Original Effective Date: 08/01/2018
Current Effective Date: 12/06/2024
Last P&T Approval/Version: 10/30/2024
Next Review Due By: 10/2025
Policy Number: C14770-A

Otrexup, Rasuvo, RediTrex (methotrexate)

PRODUCTS AFFECTED

Otrexup (methotrexate), Rasuvo (methotrexate), RediTrex (methotrexate)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Rheumatoid arthritis, Juvenile idiopathic arthritis, Psoriasis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

ALL INDICATIONS:
1. Documented diagnosis of one of the following:
    a. Moderate to severe rheumatoid arthritis
    OR

b. Polyarticular juvenile idiopathic arthritis
OR
c. Moderate to severe psoriasis (BSA ≥3%) OR <3% body surface area with plaque psoriasis that involves sensitive areas of the body or areas that would significantly impact daily function (e.g., face, neck, hands, feet, genitals)

AND

2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
3. (a) Member has had an inadequate treatment response, serious side effects, or contraindication to at least a 3-month trial of methotrexate tablets
OR
(b) Member has had an inadequate treatment response, serious side effects, or contraindication to at least a 3-month trial of IM or SC methotrexate or does not have the visual or physical acuity to draw up and administer an IM or SC injection
AND
4. (a) For females of reproductive potential: Provider attests that member has had a negative pregnancy screening and has been counseled on the use of effective contraception during treatment and per FDA labeled recommendations
OR
(b) For males with female partners of reproductive potential: Provider attests that member has been counseled on the use of effective contraception during treatment and per FDA labeled recommendations
AND
5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to methotrexate include: pregnancy, alcoholism, liver disease, immunodeficiency syndromes and preexisting blood dyscrasias, and hypersensitivity to methotrexate.]

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:

1. Adherence to therapy at least 85% of the treatment period verified by the prescriber or medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity as evidenced by routine CBC with differential and platelets, serum creatinine, and LFTs
AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms [DOCUMENTATION REQUIRED]

DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified rheumatologist or dermatologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

Polyarticular juvenile idiopathic arthritis: 2 years of age and older

NOTE: Published clinical studies evaluating the use of methotrexate in children and adolescents (i.e., patients 2 to 16 years of age) with pJIA demonstrated safety comparable to that observed in adults with

rheumatoid arthritis
Rheumatoid arthritis or Psoriasis: 18 years of age and older

QUANTITY:
4 injections per 28 days

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous injection

DRUG CLASS:
Antirheumatic Antimetabolites

FDA-APPROVED USES:
Indicated for the management of patients with severe, active rheumatoid arthritis and polyarticular juvenile idiopathic arthritis, who are intolerant of or had an inadequate response to first-line therapy. Symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy.
Limitations of Use: Otrexup, Rasuvo, RediTrex are not indicated for the treatment of neoplastic diseases

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Otrexup/Rasuvo/RediTrex (methotrexate, injection for subcutaneous use) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Administering Otrexup/Rasuvo/RediTrex any more frequently than once weekly can lead to fatal toxicity. Exclude pregnancy before treatment. Contraindications to Otresup/Rasuvo/RediTrex include: pregnancy, alcoholism, liver disease, immunodeficiency syndromes and preexisting blood dyscrasias, and hypersensitivity to methotrexate.

OTHER SPECIAL CONSIDERATIONS:
Methotrexate auto-injector and prefilled syringe agents have a black box warning for severe toxic reactions, including embryo- fetal toxicity and death, as well as bone marrow suppression, hepatotoxicity, methotrexate- induced lung disease, diarrhea and ulcerative stomatitis, malignant lymphomas, severe skin reaction, and potentially fatal opportunistic infections.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective*

at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
N/A	N/A

AVAILABLE DOSAGE FORMS:
Otrexup SOAJ 10MG/0.4ML, 12.5/0.4ML, 15MG/0.4ML, 17.5/0.4ML, 20MG/0.4ML, 22.5/0.4ML, 25MG/0.4ML auto-injector
Rasuvo SOAJ 7.5MG/0.15ML,10MG/0.2ML, 12.5MG/0.25ML, 15MG/0.3ML, 17.5MG/0.35ML, 20MG/0.4ML, 22.5MG/0.45ML, 25MG/0.5ML, 30MG/0.6ML auto-injector
RediTrex SOSY 7.5MG/0.3ML, 10MG/0.4ML, 12.5MG/0.5ML, 15MG/0.6ML, 17.5MG/0.7ML, 20MG/0.8ML, 22.5MG/0.9ML, 25MG/ML prefilled syringe

REFERENCES

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2. Rasuvo (methotrexate) injection, for subcutaneous use [prescribing information]. Chicago, IL: Medac Pharma Inc; March 2020.
3. RediTrex (methotrexate) [prescribing information]. Nashville, TN: Cumberland Pharmaceuticals Inc.; November 2019.
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5. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044
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7. Ringold, S., Angeles-Han, S., Beukelman, T., Lovell, D., Cuello, C., & Becker, M. et al. (2019). 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Care & Research, 71(6), 717-734. doi: 10.1002/acr.23870
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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Coding/Billing Information Template Update Required Medical Information	Q4 2024
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Quantity FDA-Approved Uses Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements Contraindications/Exclusions/Discontinuation References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file