Mass General Brigham
Health Plan

Gout Agents:
Allopurinol 200mg tablet
Gloperba (colchicine solution)
Krystexxa (pegloticase)
Mitigare (colchicine capsule)
Uloric (febuxostat)
Effective 10/02/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	Krystexxa (pegloticase) IV is only available through the medical benefit.		

Overview

No PA	Drugs that require PA
Colcrys®# (colchicine tablet) probenecid probenecid/colchicine Zyloprim® # (allopurinol 100mg, 300mg tablet)	allopurinol 200 mg tablet Gloperba® (colchicine solution) Krystexxa® (pegloticase) MB Mitigare® (colchicine capsule) § BP Uloric® (febuxostat) *

This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP Brand Preferred over generic equivalents. In general, requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
* A-rated generic available. Both brand and A-rated generic require PA.
§ Authorized generic available. Both brand and authorized generic require PA.
MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. The plan does not pay for this drug to be dispensed through the retail pharmacy.

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met:

Allopurinol 200 mg tablet

1. Diagnosis of gout
2. Member is ≥ 18 years of age
3. Medical necessity for the use of the 200 mg tablets instead of two 100 mg tablets, which are available without PA
4. Medical records documenting inadequate response or adverse reaction to allopurinol 100 mg tablet (two 100 mg tablets, available without PA)

Gloperba (colchicine solution)
Mitigare (colchicine capsule)
ONE of the following:

1. Diagnosis of gout prophylaxis (initiation of combination colchicine therapy with urate-lowering therapy [ULT])
    a. Member is ≥18 years of age
    b. Member will be initiated on a uric acid lowering treatment with allopurinol, febuxostat, or probenecid
    c. For **Gloperba**® (colchicine solution), member must meet the above criteria and provide medical necessity for the use of a solution formulation as noted by one of the following:
        i. Member utilizes tube feeding (G-tube/J-tube)
        ii. Member has a swallowing disorder or condition affecting ability to swallow
    d. For colchicine capsule, member must meet the above criteria and provider must document clinical rationale for use instead of colchicine tablets
2. Diagnosis of gout prophylaxis (colchicine monotherapy without ULT)
    a. Member is ≥18 years of age
    b. **ONE** of the following:
        i. Physician attestation of inadequate response (defined by serum urate levels > 6.0 mg/dL) to allopurinol at a dose of at least 600 mg/day for four weeks
        ii. Adverse reaction or contraindication (i.e. renal dysfunction or insufficiency [CrCl < 30 mL/min]) to allopurinol
    c. **ONE** of the following:
        i. Physician attestation of inadequate response (defined by serum urate levels > 6.0 mg/dL) to febuxostat at a dose of 80 mg/day or 40 mg/day if CrCl<30 mL/min for four weeks
        ii. Adverse reaction or contraindication (i.e., cardiovascular disease, high LFTs, hepatic insufficiency) to febuxostat
    d. For **Gloperba**® (colchicine solution), member must meet the above criteria and provide medical necessity for the use of a solution formulation as noted by one of the following:
        i. Member utilizes tube feeding (G-tube/J-tube)
        ii. Member has a swallowing disorder or condition affecting ability to swallow
    e. For colchicine capsule, member must meet the above criteria and provider must document clinical rationale for use instead of colchicine tablets

Krystexxa (pegloticase)

1. Diagnosis of gout
2. Member is ≥18 years of age
3. **ONE** of the following:
    a. Physician attestation of inadequate response (defined by serum urate levels > 6.0 mg/dL) to allopurinol at a dose of at least 600 mg/day for four weeks

   b. Adverse reaction or contraindication (i.e. renal dysfunction or insufficiency [CrCl < 30 mL/min]) to allopurinol
4. **ONE** of the following:
   a. Physician attestation of inadequate response (defined by serum urate levels > 6.0 mg/dL) to febuxostat at a dose of 80 mg/day or 40 mg/day if CrCl<30 mL/min for a minimum of four weeks
   b. Adverse reaction or contraindication ((i.e., cardiovascular disease, high LFTs, hepatic insufficiency) to febuxostat
5. **ONE** of the following:
   a. Physician attestation of inadequate response (defined by serum urate levels > 6.0 mg/dL) to a uricosuric agent (i.e. probenecid, or off-label use of fenofibrate or losartan) in combination with allopurinol OR febuxostat for four weeks
   b. Adverse reaction or contraindication to a uricosuric agent (i.e. probenecid, or off-label use of fenofibrate or losartan)

Uloric (febuxostat)
1. Diagnosis of gout
2. Member is ≥18 years of age
3. **ONE** of the following:
   a. Physician attestation of inadequate response (defined by serum urate levels > 6.0 mg/dL) to allopurinol at a dose of at least 600 mg/day for four weeks
   b. Adverse reaction or contraindication (i.e. renal dysfunction or insufficiency [CrCl < 30 mL/min]) to allopurinol
4. **ONE** of the following:
   a. Requested quantity is ≤ 1 tablet/day
   b. Medical necessity for exceeding quantity limit (see appendix regarding requests exceeding quantity limits)

Continuation of Therapy

Prescriber provides documentation of the following:

Colchicine capsule or Gloperba® (colchicine solution):

Gout Prophylaxis: Requests for continuation of treatment in addition to the 6 months previously approved will be evaluated as follows:
1. ONE of the following:
   a. Documentation of tophaceous gout
   b. Medical necessity for the use of continued treatment may be evaluated on a case-by case basis for assessment of continued use

Allopurinol 200 mg tablet, febuxostat, **Krystexxa**: Reauthorization by physician will infer a positive response to therapy.

Limitations
1. Initial approvals will be granted for the following:
   a. Colchicine capsule, Gloperba, Krystexxa: 6 months
   b. Allopurinol 200mg tablet, Febuxostat: 1 year
2. Reauthorizations will be granted for the following:
   a. Colchicine capsule, Gloperba: 6 months
   b. Allopurinol 200mg tablet, Febuxostat, Krystexxa: 1 year

3. **Requests for Brand Name when generic is preferred:** In addition to any prior authorization requirements that may be listed above, if an A-rated generic equivalent is available, such prior authorization requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the generic equivalent drug (history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain drug is acceptable).
4. **Requests for generic when Brand Name is preferred:** There are some drugs for which the Plan has determined it will be cost effective to prefer the use of the Brand Name formulation. In this case, the generic equivalent formulation is considered non-preferred and requires prior authorization. These requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the Brand Name formulation. For the most up to date list of drugs where the Brand Name formulation is preferred, see the MassHealth Brand Name Preferred Over Generic Drug List (BOGL) at www.mass.gov/druglist.
5. The following quantity limits apply:

colchicine capsule	372 capsules per 6 months
Gloperba	1,800 mL per 6 months
Uloric	30 tablets per 30 days

Appendix

Febuxostat – Dosing and Quantity Limits

Requests for febuxostat that > 1 tablet/day should be reviewed for medical necessity and potential dose consolidation.

- For requests > 80 mg/day up to 120 mg/day, documenting an inadequate response to dosing at 80 mg/day ≥ two weeks may be approved for 1 year.
    - Approval is not contingent on prescriber initiating therapy with the recommended starting dose of 40 mg once daily. If the approval criteria have been met, the request can be approved regardless of the starting dose.

References

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Review History

02/08/2023 - Reviewed and created for Feb P&T; Matched MH UPPL criteria to be in compliance with Masshealth unified formulary requirements. Effective 4/1/23.

09/13/23 – Reviewed and updated for P&T. Allopurinol 200 mg tablet formulation was added to criteria requiring PA. Brand preferred and mandatory generic language was added under Limitations. Effective 10/2/23