SmartPA Criteria Proposal

Drug/Drug Class:	Targeted Immune Modulators, Janus Kinase (JAK) Inhibitors PDL Edit
First Implementation Date:	January 22, 2004
Proposed Date:	September 15, 2022
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.

The U.S. Food and Drug Administration (FDA) issued a Drug Safety Communication in September 2021 that described the increased risk of serious heart-related events, cancer, thrombosis, and death associated with JAK inhibitors. Although the safety warning initially applied only to Xeljanz and Xeljanz XR, the labels of all products within the drug class were also required to be updated with boxed warnings reflecting these risks. These details were in addition to the boxed warnings of serious infections, malignancies, and thrombosis that already existed for the JAK inhibitors. Furthermore, the FDA limited the use of the agents only to those patients who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) inhibitors, thereby eliminating them as a first-line treatment option.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Xeljanz® Tabs	• Cibinqo™ • Olumiant® • Rinvoq® • Xeljanz® Soln • 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 treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, ulcerative colitis, ankylosing spondylitis, or psoriatic arthritis:
  - Documented diagnosis **AND**
  - Adequate therapeutic 6 month trial of tumor necrosis factor (TNF) inhibitor (trial defined as duration of therapy with class not agent)
- ~~**For documented diagnosis of rheumatoid arthritis:**~~
  - ~~**Adequate therapeutic trial of methotrexate OR**~~
  - ~~**Contraindication to methotrexate therapy AND**~~
- **For treatment of alopecia areata:**
  - **Prescribed by or in consultation with a dermatologist, immunologist, or allergist AND**
  - **Documented diagnosis of alopecia areata AND**
  - **Aggressive pace of disease progression as assessed by the specialist OR**
  - **Adequate therapeutic trial of 1 of the following for at least 28 days:**
    - **Topical corticosteroids for alopecia areata**
    - **Oral immunosuppressant for alopecia areata**
- **For treatment of atopic dermatitis:**
  - **Prescribed by or in consultation with a dermatologist, immunologist, or allergist AND**
  - **Documented diagnosis of atopic dermatitis AND**
  - **Failure to achieve desired therapeutic outcome with trial of at least any two of the following classes of therapy for 60 days each (one of which must be a systemic therapy):**
    - **Topical corticosteroid**
    - **Topical calcineurin Inhibitor**
    - **IL-4 receptor alpha antagonist (i.e., Dupixent®)**
    - **IL-13 antagonist (i.e., Adbry™)**
    - **Phototherapy**
    - **Phosphodiesterase-4 (PDE-4) inhibitor**
    - **Oral corticosteroid for the treatment of atopic dermatitis**
    - **Oral immunosuppressant for the treatment of atopic dermatitis**
    - **Topical JAK inhibitor**
- Requests for non-preferred agents: Participants must have documented failure to achieve desired therapeutic outcomes with trial on at least 1 preferred agent:
  - Documented trial period of preferred agents (6 months of therapy) **OR**
  - Documented ADE/ADR to preferred agents **AND**
- Additional product specific requirements:
  - For Xeljanz XR: Clinical Consultant Review for medical necessity and reason why participant cannot utilize Xeljanz IR
  - For Xeljanz solution: Clinical Consultant Review for participants aged 10 years or older

Denial Criteria

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

Drug Description	Generic Equivalent	Max Dosing Limitation
CIBINQO 50 MG TABLET	**ABROCITINIB**	**1 tablet per day**
CIBINQO 100 MG TABLET	**ABROCITINIB**	**1 tablet per day**
CIBINQO 200 MG TABLET	**ABROCITINIB**	**1 tablet per day**
OLUMIANT 1 MG TABLET	BARICITINIB	1 tablet per day
OLUMIANT 2 MG TABLET	BARICITINIB	1 tablet per day
OLUMIANT 4 MG TABLET	**BARICITINIB**	**1 tablet per day**
RINVOQ ER 15 MG TABLET	UPADACITINIB	1 tablet per day
XELJANZ 1 MG/ML SOLUTION	TOFACITINIB CITRATE	10 mL 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

- Evidence-Based Medicine Analysis: “Targeted Immune Modulators (Biologics – DMARDS [IL-6, TNF, IL-17A Antibody/IL-17 RA & IL-23/IL-12, JAK Inhibitors, CAPs agents, Select/Other Agents])”. UMKC-DIC; August 2022.
- 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.
- Cohen, S. & Cannella, A. (2020). Treatment of rheumatoid arthritis in adults resistant to initial conventional nonbiologic DMARD therapy. In P.L. Romain (Ed.), *UpToDate.*
- 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis, Singh et al. Arthritis Care & Research – DOI 10.1002/acr.22783
- IPD Analytics. Rx Brief: JAK Inhibitor Safety: FDA Warnings and Payer Implications. September 2021.
- Olumiant [package insert]. Indianapolis, IN: Eli Lilly and Company; May 2022.
- Cibinqo [package insert]. New York, NY: Pfizer Inc; January 2022.
- Rinvoq [package insert]. North Chicago, IL: AbbVie Inc; April 2022.
- Xeljanz [package insert]. New York, NY: Pfizer; January 2022.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.