial of one of the following within the last 30 days: NSAID (i.e., indomethacin, naproxen, ibuprofen, sulindac, ketoprofen); OR Oral corticosteroid unless one of the following.
    a. Allergy to all medications not requiring prior approval
    b. Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
    c. History of unacceptable/toxic side effects to medications not requiring prior approval
4. Colchicine capsules can be approved if the patient had a trial and failure with colchicine tablets

Approval duration: 12 months for quantity of no more than 6 tablets/claim

C. Chronic Gout (must meet all)**:**

1. Diagnosis of Chronic Gout
2. Age ≥ 16 years
3. Trial of xanthine oxidase inhibitor unless one of the following.
    a. Allergy to all medications not requiring prior approval
    b. Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
    c. History of unacceptable/toxic side effects to medications not requiring prior approval
4. Dose does not exceed 1.2 mg (2 tablets) per day.
5. Colchicine capsules can be approved if the patient had a trial and failure with colchicine tablets

Approval duration: 12 months for quantity of no more than 60 tablets/30 days

II. Initial Approval Criteria -prescribed drug is Gloperba solution (colchicine)

A. Prevention of gout flares in adults (must meet all)

1. Diagnosis of Prophylaxis of gout flares in adults
2. Age ≥ 16 years
3. Inability to swallow colchicine tablets
3. Trial of one of the following within the last 30 days: NSAID (i.e., indomethacin, naproxen, ibuprofen, sulindac, ketoprofen); OR oral corticosteroid unless one of the following.

a. Allergy to all medications not requiring prior approval
b. Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
c. History of unacceptable/toxic side effects to medications not requiring prior approval

4. Dose does not exceed 1.2 mg per day.

Approval duration: 12 months

III. Initial approval Criteria Prescribed drug is (febuxostat) ULORIC

A. Hyperuricemia (must meet all)**:**

1. Diagnosis of Hyperuricemia associated with gout
2. Trial of at least 30 days of maximum allopurinol dose, or intolerance/contraindication to allopurinol, unless one of the following
   a. Allergy to all medications not requiring prior approval
   b. Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
   c. History of unacceptable/toxic side effects to medications not requiring prior approval

Approval duration: 12 months

IV. 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.

V. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
PA: Prior Authorization
ER: Extended Release

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 for all relevant lines of business 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
probenecid	250 to 500 mg PO BID	2 g/day
colchicine (Colcrys®, Mitigare®)	0.5 mg to 1 mg/day PO QD or BID	1.8 mg/day
Colchicine (Gloperba solution)	0.6mg PO QD or BID	1.2mg/day
allopurinol (Aloprim®, Zyloprim®)	Gout: (mild) 100 to 300 mg/day PO as a single or divided dose (2-3 times daily) Gout: (moderate to severe) 400 to 600 mg/day PO as a single or divided dose (2-3 times daily)	800 mg/day
Uloric (febuxostat)	40 mg PO QD; may be increased to 80 mg QD if serum uric acid levels are not less than 6 mg/dL after 2 weeks	80 mg/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: Contraindications/Boxed Warnings

- Refer to clinical pharmacology or other appropriate clinical resource

VI. Dosage and Administration

Drug name	Indication	Dosing Regimen	Maximum Dose
colchicine (Colcrys®, Mitigare®)	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*
Febuxostat (Uloric)	Hyperuricemia in patients with gout	40 mg or 80 mg PO QD	80 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.*

VII. Product Availability

Drug Name	Availability
colchicine (Mitigare)	0.6mg capsule
colchicine (Colcrys)	0.6mg tablet
Colchicine (Gloperba)	0.6mg/5ml oral solution
Febuxostat (Uloric)	40mg and 80mg tablet

VIII. References.

Refer to package insert.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created	10.19	
Added section II. Initial Approval Criteria -prescribed drug is Gloperba solution (colchicine); added Globerpa information in Appendix B and section VII. Product Availability	07.20	
Annual review – no revisions	06.21	
Added Colchicine capsules can be approved if the patient had a trial and failure with colchicine tablets – updated colchicine capsules to be non-preferred	11-21	

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.