ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Initial Request** ☐ **Renewal** ☐ **Appeal/Redetermination**[1]

☐ **Urgent**[2] ☐ **Non-Urgent**

Requested Drug Name: Jakafi® (ruxolitinib) – Medicare Part D

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Jakafi® (ruxolitinib)

Diagnosis (documentation supportive of diagnosis is required)

☐ Myelofibrosis
- ☐ Intermediate (2 prognostic factors) **OR**
- ☐ High-risk (3 or more prognostic factors)

☐ Other (please state): _____

Clinical Consideration (for approval, please indicate and provide documentation of the following):

INITIAL REQUEST for Myelofibrosis

☐ Palpable splenomegaly at least 5 cm below the costal margin
☐ Platelet count ≥ 50 X 10^9/L at start of therapy

*Note: Initial dose of Jakafi is based on the platelet count due to risk of hematological adverse reactions. The platelet count must be 50 x 10^9/L or greater for approval

*Initial approval will be given for 6 months

*Note: Treatment should be discontinued after 6 months if insufficient response

RENEWAL REQUEST for Myelofibrosis

☐ 35% reduction in spleen size and decrease in symptoms vs. baseline

Physician Specialty

☐ Oncology
☐ Other (please state):_____

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	

Product will be delivered to: ☐ Patient's Home ☐ Physician Office Other:

Prescriber or Authorized Signature: Date:

Dispensing Pharmacy Name and Phone Number:

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. Appeal/redetermination requests can be made for this medication within 60 calendar days from the date on the faxed/written denial notice you received at the time of the original request.

2. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request.

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Jakafi® (ruxolitinib)

CLASSIFICATION

- Tyrosine Kinase Inhibitor

DESCRIPTION

- Ruxolitinib inhibits dysregulated Janus Associated Kinase (JAK) 1 and JAK2 signaling associated with myelofibrosis. JAK1 and JAK2 recruit signal transducers and activators of transcription (STATs) to cytokine receptors leading to modulation of gene expression.
- Ruxolitinib is indicated to treat intermediate- or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis. It is also indicated for polycythemia vera in patients with an inadequate response to or intolerance of hydroxyurea.
- A randomized, open-label, active-controlled, Phase 3 trial in patients with polycythemia vera with an inadequate response or intolerance of hydroxyurea (n=222) showed a significantly higher response rate (defined as a percentage of patients achieving both hematocrit control and at least a 35% reduction in spleen volume from baseline) in patients treated with Jakafi compared with best available therapy (e.g., hydroxyurea, interferon, peginterferon, anagrelide, pipobroman, lenalidomide, thalidomide) at week 32 (21% v <1%). The response was maintained through week 48 (19% v <1%). Complete hematological remission was observed at week 32 (24% v 9%).
- In the COMFORT-I trial (n=309), patients with myelofibrosis (primary myelofibrosis, 50%; post-polycythemia vera myelofibrosis, 31%; post-essential thrombocythemia myelofibrosis, 18%) who were refractory to or not candidates for available therapy and had palpable splenomegaly at least 5 cm below the costal margin (median, 16 cm; 10 cm or greater, 81%) and risk category (International Working Group Consensus Criteria) of intermediate risk (2 prognostic factors) or high risk (3 or more prognostic factors) were randomized 1:1 to ruxolitinib or placebo. The primary outcome, a 35% or greater reduction in spleen volume at week 24, was achieved by a significantly higher proportion of patients in the ruxolitinib group than in the placebo group (41.9% vs. 0.7%; p <0.0001). Among responders with a 35% or greater decrease in spleen volume, 67% (95% CI, 46.4% to 81.1%) had a reduction that was maintained for 48 weeks or more. At week 24, myelofibrosis symptoms (measured by modified Myelofibrosis Symptom Assessment Form) were improved (50% or greater reduction in MFSAF score from baseline) in a significantly higher proportion of patients in the ruxolitinib group (n=148) than in the placebo group (n=152); 45.9% vs 5.3%; odds ratio 15.3 (95% CI, 6.9 to 33.7; p < 0.001). The improvement in symptoms was rapid and maintained over the duration of the 24-week study; however, following interruption of ruxolitinib therapy, myelofibrosis-related symptoms returned to baseline levels over a period of approximately 1 week. At the time of data cutoff, there were 10 deaths (6.5%) reported in the ruxolitinib group compared with 14 deaths (9.1%) in placebo; hazard ratio (HR), 0.67; 95% CI, 0.3 to 1.5; p=0.33), and when 4 additional months were added to the analysis (median follow-up 51 weeks), the mortality rate was 8.4% (13 deaths) vs 15.6% (24 deaths), respectively; HR 0.5 (95% CI, 0.25 to 0.98; p=0.04).
- In the COMFORT-II open-label trial (n=219), patients with myelofibrosis who were refractory to or not candidates for available therapy and had palpable splenomegaly at least 5 cm below the costal margin (median, 15 cm; 10 cm or greater, 70%) and a IWG risk category of intermediate risk (2 prognostic factors) or high risk (3 or more prognostic factors) were randomized in a 2:1 ratio to ruxolitinib or best available individualized therapy as determined by the investigator (hydroxyurea,

47%; glucocorticoids, 16%). At baseline, median spleen volume measured by MRI or CT was 2381 cm^3 (range, 451 to 7765 cm^3; ULN, approximately 300 cm^3). The primary outcome, a 35% or greater reduction in spleen volume at week 48, was achieved by a significantly higher proportion of patients in the ruxolitinib group than in the best available therapy group (n=73; 28.5% vs. 0%; p <0.0001).
- Most common adverse effects (>15%): thrombocytopenia, anemia, bruising, dizziness, HA

FORMULARY COVERAGE

Prior authorization:	Yes
Good Health Formulary:	Tier 4
Commercial Formulary:	Tier 4
Medicare Part D coverage:	Tier 5

COVERAGE CRITERIA

Jakafi® (ruxolitinib) meets the definition of **medical necessity** for all FDA-approved indications, not otherwise excluded from Part D, including the following:
- Myelofibrosis that is intermediate-2 (2 prognostic factors) or high-risk (3 or more prognostic factors), including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis
  - Documentation supportive of the following is required:
    - Diagnosis
    - 2 or more prognostic factors (intermediate or high-risk)
    - Palpable splenomegaly at least 5 cm below the costal margin
    - Platelet count ≥ 50 X 10^9/L at start of therapy
    - For renewals: 35% reduction in spleen size and decrease in symptoms vs. baseline

For Myelofibrosis:
Prognostic factors based on the International Working Group Consensus Criteria (IWG):
- Age greater than 65 years old,
- Leukocytosis (white blood cell count greater than 25 x 10^9 /L),
- Marked anemia (hemoglobin less than 10 g/dL),
- Peripheral blood blast greater than or equal to 1 percent,
- Positive for constitutional symptoms (e.g. fever, weight loss, night sweats, and bone pain).

Four risks groups delineated:
- presence of 0 (low risk)
- 1 (intermediate risk-1)
- 2 (intermediate risk-2)
- ≥ 3 (high risk)

Jakafi® (ruxolitinib) is considered **experimental** for the following:
- Any condition or diagnosis not FDA approved or Compendia supported
- Platelet count less than 50 X 10^9/L at start of therapy.
- Chronic myelogenous leukemia, myelodysplastic syndrome, or other myeloid neoplasm

Required Provider Specialty:
- Approval is limited to Oncology

APPROVAL DURATION
- Initial: 6 months

DOSAGE/ADMINISTRATION

Adult Dosing (safety and efficacy has not been determined for pediatric patients less than 18 years):

- Myelofibrosis
  - Starting doses:
    - Platelet count greater than 200 x 10^9/L: 20 mg ORALLY twice daily
    - Platelet count 100 x 10^9/L to 200 x 10^9/L: 15 mg ORALLY twice daily
    - Platelet count 50 x 10^9/L to <100 x 10^9/L: 5mg ORALLY twice daily
  - Based on limited clinical data in patients who started Jakafi with a platelet count of 100 x 10^9/L or greater, long-term maintenance at a 5mg twice daily dose has not shown responses and continued use at this dose should be limited to patients in whom the benefits outweigh the potential risks

- Polycythemia Vera
  - 10mg BID

- Discontinue treatment after 6 months if insufficient response (no decrease in spleen size or improvement in symptoms).

- Dose modifications are necessary for certain patient populations, for insufficient responses, and for certain Hgb and platelet values: Refer to manufacturer's prescribing information

PRECAUTIONS

- Hematologic toxicity, including thrombocytopenia, anemia, and neutropenia, may occur. Perform a pre-treatment complete blood count (CBC) and monitor CBCs every 2 to 4 weeks until doses are stabilized, and then as clinically indicated. Dose interruptions or reductions may be necessary.
- Herpes zoster may occur. Education on signs and symptoms and seek treatment as early as possible.
- Bleeding may occur and may require dose adjustment or therapy interruption.
- Concomitant use with strong CYP3A4 inhibitors, with platelet counts less than 100 x 10^9/L, avoid use; with platelet counts of 100 x 10^9/L or greater, dose adjustment recommended.
- Discontinuation of therapy - gradual tapering of dose recommended.
- Hepatic impairment, with platelet counts less than 100 x $10^{9/}$L, avoid use; with platelet counts of 100 to 150 x 10^9/L, dose adjustment recommended.
- Serious infections (e.g., bacterial, mycobacterial, fungal, or viral) may occur.
- Progressive multifocal leukoencephalopathy has been reported. Discontinuation of therapy required if suspected.
- Renal disease, ESRD (CrCl < 15 mL/min) not on dialysis: avoid use; ESRD on dialysis and platelet count 100 x 10^9/L or greater, dose adjustment recommended.
- Renal impairment, moderate (CrCl 30 to 59 mL/min) or severe (CrCl 15 to 29 mL/min) and platelet counts less than 100 x 10^9/L, avoid use; moderate or severe and platelet counts 100 to 150 x 10^9/L, dose adjustment recommended.
- Tuberculosis has been reported. Consider possibility of latent or active tuberculosis. Monitoring is recommended.

Billing/Coding information

HCPCS Coding:

C9399	Unclassified drugs or biologicals (Hospital Outpatient Use only)
J 8999	Prescription drug, oral, chemotherapeutic, Not otherwise specified

COST

- AWP (March 2012): Jakafi oral tablet (all strengths) (60): $8,400.00
- AWP (March 2014): Jakafi oral tablet (all strengths) (60): $10,502.40
- AWP (February 2015): Jakafi oral tablet (all strengths) (60): 11, 001.60

COMMITTEE APPROVAL

- March 2012

GUIDELINE UPDATE INFORMATION

March 2012	Coverage Policy created
May 2014	Coverage Policy updated
February 2015	Coverage Policy updated

REFERENCES

- DRUGDEX®, accessed 03/14/2012, 5/19/2014, 2/12/15
- Product Information: Jakafi® (ruxolitinib) tablets for oral use. Incyte Corporation, Wilmington, DE, 2011, 2013.