SmartPA Criteria Proposal

Drug/Drug Class:	Targeted Immune Modulators, Janus Kinase (JAK) Inhibitors PDL Edit
First Implementation Date:	January 22, 2004
Proposed Date:	June 17, 2021
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: Janus kinase (JAK) is a cytoplasmic protein tyrosine kinase that is essential for signal transduction to the nucleus from common plasma membrane receptors for some interleukins. JAKs activate signal transducers and activators of transcriptions which regulate gene function and intracellular activity. Inhibiting the JAK enzymes will prevent cytokine or growth factor-mediated gene expression and intracellular activity thus decreasing immunological responses. All JAK inhibitors are available in an oral formulation and are classified as targeted synthetic disease-modifying anti-rheumatic drugs (tsDMARDs). tsDMARDs may be an appropriate therapy choice in participants who do not prefer agents that have a subcutaneous or intravenous administration technique. These agents are most commonly used in participants with moderate to severe rheumatoid arthritis after DMARDs and a failure of at least two biologic agents. There are many JAK inhibitors marketed including Olumiant® (baricitinib), Rinvoq™ (upadactinib), Xeljanz® and Xeljanz® XR (tofacitinib). Tofacitinib can be used in combination with methotrexate or as monotherapy in participants with an inadequate response to methotrexate alone. Baricitinib is limited to use only in participants who have not responded to TNF inhibitor therapy. Upadacitinib can be used as monotherapy or in combination with methotrexate or other non-biological DMARDs. Initiation of therapy should be avoided in those with an ANC < 1000 mm^3, lymphocyte count < 500 µL, and/or a hemoglobin count of < 9 g/dL. The FDA does not recommend using JAK inhibitors with azathioprine or cyclosporine. Some common adverse effects include infections, nausea, and nasopharyngitis. A boxed warning for all JAK inhibitors is an increased risk of serious infection (tuberculosis) and malignancies (lymphoma). Baricitinib has an additional boxed warning for an increased risk of thrombosis.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Xeljanz®	• Olumiant® • Rinvoq™ • Xeljanz® XR

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: Targeted Immune Modulators, Janus Kinase (JAK) Inhibitors
- Age range: All appropriate MO HealthNet participants aged **18** years or older unless otherwise indicated

Approval Criteria

- **Documented compliance on current therapy OR**
- **For documented diagnosis of polyarticular juvenile idiopathic arthritis:**
  - **Claim is for Xeljanz IR AND**
  - **Adequate therapeutic 6 month trial of tumor necrosis factor (TNF) inhibitors defined as:**
    - **Combination therapy of 2 TNF inhibitors OR**
    - **Monotherapy of 1 TNF inhibitor**
- **For all other indications:**
  - Adequate therapeutic 6 month trial of TNF inhibitors defined as:
    - Combination therapy of 2 TNF inhibitors **OR**
    - Monotherapy of 1 TNF inhibitor **AND**
  - Failure to achieve desired therapeutic outcomes with trial on 1 preferred agent
    - Documented trial period of preferred agents (6 months of therapy) **OR**
    - Documented ADE/ADR to preferred agents **AND**
  - For Xeljanz XR: clinical consultant review for medical necessity **AND**
  - Documented diagnosis of rheumatoid arthritis:
    - Adequate therapeutic trial of methotrexate **OR**
    - Contraindication to methotrexate therapy **AND**
  - Documentation of appropriate diagnosis and participant age range for requested agent:

Generic	Brand	Indication
Baricitinib	Olumiant®	• Rheumatoid arthritis
Tofacitinib	Xeljanz®	• **Polyarticular juvenile idiopathic arthritis (aged 2 or older)** • Psoriatic arthritis • Rheumatoid arthritis • Ulcerative colitis
Tofacitinib	Xeljanz® XR	• Psoriatic arthritis • Rheumatoid arthritis • Ulcerative colitis
Upadacitinib	Rinvoq™	• Rheumatoid arthritis

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Lack of adequate trial on required preferred agent
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
OLUMIANT 1 MG TABLET	BARICITINIB	1 tablet per day
OLUMIANT 2 MG TABLET	BARICITINIB	1 tablet per day
RINVOQ ER 15 MG TABLET	UPADACITINIB	1 tablet per day
XELJANZ 5 MG TABLET	TOFACITINIB CITRATE	2 tablets per day

XELJANZ 10 MG TABLET	TOFACITINIB CITRATE	2 tablets per day
XELJANZ XR 11 MG TABLET	TOFACITINIB CITRATE	1 tablet per day
XELJANZ XR 22 MG TABLET	TOFACITINIB CITRATE	1 tablet per day

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. USPDI, Micromedex; 2021.
2. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.
3. Olumiant [package insert]. Indianapolis, IN: Eli Lilly and Company; July 2020.
4. Rinvoq [package insert]. North Chicago, IL: AbbVie Inc; July 2020.
5. Xeljanz/Xeljanz XR [package insert]. New York, NY: Pfizer; December 2019.
6. Cohen, S. & Cannella, A. (2020). Treatment of rheumatoid arthritis in adults resistant to initial conventional nonbiologic DMARD therapy. In P.L. Romain (Ed.), *UpToDate.*
7. Evidence-Based Medicine and Fiscal Analysis: "Targeted Immune Modulators: Janus Kinase (JAK) Inhibitors – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; June 2021.
8. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis, Singh et al. Arthritis Care & Research – DOI 10.1002/acr.22783
9. Evidence-Based Medicine Analysis: "Targeted Immune Modulators (Biologics – DMARDS)". UMKC-DIC; April 2021.