SmartPA Criteria Proposal

Drug/Drug Class:	Targeted Immune Modulators, Small Molecule Janus Kinase (JAK) Inhibitors Clinical Edit
First Implementation Date:	October 20, 2022
Revised Date:	October 26, 2023
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Targeted Immune Modulators, Small Molecule Janus Kinase (JAK) Inhibitors.

Why Issue Selected: Janus kinase (JAK) is a group of cytoplasmic protein tyrosine kinases that are essential for signal transduction to the nucleus from common plasma membrane receptors for some interleukins. JAKs are comprised of Janus kinase 1 (JAK1), Janus kinase 2 (JAK2), Janus kinase 3 (JAK3), and tyrosine kinase 2 (TYK2). Inhibition of these enzymes results in decreased cytokine or growth factor-mediated gene expression and intracellular activity leading to reduced immunological responses. Jakafi® (ruxolitinib) was FDA-approved in 2011 and is currently indicated for intermediate and high-risk myelofibrosis, polycythemia vera, and steroid-refractory graft-versus-host disease. Inrebic® (fedratinib) was approved by the FDA in 2019 for the indication of intermediate or high-risk myelofibrosis. Vonjo® was FDA-approved in 2022 for the indication of intermediate or high-risk myelofibrosis in adults with a platelet count below 50 x 10^9/L. All three medications are available as oral formulations. Other JAK inhibitors differ slightly in their inhibition of the specific kinases and do not share any of the same indications as Jakafi, Inrebic, or Vonjo.

Due to the high cost and specific approved indications, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Targeted Immune Modulators, Small Molecule Janus Kinase (JAK) Inhibitors.

Program-Specific Information:

Date Range FFS 4-1-2022 to 3-31-2023			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
INREBIC 100 MG CAP	0	-	-
JAKAFI 5 MG TAB	28	$304,536.09	$10,876.29
JAKAFI 10 MG TAB	38	$492,460.07	$12,959.48
JAKAFI 15 MG TAB	12	$185,013.26	$15,417.77
JAKAFI 20 MG TAB	23	$315,497.52	$13,717.28
JAKAFI 25 MG TAB	8	$128,909.14	$16,113.64
VONJO 100 MG CAP	6	$120,429.66	$20,071.61

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, Small Molecule Janus Kinase (JAK) Inhibitors
- Age range: All appropriate MO HealthNet participants

Approval Criteria

Initial Therapy:

- Prescribed by or in consultation with an appropriate specialist in the treated disease state **AND**
- Documented diagnosis of intermediate or high-risk myelofibrosis **AND**
  - Participant is aged at least 18 years **AND**
  - For Vonjo: documentation of platelet count < 50 x 10^9/L
  - For Inrebic: failure to achieve therapeutic response after minimum of 90 days of therapy with Jakafi
  - Initial approval is for 6 months
- Documented diagnosis of symptomatic low-risk myelofibrosis **AND**
  - For Jakafi only:
    - Participant is aged at least 18 years **AND**
    - Documented adequate therapeutic trial of hydroxyurea (3 claims in past 12 months) **AND**
    - Documented adequate therapeutic trial of peginterferon alfa-2a (3 claims in past 12 months)
    - Initial approval is for 6 months
- Documented diagnosis of polycythemia vera **AND**
  - For Jakafi only:
    - Participant is aged at least 18 years **AND**
    - Participant is considered high-risk based on
      - Age > 60 years **OR**
      - Age ≤ 60 year and thrombosis history **AND**
    - Documented therapeutic trial of peginterferon alfa-2a (3 claims in past 12 months) **AND**
    - Patient must have resistance or intolerance to hydroxyurea defined by:
      - Need for phlebotomy to keep hematocrit < 45% after 3 months of at least 2 g/day of hydroxyurea **OR**
      - Platelet count >400 x 10^9/L and white blood cell count >10 x 10^9/L after 3 months of at least 2 g/day of hydroxyurea **OR**
      - Reduction of splenomegaly < 50% after 3 months of at least 2 g/day of hydroxyurea **OR**
      - Absolute neutrophil count <1.0 x 10^9/L or platelet count <100 x 10^9/L or hemoglobin <10 g/dL **OR**
      - Documentation of previous therapeutic trial (at least 3 months of therapy) or concurrent treatment, intolerance, insufficient response, or contraindication with hydroxyurea.
    - Initial approval for 6 months
- Documented diagnosis of acute graft-versus-host disease **AND**
  - For Jakafi only:
    - Participant is aged at least 12 years **AND**
    - Documentation that participant is steroid-refractory defined by:

        - Progression of acute GVHD within 3-5 days of therapy onset with ≥ 2 mg/kg/day of prednisone **OR**
        - Failure to improve within 5-7 days of treatment initiation **OR**
        - Incomplete response after more than 38 days of immunosuppressive treatment including steroids **OR**
        - Documented ADE/ADR to oral corticosteroids
    - Initial approval for 6 months
- Documented diagnosis of chronic graft-versus-host disease **AND**
    - For Jakafi only:
        - Participant is aged at least 12 years **AND**
        - Documentation that participant is steroid-refractory defined by:
            - Chronic GVHD progression while on prednisone at ≥ 1 mg/kg/day for 1-2 weeks **OR**
            - Stable GVHD disease while on ≥ 0.5 mg/kg/day (or 1 mg/kg every other day) of prednisone for 1-2 months **OR**
            - Documented ADE/ADR to oral corticosteroids
            - Initial approval for 6 months

Continuation of Therapy

- Documented compliance to prescribed drug therapy (3 claims in past 120 days)
- Continued approval for up to 12 months

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Participant is currently pregnant

Required Documentation

Laboratory Results:		Progress Notes:	
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

6 months

References

- Inrebic (fedratinib) [package insert]. Summit, NJ: Celgene Corporation; May 2023.
- Jakafi (ruxolitinib) [package insert]. Wilmington, DE: Incyte Corporation; January 2023.
- Vonjo (pacritinib) [package insert]. Seattle, WA: CTI BioPharma Corporation; February, 2022.
- IPD Analytics: New Drug Review: Vonjo (pacritinib). Accessed April 22, 2022.

- National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Myeloproliferative Neoplasms. Version 2.2022 – April 13, 2022. mpn.pdf (nccn.org). Accessed April 22, 2022.
- National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Hematopoietic Cell Transplantation (HCT). Version 1.2022 – April 1, 2022. hct.pdf (nccn.org). Accessed April 22, 2022.