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Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	November 29, 2019
Subject:	Gloperba	**Page:**	1 of 4

Last Review Date: June 13, 2024

Gloperba

Description

Gloperba (colchicine) Oral Solution

Background
Gloperba (colchicine)'s effectiveness as a prophylactic treatment for gout has been postulated to be due to its ability to block neutrophil-mediated inflammatory responses induced by monosodium urate crystals in synovial fluid. Colchicine disrupts the polymerization of β-tubulin into microtubules, thereby preventing the activation, degranulation, and migration of neutrophils to site of inflammation. Colchicine also interferes with the inflammasome complex found in neutrophils and monocytes that mediates interleukin-1β (IL-1 β) activation (1).

Regulatory Status
FDA-approved indication: Gloperba (colchicine) is indicated for the prophylaxis of gout flares in adults (1).

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 (1).

Myelosuppression, leukopenia, granulocytopenia, thrombocytopenia, pancytopenia, and aplastic anemia have been reported with colchicine used in therapeutic doses (1).

Because colchicine is a substrate for both the CYP3A4 metabolizing enzyme and the P-gp efflux transporter, inhibition of either of these pathways may lead to colchicine-related toxicity. Concomitant use of Gloperba with inhibitors of both CYP3A4 and P-gp should be avoided. If treatment with colchicine is necessary, a reduced daily dose should be considered, and the patient should be closely monitored for colchicine toxicity. Use of Gloperba in conjunction with drugs that inhibit both CYP3A4 and P-gp is contraindicated in patients with renal or hepatic impairment (1).

The safety and effectiveness of Gloperba in pediatric patients less than 18 years of age have not been established (1).

Related policies
Duzallo, Krystexxa, Uloric, Zurampic

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Gloperba may be considered **medically necessary** if the conditions indicated below are met.

Gloperba may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Gout flares

AND ALL of the following:

1. Used as prophylaxis for gout flares

2. Patient is unable to swallow or has difficulty swallowing colchicine tablets/capsules
3. Prescriber agrees to monitor serum uric acid levels
4. Patients with renal **OR** hepatic impairment **only**: Gloperba will not be given in conjunction with drugs that inhibit both CYP3A4 and P-glycoprotein (P-gp)
5. Prescriber agrees to discontinue Gloperba if patient develops both renal and hepatic impairment
6. Prescriber will monitor for colchicine toxicity and neuromuscular toxicity

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 6 bottles (900 mL) per 90 days

Duration 6 months

Prior – Approval *Renewal* Limits

Quantity 6 bottles (900 mL) per 90 days

Duration 12 months

Rationale

Summary

The effectiveness of Gloperba (colchicine) as a prophylactic treatment for gout has been postulated to be due to its ability to block neutrophil-mediated inflammatory responses induced by monosodium urate crystals in synovial fluid. Colchicine disrupts the polymerization of β-tubulin into microtubules, thereby preventing the activation, degranulation, and migration of neutrophils to site of inflammation. Colchicine also interferes with the inflammasome complex found in neutrophils and monocytes that mediates interleukin-1β (IL-1 β) activation. The safety

and effectiveness of Gloperba in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Gloperba while maintaining optimal therapeutic outcomes.

References

1. Gloperba [package insert]. Alpharetta, GA: Avion Pharmaceuticals, LLC; July 2019.

Policy History

Date	Action
November 2019	Addition to PA
March 2020	Annual review
June 2021	Annual review and reference update
June 2022	Annual review
June 2023	Annual review. Changed policy number to 5.70.076
December 2023	Annual review
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.