Autoinjectable Methotrexate (Otrexup)

Policy # 00520
Original Effective Date: 01/01/2017
Current Effective Date: 08/10/2020

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 also an autoinjectable methotrexate product that carries the same indications as Otrexup™‡, however Rasuvo is not subject to this medical policy.

When Services Are 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 autoinjectable methotrexate product, Otrexup™‡, to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for the autoinjectable methotrexate product, Otrexup, 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 autoinjectable methotrexate product, Otrexup, 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 contains methotrexate in various strengths in an auto injectable form and is 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. Otrexup is also approved for the symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy. 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, however it is not subject to this medical policy. Otrexup and Rasuvo essentially give an auto injectable 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 options.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Otrexup was approved in October of 2013. Otrexup is 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. It is 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 being approved.

Rationale/Source

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 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.

Policy History

Original Effective Date: 01/01/2017
Current Effective Date: 08/10/2020

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
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.

Next Scheduled Review Date: 07/2021

**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.