

## Methotrexate Injectable Solution

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

### Summary

Methotrexate is an antimetabolite and antifolate drug used in the treatment of certain neoplastic diseases, severe psoriasis, and adult rheumatoid arthritis. Injectable methotrexate is available as prefilled auto-injector pens (Rasuvo, Otrexup) and generic single-dose vials for subcutaneous use. This policy requires the use of the preferred branded products Rasuvo and Otrexup prior to coverage of generic injectable methotrexate.

### Definitions

"**Antimetabolites**" are drugs that interfere with one or more enzymes or their reactions that are necessary for DNA synthesis.

“**Auto-injector**” is a device that allows a person to self-administer a specific dose of medication via injection.

“**Neoplastic diseases**” are conditions characterized by the abnormal growth of cells, which can lead to tumors, either benign or malignant.

“**Rheumatoid arthritis**” is a chronic inflammatory disorder that typically affects the small joints in the hands and feet, causing painful swelling that can eventually result in bone erosion and joint deformity.

### Coverage Criteria

Coverage of **generic injectable methotrexate** requires the following criteria be met:

1. Trial and failure, contraindication, or intolerance to **BOTH** of the following preferred products:
  - a. Rasuvo (methotrexate) injection; **AND**
  - b. Otrexup (methotrexate) injection.

**If the above prior authorization criteria are met, the requested product will be authorized for 12-months.**

### References

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2. Menter et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020 Jun;82(6):1445-1486. doi: 10.1016/j.jaad.2020.02.044. Epub 2020 Feb 28. PMID: 32119894.
3. Methotrexate injection [prescribing information]. Durham, NC: Accord Healthcare Inc; March 2022.
4. Methotrexate Sodium injection [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals USA Inc; June 2021.
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6. Otrexup (methotrexate injection) [prescribing information]. Ewing, NJ: Antares Pharma Inc; December 2019.
7. Otrexup PFS (methotrexate injection) [prescribing information]. Ewing, NJ: Antares Pharma Inc; December 2019.

8. Rasuvo (methotrexate) [prescribing information]. Chicago, IL: Medexus Pharma Inc; March 2020.

**Clinical Guideline Revision / History Information**

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