Pharmacy Medical Necessity Guidelines:
Xatmep (methotrexate)

Effective: April 14, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	Rx	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Xatmep (methotrexate) solution is indicated for the treatment of pediatric patients with acute lymphoblastic leukemia (ALL) as part of a multi-phase, combination chemotherapy maintenance regimen. It is also indicated in the management of pediatric patients with active polyarticular juvenile idiopathic arthritis (pJIA) who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs).

COVERAGE GUIDELINES

The plan may authorize coverage of **Xatmep (methotrexate)** oral solution for Members, when **ALL** the following criteria are met:

Acute Lymphoblastic Leukemia (ALL)

1. The member is less than 18 years of age or older

AND

2. Documentation the member is unable to swallow the methotrexate tablets

AND

3. Documented diagnosis of acute lymphoblastic leukemia

AND

4. The medication is being prescribed by an oncologist or hematologist

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

1. The member is less than 18 years of age or older

AND

2. Documentation the member is unable to swallow the methotrexate tablets

AND

3. Documented diagnosis of polyarticular juvenile idiopathic arthritis

AND

4. The medication is being prescribed by a rheumatologist

LIMITATIONS

1. Xatmep (methotrexate) will not be authorized for use for conditions other than those listed above without proper documentation.

CODES

None

REFERENCES

1. Xatmep prescribing information. Wilmington, MA: Azurity Pharmaceuticals, Inc.; June 2022 .

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. June 13, 2023: No changes.
2. March 12, 2024: Effective April 1, 2024, updated RxUM fax number.
3. March 11, 2025: No changes
4. April 14, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services