

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Methotrexate Agents PDL Edit
<b>First Implementation Date:</b>	October 5, 2017
<b>Revised Date:</b>	October 14, 2021
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

**Why Issue Selected:** Methotrexate is one of the most effective and widely used agents for treating rheumatoid arthritis (RA) and other inflammatory types of arthritis. In participants with rheumatoid arthritis, effects of methotrexate on articular swelling and tenderness can be seen as early as 3 to 6 weeks. Although methotrexate clearly ameliorates symptoms of inflammation (pain, swelling, stiffness), there is no evidence that it induces RA remission nor has a beneficial effect been demonstrated on bone erosions and other radiologic changes which result in impaired joint use, functional disability, and deformity. Limited data from long-term studies indicate that an initial clinical improvement is maintained for at least two years with continued therapy. Studies comparing oral vs subcutaneous administration of methotrexate have found a greater achievement of American College of Rheumatology response criteria in participants treated with subcutaneous methotrexate, although oral is typically preferred due to its ease of use and low cost. In all participants receiving chronic methotrexate, it is recommended to take concomitantly with folic acid in order to reduce the risk of folate depletion. Methotrexate is indicated in the management of selected adults with severe, active rheumatoid arthritis (ACR criteria), or children with active polyarticular-course juvenile rheumatoid arthritis, 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. Methotrexate is indicated for 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, via 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. In psoriasis, the rate of epithelial cell production in the skin is greatly increased over normal skin. This proliferation rate differential is the basis for methotrexate use to control the psoriatic process.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> <li>Methotrexate PF Vials</li> <li>Methotrexate Tabs/Vials</li> </ul>	<ul style="list-style-type: none"> <li>Otrexup® Auto-Injector</li> <li>Rasuvo® Auto-Injector</li> <li><b>RediTrex® Syringe</b></li> <li>Trexall® Tabs</li> <li>Xatmep® Soln</li> </ul>

Type of Criteria:  Increased risk of ADE  
 Appropriate Indications

Preferred Drug List  
 Clinical Edit

Data Sources:  Only Administrative Databases

Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Methotrexate Agents
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 1 or more preferred agents
  - Documented trial period for preferred agents **OR**
  - Documented ADE/ADR to preferred agents

## Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

## Required Documentation

Laboratory Results:   
MedWatch Form:

Progress Notes:   
Other:

## Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)  
Rule Type: PDL

## Default Approval Period

1 year

## References

1. Evidence-Based Medicine and Fiscal Analysis: "Methotrexate Products – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; June 2021.
2. Evidence-Based Medicine Analysis: "Methotrexate", UMKC-DIC; May 2021.
3. USPDI, Micromedex; 2021.
4. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.
5. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis, Singh et al. Arthritis Care & Research – DOI 10.1002/acr.22783