Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Jakafi (ruxolitinib)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***December 2011 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Jakafi (ruxolitinib).

Jakafi (ruxolitinib) is indicated for the treatment of patients with:

- Intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis.
- Polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea.

DEFINITIONS

Myelofibrosis – a myeloproliferative disorder (of the bone marrow cells) in which collagen accumulates fibrous scar tissue in the marrow cavity, leading to anemia, neutropenia, thrombocytopenia, weakness, fatigue, and often, an enlarged spleen and liver. A diagnosis of myelofibrosis can be confirmed by (1) having megakaryocyte proliferation and atypia with fibrosis, (2) indicating a clonal marker (e.g. JAK2V617F or other markers), (3) not meeting World Health Organization criteria for polycythemia

vera, myelodysplastic syndrome, CML, or other myeloid neoplasms, and (4) having the presence of at least two of the following: leukoerythroblastosis, increased serum lactate dehydrogenase (LDH) levels, anemia, palpable splenomegaly. These characteristics can be confirmed through a variety of procedures, such as a bone marrow biopsy, CT/MRI, CBC and other blood tests, or clinical findings.

Phlebotomy – the removal of blood and a procedure recommended for all patients with polycythemia vera to maintain the hematocrit at less than 45%.

Polycythemia vera – a myeloproliferative disorder characterized by clonal proliferation of the erythroid, myeloid, and megakaryocyte lineages. Increase erythrocyte production results in increase red blood cell mass, and white blood cell and platelet counts may also be elevated. Symptoms may include fatigue, pruritis, night sweats, and enlarge spleen.

Risk stratification – based on the Dynamic International Prognostic Scoring System (DIPSS), which estimates the survival for myelofibrosis patients using the following five prognostic variables: age > 65 years, hemoglobin < 10 g/dL, white blood cell count > 25 x 109/L, circulating blood blasts ≥ 1%, and constitutional symptoms (e.g. weight loss >10%, unexplained fever, excessive sweating). Patients are classified as low-risk with 0 factors, intermediate-risk with 1-2 factors, and high risk with ≥ 3 factors.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Jakafi (ruxolitinib), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. **Myelofibrosis:**
   - Must be prescribed by a hematologist or an oncologist
   - Must have a diagnosis of intermediate or high-risk myelofibrosis (includes primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis)

- Must have documentation of a baseline platelet count of at least 50,000 cells/mm3 prior to initiation of Jakafi (ruxolitinib)
- Must have no evidence of infection

2. Polycythemia vera:

- Must be prescribed by a hematologist or an oncologist
- Must have a diagnosis of polycythemia vera, currently requiring phlebotomy
- Must have an inadequate response to or intolerance of hydroxyurea
- Must have documentation of a baseline platelet count of at least 50,000 cells/mm3
- Must have no evidence of infection

Reauthorization Criteria:

All prior authorization renewals are reviewed every 6 months to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 6-month intervals based upon the following:

- **Myelofibrosis:**
  - For baseline platelet counts 50,000 to less than 100,000 cells/mm3: must have a recent platelet count ≥ 25,000 cells/mm3 and
  - For baseline platelet counts greater than 100,000 cells/mm3: must have a recent platelet count ≥ 50,000 cells/mm3
  - Must have a recent absolute neutrophil count (ANC) ≥ 0.5 x109/L
  - Must have a spleen size reduction since initiation of ruxolitinib or have symptom improvement based upon the prescriber's assessment while on therapy
  - Must have no evidence of infection
- **Polycythemia vera:**
  - Must have a recent hemoglobin count ≥8 g/dL
  - Must have a recent platelet count ≥50,000 cells/mm3
  - Must have a recent absolute neutrophil count (ANC) ≥0.5 x109/L
  - Must have a spleen size reduction or hematologic improvement (decrease of hematocrit, platelet count, or white blood cell count) since initiation of ruxolitinib based upon the prescriber's assessment while on therapy
  - Must have no evidence of infection

Limitations:

Length of Authorization (if above criteria met)

Initial Authorization	• Up to <time frame> or duration of member's membership with plan (if indefinite auth) • Can bullet by diagnosis if duration will differ
Reauthorization	Same as initial OR Up to <time frame>
Quantity Level Limit	
Jakafi	60 tablets per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Jakafi [package insert]. Wilmington, DE: Incyte Corporation; December 2014.
2. Abdel-Wahab OI, Levine RL. Primary Myelofibrosis: Update on Definition, Pathogenesis, and Treatment. *Annu Rev Med* 2009;60:233-245.
3. Barosi G, Rosti V, Vannucchi AM. Therapeutic approaches in myelofibrosis. *Expert Opin Pharmacother* 2011;12(10):1597-611. Epub 2011 Apr 4.
4. COMFORT: Phase III study for myelofibrosis. Incyte Corporation. Available from: www.comfortstudy.com. Accessed on: 12 December 2011.
5. Tefferi A. Primary myelofibrosis: 2012 update on diagnosis, risk stratification, and management. *Am J Hematol* 2011;86(12):1017-26.
6. Cervantes F, Dupriez B, Pereira A, et al. New prognostic scoring system for primary myelofibrosis based on a study of the International Working Group for Myelofibrosis Research and Treatment. *Blood* 2009;113(13):2895-901.
7. Passamonti F, Cervantes F, Vannucchi AM, et al. A dynamic prognostic model to predict survival in primary myelofibrosis: a study by the IWG-MRT (International Working Group for Myeloproliferative Neoplasms Research and Treatment). *Blood* 2010;115(9):1703-8.
8. Tefferi A, Thiele J, Orazi A, et al. Proposals and rationale for revision of the World Health Organization diagnostic criteria for polycythemia vera, essential thrombocythemia, and primary myelofibrosis: recommendations from an ad hoc international expert panel. *Blood* 2007;110(4):1092-.
9. Verstovsek S, Passamonti F, Rambaldi A, et al. A phase 2 study of ruxolitinib, an oral JAK1 and JAK2 inhibitor, in patients with advanced polycythemia vera who are refractory or intolerant to hydroxyurea. Cancer 2014; 120: 513-20.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*