

SmartPA Criteria Proposal

Drug/Drug Class:	Targeted Immune Modulators, Janus Kinase (JAK) Inhibitors PDL Edit
First Implementation Date:	January 22, 2004
Proposed Date:	July 18, 2023
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<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: 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
	<ul style="list-style-type: none"> Xeljanz[®] Tabs 	<ul style="list-style-type: none"> Cibinqo[™] Olumiant[®] Rinvoq[®] Xeljanz[®] Soln Xeljanz[®] XR

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: 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, **non-radiographic axial spondyloarthritis**, 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 treatment of Crohn's disease:**
 - **Claim is for Rinvoq AND**
 - **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 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 **for indications other than Crohn's disease**: 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

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- 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
RINVOQ ER 30 MG TABLET	UPADACITINIB	1 tablet per day
RINVOQ ER 45 MG TABLET	UPADACITINIB	84 tablets every 365 days
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:
MedWatch Form:

Progress Notes:
Other:

Disposition of Edit

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

Default Approval Period

1 year

References

- Evidence-Based Medicine and Fiscal Analysis: "Therapeutic Class Review: IMMUNOLOGIC AGENTS: Targeted Immune Modulators, JAK Inhibitors", Gainwell Technologies; Last updated April 28, 2023.
- 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; March 2023.
- IPD Analytics. Rx Brief: JAK Inhibitor Safety: FDA Warnings and Payer Implications. September 2021.
- Cibinqo [package insert]. New York, NY: Pfizer Inc; February 2023.
- Olumiant [package insert]. Indianapolis, IN: Eli Lilly and Company; June 2022.
- Rinvoq [package insert]. North Chicago, IL: AbbVie Inc; May 2023.

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- Xeljanz [package insert]. New York, NY: Pfizer; December 2021.
- USPDI, Micromedex; 2023.
- Clinical Pharmacology [online]. Tampa (FL): Elsevier. 2023.

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