SmartPA Criteria Proposal

Drug/Drug Class:	Methotrexate Agents PDL Edit
First Implementation Date:	October 5, 2017
Revised Date:	October 1, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐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 remission of rheumatoid arthritis 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 SC administration of methotrexate have found a greater achievement of American College of Rheumatology response criteria in participants treated with SC 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 in 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. In psoriasis, the rate of production of epithelial cells in the skin is greatly increased over normal skin. This differential in proliferation rates is the basis for the use of methotrexate to control the psoriatic process.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Methotrexate PF Vials • Methotrexate Tabs/Vials	• Otrexup™ Auto-Injector • Rasuvo® Auto-Injector • Trexall® Tabs • Xatmep™ Soln

Type of Criteria:	☐ **Increased risk of ADE**	☒ **Preferred Drug List**
	☐ **Appropriate Indications**	☐ **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:	☐	Progress Notes:	☐
MedWatch Form:	☐	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; April 2020.
2. Evidence-Based Medicine Analysis: “Methotrexate”, UMKC-DIC; April 2020.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
4. USPDI, Micromedex; 2020.
5. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.
6. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis, Singh et al. Arthritis Care & Research – DOI 10.1002/acr.22783