MEDICAL MUTUAL®

Drug Policy

Policy:	Xatmep (methotrexate oral solution)	Annual Review Date: 02/20/2025 Last Revised Date: 02/20/2025

OVERVIEW

Methotrexate is indicated for rheumatoid arthritis (including polyarticular juvenile idiopathic arthritis) and psoriasis as well as neoplastic disease. Xatmep is indicated for pediatric patients with acute lymphoblastic leukemia (ALL) or polyarticular juvenile idiopathic arthritis (pJIA).

POLICY STATEMENT

This policy involves the use of Xatmep (methotrexate oral solution). Prior authorization is recommended for pharmacy benefit coverage of Xatmep (methotrexate oral solution). Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Xatmep (methotrexate oral solution) is recommended in those who meet the following criteria:

1. **Acute lymphoblastic leukemia (ALL)**
   Criteria. *Patient must meet the following criteria (A and either B or C)*
   A. The patient is under the age of 18 years old; AND
   B. The patient has tried oral methotrexate tablets; OR
   C. The patient cannot swallow tablets.

2. **Polyarticular Juvenile Idiopathic arthritis (pJIA)**
   Criteria. *Patient must meet the following criteria. (A and either B or C)*
   A. The patient is under the age of 18 years old; AND
   B. The patient has tried oral methotrexate tablets; OR
   C. The patient cannot swallow tablets.

Initial Approval/ Extended Approval.
A) *Initial Approval: 1 year (365 days)*

B) *Extended Approval: 1 year (365 days)*

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Xatmep (methotrexate oral solution) has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Xatmep oral solution [prescribing information]. Greenwood Village, CO. Silvergate Pharmaceuticals, Inc.; September 2020.
2. Methotrexate. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated on 19 June 2018. Accessed on 17 July 2018.