MEDICAL MUTUAL®

Drug Policy

Policy:	**Methotrexate** **Preferred Step Therapy Policy**	**Annual Review Date:** **07/20/2023**
Impacted Drugs:	**Otrexup (MTX injection, SQ autoinjector)** **Rasuvo (MTX injection, SQ autoinjector)** **RediTrex (MTX injection for SQ use)**	**Last Revised Date:** **07/20/2023**

OVERVIEW

Injectable Otrexup and Rasuvo indicated for rheumatoid arthritis (including polyarticular juvenile idiopathic arthritis) and psoriasis. 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

A step therapy program has been developed to encourage the use of a generic preferred products prior to the use of the non-preferred products. Coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration. Note: Unless administered by a healthcare provider, all of the injectable MTX products, including the RediTrex, Rasuvo and Otrexup autoinjectors, require proper patient training in sterile injection technique and require a patient or caregiver to have the manual dexterity self-inject.

Automation: A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Preferred Medications

- Methotrexate injection (generic)

Non-Preferred Step 2 Medications

- Otrexup (MTX injection, for subcutaneous [SC] use, autoinjector)
- Rasuvo (MTX injection for SC use, autoinjector)
- RediTrex (MTX injection for SC use)

PREFERRED STEP THERAPY CRITERIA

1. Authorization for a non-preferred product (Oxtreup, Rasuvo or RediTrex) may be given if BOTH of the following conditions are met (A and B):
   - **A)** The patient has tried one preferred product (methotrexate sodium solution for injection); AND
   - **B)** According to the prescriber, the patient and caregiver are unable to administer generic methotrexate injection (single-dose or multi-dose vial NOT including Otrexup, RediTrex or Rasuvo).

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Approval Duration: 365 days (1 year)

Preferred Step Therapy Exception Criteria

In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

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. Methotrexate injection [prescribing information]. Rockford, IL: Mylan; September 2014.
2. Otrexup™ injection [prescribing information]. Ewing, NJ: Antares Pharma, Inc.; December 2019.
3. Rasuvo® injection [prescribing information]. Chicago, IL: Medac Pharma, Inc.; March 2020.
4. Methotrexate. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated on 19 June 2018. Accessed on 17 July 2018.
5. RediTrex™ injection [prescribing information]. Nashville, TN: Cumberland Pharmaceuticals; November 2019.
6. Methotrexate sodium. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 23 June 2020. Accessed on 9 July 2020.