Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Methotrexate Auto-Injector Agents

Override(s)	Approval Duration
Prior Authorization Step Therapy Quantity Limit	1 year

Medications	Quantity Limit
Otrexup (methotrexate)	May be subject to quantity limit
Rasuvo (methotrexate)	
RediTrex (methotrexate preservative-free)	

APPROVAL CRITERIA

Requests for a methotrexate auto-injector agent (Otrexup, Rasuvo, RediTrex) may be approved if the following STEP THERAPY **and** PRIOR AUTHORIZATION criteria are met:

STEP THERAPY CRITERIA:

I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one generic oral methotrexate agent;

AND

II. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of one generic injectable methotrexate agent, unless the following applies:
   A. A caregiver is unavailable or unable to assist with medication reconstitution and/or administration using a vial and syringe;
   AND
   B. Individual has reduced manual dexterity, a barrier to learning, or a visual impairment prohibiting ability to self-reconstitute and/or administer medication using a vial and syringe.

PRIOR AUTHORIZATION CRITERIA:

I. Individual is 18 years of age or older; **AND**
II. Individual has a diagnosis of active, severe rheumatoid arthritis (RA); **AND**
III. Individual has had a trial and inadequate response or intolerance to first-line therapy;

Market Applicability							
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Applicable	X	X	X	X	X	X	X

OR

IV. Individual is 2 years of age or older; **AND**
V. Individual has a diagnosis of active polyarticular juvenile idiopathic arthritis (PJIA); **AND**
VI. Individual has had a trial and inadequate response or intolerance to first-line therapy;

OR

VII. Individual is 18 years of age or older; **AND**
VIII. Individual has an established diagnosis of severe, recalcitrant, disabling psoriasis; **AND**
IX. Individual has had a trial and inadequate response or intolerance to conventional therapies (such as but not limited to phototherapy).

Methotrexate auto-injector agents (Otrexup, Rasuvo, RediTrex) may **not** be approved for the following:

I. Individual is requesting for the treatment of neoplastic diseases; **OR**
II. Individual has a diagnosis of alcoholism, alcoholic liver disease, or other chronic liver disease; **OR**
III. Individual has a diagnosis of an overt or laboratory assay-confirmed immunodeficiency syndrome; **OR**
IV. Individual has a diagnosis of blood dyscrasias, such as but not limited to bone marrow hypoplasia, leukopenia, or thrombocytopenia; **OR**
V. Individual requires weekly doses of less than 7.5 mg or more than 30 mg, high-dose regimens, or dose adjustments in increments between the available strengths.

Note: Methotrexate auto-injector agents (Otrexup, Rasuvo, RediTrex) have a black box warning for severe toxic reactions, including embryo-fetal toxicity and death. Individuals should be monitored for bone marrow, liver, lung, skin, and kidney toxicities. Otrexup and Rasuvo should only be used for severe, recalcitrant, disabling rheumatoid arthritis or psoriasis unresponsive to other therapies. Use is not recommended in women of childbearing potential and is contraindicated in pregnant women. Death, fetal death and/or congenital anomalies, severe sometimes fatal lung disease, tumor lysis syndrome, skin reactions, and *Pneumocystis jiroveci* pneumonia have been reported. Unexpectedly severe (sometimes fatal) bone marrow suppression, aplastic anemia, and gastrointestinal toxicity have been reported with concomitant administration (usually high doses) with some NSAIDs. Hepatotoxicity, fibrosis, and cirrhosis may occur with prolonged use. Methotrexate elimination is reduced in individuals with impaired renal function, ascites, or pleural effusions; dose reduction and discontinuation may be necessary. Diarrhea and ulcerative stomatitis require therapy interruption. Use increases risk of soft tissue necrosis and osteonecrosis with concomitant radiotherapy. Malignant lymphoma may occur during therapy, discontinue use.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: February 26, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. U.S. Food and Drug Administration Center for Drug Evaluation and Research. Medical Review(s) for NDA 20-4824 (Otrexup). FDA website, available at: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204824Orig2s000MedR.pdf. Accessed on: February 26, 2020.
6. U.S. Food and Drug Administration Center for Drug Evaluation and Research. Medical Review(s) for NDA 205-776 (Rasuvo). FDA website, available at: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/205776Orig1s000MedR.pdf. Accessed on: February 26, 2020.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.