

SPECIALTY GUIDELINE MANAGEMENT

OTREXUP (methotrexate injection)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

1. Rheumatoid Arthritis (RA) including Polyarticular Juvenile Idiopathic Arthritis (pJIA)
Otrexup is indicated in the management of selected adults with severe, active rheumatoid arthritis (RA) 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).
2. Psoriasis
Otrexup is 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.

Limitations of use: *Otrexup is not indicated for the treatment of neoplastic diseases*

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- A. Chart notes, medical record documentation, or claims history supporting previous use of generic oral methotrexate and inadequate response or intolerance to therapy.
- B. Chart notes or medical record documentation of member’s inability to prepare and administer generic injectable methotrexate.

III. CRITERIA FOR INITIAL APPROVAL²⁻⁷

Authorization of 12 months may be granted for treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), or psoriasis when BOTH of the following criteria are met:

- A. Member has tried and had an inadequate response or intolerance to generic oral methotrexate.
- B. Member has inability to prepare and administer generic injectable methotrexate.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members (including new members) who meet ALL initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy with Otrexup as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Reference number(s)
2019-A

V. REFERENCES

1. Otrexup [package insert]. Ewing, NJ: Antares Pharma, Inc.; December 2019.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016;68(1)1-26.
3. Smolen JS, Landewé R, Billsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis*. 2020;79:685-699.
4. Ringold, S, Angeles-Han, S, Beukelman, T, et al. 2019 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: Therapeutic approaches for non-systemic polyarthritis, sacroilitis, and enthesitis. *Arthritis Care Res*. 2019;71(6):717-734
5. Clinical Consult. CVS Caremark Clinical Programs Review: Focus on Rheumatology Clinical Programs. November 2014.
6. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4: Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. *J Am Acad Dermatol*. 2009;61:451-485.
7. Clinical Consult. CVS Caremark Clinical Programs Review: Focus on Dermatology Programs. October 28, 2016.