Methotrexate Injections

Description

Otrexup, Rasuvo (methotrexate)

Background
Otrexup and Rasuvo are types of medication that mimics folate, a natural human vitamin, to interfere with the growth of quickly dividing cells in the body. By lowering the ability of these cells to replicate, the immune system is unable to respond as quickly or effectively. This process decreases symptoms of diseases where the immune system of a person attacks itself (autoimmune), such as rheumatoid arthritis and psoriasis. Otrexup and Rasuvo are injected underneath the skin via an auto-injector device. Other forms of methotrexate include oral tablets and solutions for injection. Otrexup and Rasuvo are only for once a week use and is not to be used daily (1-2).

Regulatory Status
FDA-approved indication: Otrexup and Rasuvo are folate analog metabolic inhibitors indicated for: (1-2)

Rheumatoid Arthritis (RA) including Polyarticular Juvenile Idiopathic Arthritis (pJIA) - Otrexup and Rasuvo are indicated in the management of patients with severe, active rheumatoid arthritis (RA) or children with active polyarticular juvenile idiopathic arthritis (pJIA), who are not intolerant of or had an inadequate response to first-line therapy.

Psoriasis - Otrexup and Rasuvo are indicated in adults for the symptomatic control of severe, recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy.
Limitations of Use – Otrexup and Rasuvo are not indicated for the treatment of neoplastic diseases (1-2).

Otrexup and Rasuvo carry boxed warnings regarding severe toxic reactions, including embryo-fetal toxicity. Otrexup and Rasuvo should only be prescribed by physicians with experience with antimetabolites therapy. Because of the potential for possibly fatal and toxic reactions, Otrexup and Rasuvo should only be used in patients with severe and disabling RA or psoriasis that is not responsive to other therapies. Close monitoring for acute and/or chronic bone marrow, liver, lung, skin, and kidney toxicities is required (1-2).

Because methotrexate has been reported to cause fetal death and/or congenital anomalies, Otrexup and Rasuvo are contraindicated in pregnant women. Use in women of child bearing age without a reliable form of birth control is not recommended (1-2).

Prolonged use of methotrexate can cause hepatic fibrosis and cirrhosis. Liver enzyme elevations are commonly seen, but are not always indicative of hepatic disease; therefore, periodic liver biopsies are recommended for those under long term methotrexate treatment (1-2).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Otrexup and Rasuvo may be considered medically necessary in patients 2 years of age and older with active Polyarticular Juvenile Idiopathic Arthritis (pJIA); and in patients 18 years of age and older with moderately to severely active Rheumatoid Arthritis (RA) or Psoriasis; with an inadequate response, intolerance, or contraindication to either NSAIDs, topical corticosteroids (if Psoriasis), and oral methotrexate; must have documented reason for requiring special injection device such as: lack of dexterity, visual acuity issues; and not being used in combination with another form or brand of methotrexate.

Otrexup and Rasuvo are considered investigational in patients below 2 years of age and for all other indications.

Prior-Approval Requirements
Diagnoses

Patient must have **ONE** of the following:

**Age** 2 years of age or older

1. Active Polyarticular Juvenile Idiopathic Arthritis (pJIA)
   a. An inadequate response, intolerance, or contraindication to NSAIDs, and oral methotrexate

**Age** 18 years of age or older

1. Severely Active Rheumatoid Arthritis (RA)
   a. An inadequate response, intolerance, or contraindication to NSAIDs, and oral methotrexate

   **OR**

2. Active Psoriasis
   a. An inadequate response, intolerance, or contraindication to NSAIDs, topical corticosteroids and oral methotrexate

**AND ALL** of the following:

1. Must have documented reason for requiring special injection device such as: lack of dexterity, visual acuity issues
2. **NOT** being used in combination with another form or brand of methotrexate

Prior – Approval **Renewal Requirements**

Diagnoses

Patient must have **ONE** of the following:

**Age** 2 years of age or older

1. Polyarticular Juvenile Idiopathic Arthritis (JIA)

**Age** 18 years of age or older

1. Rheumatoid Arthritis (RA)
2. Psoriasis

**AND** the following:
Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Duration 12 months

Prior – Approval Renewal Limits

Duration 12 months

Rationale

Summary
Otrexup and Rasuvo are folate analog metabolic inhibitors indicated for the treatment of Polyarticular Juvenile Idiopathic Arthritis (pJIA), moderately to severely Active Rheumatoid arthritis (RA), and active psoriasis, who have failed other first-line therapies. Otrexup and Rasuvo carry boxed warnings regarding severe toxic reactions, including embryo-fetal toxicity. Close monitoring for acute and/or chronic bone marrow, liver, lung, skin, and kidney toxicities is required (1-2).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Otrexup and Rasuvo while maintaining optimal therapeutic outcomes.

References

Section: Prescription Drugs  Effective Date: April 1, 2019
Subsection: Analgesics and Anesthetics  Original Policy Date: January 9, 2015
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<table>
<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>December 2014</td>
<td>Addition to PA</td>
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<tr>
<td>March 2015</td>
<td>Annual editorial review and reference update</td>
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| March 2016    | Annual editorial review  
                 Policy number changed from 5.02.37 to 5.70.37                     |
| March 2017    | Annual editorial review and reference update                            |
| March 2018    | Annual editorial review and reference update  
                 Addition of “no combination with other methotrexate products” in renewal  
                 criteria                                                           |
| March 2019    | Annual review and reference update                                      |

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.