

PHARMACY PRE-AUTHORIZATION CRITERIA

DRUG	<u>Methotrexates</u> Otrexup (methotrexate subcutaneous injection) Rasuvo (methotrexate subcutaneous auto-injector) Xatmep (methotrexate oral solution)
POLICY #	12100
INDICATIONS	<p>Otrexup and Rasuvo are indicated in the management of selected adults with severe, active rheumatoid arthritis (RA) (ACR criteria), or children with active polyarticular juvenile idiopathic arthritis (pJIA), who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs).</p> <p>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, but only when the diagnosis has been established, as by biopsy and/or after dermatologic consultation. It is important to ensure that a psoriasis “flare” is not due to an undiagnosed concomitant disease affecting immune responses.</p> <p>Xatmep is a folate analog metabolic inhibitor indicated for the treatment of pediatric patients with acute lymphoblastic leukemia (ALL) as a component of a combination chemotherapy maintenance regimen, and management of pediatric patients with active polyarticular juvenile idiopathic arthritis (pJIA) who are intolerant of or had an inadequate response to first-line therapy</p>
CRITERIA	<p>ConnectiCare considers Otrexup and Rasuvo to be medically necessary for patients who meet the following criteria:</p> <ul style="list-style-type: none"> • Patient is diagnosed with active rheumatoid arthritis, juvenile idiopathic arthritis <p>AND</p> <ul style="list-style-type: none"> • Patient has a documented intolerance to, or treatment failure of an adequate trial of NSAIDs <p>AND</p> <ul style="list-style-type: none"> • Patient has a documented intolerance to, or treatment failure of an adequate trial of methotrexate tablets <p>AND</p> <ul style="list-style-type: none"> • Patient has had a documented intolerance to, or treatment failure of an adequate trial of methotrexate IM injection <p>OR</p> <ul style="list-style-type: none"> • Patient is diagnosed with severe, recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy

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	<p>ConnectiCare considers Xatmep to be medically necessary for pediatric patients who meet the following criteria:</p> <ul style="list-style-type: none">• Patient is diagnosed with acute lymphoblastic leukemia or juvenile idiopathic arthritis <p>AND</p> <ul style="list-style-type: none">• Patient has a documented intolerance to, or treatment failure of oral methotrexate <p>OR</p> <ul style="list-style-type: none">• Patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting. <p>ConnectiCare does not consider needlephobia to be a clinical reason to use Otrexup, Rasuvo or Xatmep over injectable medications.</p>
LIMITATIONS	Otrexup and Rasuvo are not indicated for the treatment of neoplastic diseases
REFERENCES	<ol style="list-style-type: none">1. Otrexup package insert, Ewing, NJ, Antares Pharma, Inc.2. Rasuvo package insert, Chicago, IL, Medac Pharma Inc.
P&T REVIEW HISTORY	6/14, 11/15, 5/16, 5/17, 8/17, 5/18, 5/19
REVISION RECORD	11/14, 9/15, 8/17, 5/19