PHARMACY PRE-AUTHORIZATION CRITERIA

DRUG	**Methotrexates** **Otrexup (methotrexate subcutaneous injection)** **Rasuvo (methotrexate subcutaneous auto-injector)** **Reditrex (methotrexate injection, solution)** **Xatmep (methotrexate oral solution)**
POLICY #	**12100**
INDICATIONS	**Otrexup, Rasuvo, and Reditrex** 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). **Otrexup, Rasuvo, and Reditrex** 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. **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
CRITERIA	ConnectiCare considers **Otrexup, Rasuvo, and Reditrex** to be medically necessary for patients who meet the following criteria: • Patient is diagnosed with active rheumatoid arthritis, juvenile idiopathic arthritis AND • Patient has a documented intolerance to, or treatment failure of an adequate trial of NSAIDs AND • Patient has a documented intolerance to, or treatment failure of an adequate trial of methotrexate tablets AND • Patient has had a documented intolerance to, or treatment failure of an adequate trial of methotrexate IM injection OR • Patient is diagnosed with severe, recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy

PHARMACY PRE-AUTHORIZATION CRITERIA

DRUG	**Methotrexates** **Otrexup (methotrexate subcutaneous injection)** **Rasuvo (methotrexate subcutaneous auto-injector)** **Reditrex (methotrexate injection, solution)** **Xatmep (methotrexate oral solution)**
	ConnectiCare considers **Xatmep** to be medically necessary for pediatric patients who meet the following criteria: • Patient is diagnosed with acute lymphoblastic leukemia or juvenile idiopathic arthritis AND • Patient has a documented intolerance to, or treatment failure of oral methotrexate OR • Patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting. ConnectiCare does not consider needlephobia to be a clinical reason to use Otrexup, Rasuvo or Xatmep over injectable medications.
LIMITATIONS	Otrexup , Rasuvo, and Reditrex are not indicated for the treatment of neoplastic diseases
REFERENCES	1. Otrexup package insert, Ewing, NJ, Antares Pharma, Inc. 2. Rasuvo package insert, Chicago, IL, Medac Pharma Inc. 3. Product Information: REDITREX subcutaneous injection, methotrexate subcutaneous injection. Cumberland Pharmaceuticals. Nashville, TN, 2019.
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, 2/21 (Added Reditrex to policy to align with FDA label)