Auto-injectable/Pre-filled Syringe Methotrexate (Otrexup™, Reditrex™)

Policy # 00520
Original Effective Date: 01/01/2017
Current Effective Date: 06/10/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Rasuvo®‡ is an auto-injectable methotrexate product that carries the same indications as Otrexup™‡ and Reditrex™‡, however Rasuvo is not subject to this medical policy.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the auto-injectable methotrexate product, Otrexup™‡, and the pre-filled syringe methotrexate product, Reditrex™‡, to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for the auto-injectable methotrexate product, Otrexup, and the pre-filled syringe methotrexate product, Reditrex, will be considered when BOTH of the following criteria are met:

- Patient has tried and failed (e.g. intolerance or inadequate response) a generic oral methotrexate product, unless there is clinical evidence or patient history that suggests a generic oral methotrexate product will be/was ineffective or will/did cause an adverse reaction to the patient; AND
- Patient has tried and failed (e.g. intolerance or inadequate response) a generic injectable methotrexate product, unless there is clinical evidence or patient history that suggests a generic injectable methotrexate product will be/was ineffective or will/did cause an adverse reaction to the patient.

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of the auto-injectable methotrexate product, Otrexup, and the pre-filled syringe methotrexate product, Reditrex, WITHOUT evidence that the patient has tried and failed a generic oral methotrexate product AND a generic injectable methotrexate product to be **not medically necessary.****

Background/Overview

Otrexup and Reditrex both contain methotrexate in various strengths in an injectable form and are U.S. Food and Drug Administration (FDA) approved for the treatment of patients with severe, active rheumatoid arthritis and polyarticular juvenile idiopathic arthritis, who are tolerant of or had an inadequate response to first line therapy. They are also approved for the symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy. Otrexup is available in an auto-injectable formulation while Reditrex is available in a pre-filled syringe formulation. Typically, methotrexate in these inflammatory conditions is first initiated orally and then could potentially be converted to an injectable form of methotrexate. Another auto-injectable product, Rasuvo, carries the same indications as Otrexup and Reditrex, however it is not subject to this medical policy. Otrexup, Reditrex, and Rasuvo essentially give an auto-injectable or pre-filled syringe methotrexate option for patients to use as an alternative to generic forms of injectable methotrexate, which have been available for quite some time. The generic formulations are equally as effective and are available at a fraction of the cost of the auto-injectable or pre-filled syringe options.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Otrexup was approved in October of 2013. Reditrex was approved in December of 2019. Both are FDA approved for the treatment of patients with severe, active rheumatoid arthritis and polyarticular juvenile idiopathic arthritis, who are tolerant of or had an inadequate response to first line therapy. They are also approved for the symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy. Both generic oral and injectable forms of methotrexate have been around for a substantial amount of time prior to Otrexup and Reditrex being approved.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests BOTH generic oral and generic injectable methotrexate will be/was ineffective or will/did cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveats, there is no advantage of using Otrexup or Reditrex over generic oral and generic injectable methotrexate products.

References

1. Rasuvo [package insert]. Medac Pharma, Inc. Chicago, Illinois. Updated November 2014.
2. Otrexup [package insert]. Antares Pharma, Inc. Ewing, New Jersey. Updated March 2016.
3. Reditrex [package insert]. Cumberland Pharmaceuticals, Inc. Nashville, Tennessee. Updated November 2019.

Policy History

Original Effective Date: 01/01/2017
Current Effective Date: 06/10/2024

08/04/2016	Medical Policy Committee review
08/17/2016	Medical Policy Implementation Committee approval. New policy.
07/06/2017	Medical Policy Committee review
07/19/2017	Medical Policy Implementation Committee approval. Removed Rasuvo from the Medical Policy. Updated background information. Changed title to reflect removal of Rasuvo from the policy.
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/03/2019	Medical Policy Committee review

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07/18/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/02/2020	Medical Policy Committee review
07/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/06/2021	Medical Policy Committee review
05/12/2021	Medical Policy Implementation Committee approval. Added a new product, Reditrex, to the policy. Updated the title to include the pre-filled syringe version of injectable methotrexate.
05/05/2022	Medical Policy Committee review
05/11/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/04/2023	Medical Policy Committee review
05/10/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/02/2024	Medical Policy Committee review
05/08/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 05/2025

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.