VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Jakafi® (ruxolitinib tablets – Incyte)

TAC APPROVAL DATE: 02/27/2019; selected revision 06/05/2019

OVERVIEW

Jakafi, a kinase inhibitor, is indicated for treatment of patients with 1) intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis, and 2) polycythemia vera in patients who have had an inadequate response to or are intolerant of hydroxyurea, and 3) steroid-refractory acute graft-vs.-host disease in adult and pediatric patients ≥ 12 years of age.[1] Jakafi specifically inhibits Janus Associated Kinases (JAKs) JAK1 and JAK2 which mediate the signaling of various cytokinase and growth factors that are vital for hematopoiesis and immune function.

Disease Overview

Myelofibrosis, polycythemia vera, and essential thrombocythemia are a group of uncommon heterogeneous disorders involving the hematopoietic system.[2-4] In the US, the prevalence of myelofibrosis, essential thrombocythemia, and polycythemia vera were approximately 13,000, 134,000, and 148,000 cases respectively.[2] It is a cancer that impacts the normal production of red blood cells and involves the replacement of bone marrow by fibrous scare tissue. There is a lack of red blood cells, and an overabundance of white blood cells. The symptom profile in myeloproliferative neoplasms is complex and symptoms vary among the subtype. Patients may experience fatigue, pruritis, weight loss, splenomegaly, and various laboratory abnormalities (e.g., erythrocytosis, thrombocytosis, and leukocytosis). The disease can be slowly progressive and early in the disease process patients may be asymptomatic. However, some patients with this condition may have the disease transform into acute myeloid leukemia which is associated with a poor prognosis. The management of myeloproliferative neoplasms involves identification of specific mutations which guide targeted therapies and have resulted in improvement of disease symptoms. Other treatment are symptom-based.

Disease Overview

The National Comprehensive Cancer Network has guidelines regarding myeloproliferative neoplasms (version 2.2019 – October 29, 2018) that include Jakafi.[2] Jakafi is recommended among patients with low-, intermediate-, and high-risk myelofibrosis. It is also a recommended therapy for patients with high-risk polycythemia vera.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Jakafi. All approvals are provided for the durations noted below.

Automation: The ICD-9/ICD-10 codes for myelofibrosis (ICD-9: 289.83 and ICD-10: D75.81) will be used as part of automation to allow approval of the requested medication.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Jakafi is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Graft versus Host Disease, Acute.** Approve for 1 year if the patient has tried one systemic corticosteroid.

2. **Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF.** Approve Jakafi for 3 years.

3. **Polycythemia Vera.** Approve Jakafi for 3 years if the patient has tried hydroxyurea.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Jakafi has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Refractory Leukemia.** Limited data have investigated Jakafi in adults with relapsed and/or refractory acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL), myelodysplastic syndromes (MDS) [including chronic myelomonocytic leukemia {CMML}], or chronic myelocytic leukemia (CML).[5,6] Further studies are needed to determine the place in therapy of Jakafi for the treatment of refractory leukemias.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Jakafi® tablets [prescribing information]. Wilmington, DE: Incyte; May 2019.
2. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (Version 2.2019 – October 29, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on February 9, 2019.
3. Tremblay D, Marcellino B, Mascarenhas J. Pharmacotherapy of myelofibrosis. *Drugs.* 2017;77(14):1549-1563.
4. Vannucchi AM, Guglielmelli P. What are the current treatment approaches for patients with polycythemia vera and essential thrombocythemia? *Hematology Am Soc Hematol Educ Program*. 2017;2017(1):480-488.
5. Eghtedar A, Verstovsek S, Estrov Z, et al. Phase 2 study of the JAK kinase inhibitor ruxolitinib in patients with refractory leukemias, including postmyeloproliferative neoplasm acute myeloid leukemia. *Blood.* 2012;119:4614-4618.
6. Pemmaraju N, Kantarjian H, Kadia T, et al. A Phase I/II study of the Janus Kinase (JAK)1 and 2 inhibitor ruxolitinib in patients with relapsed or refractory acute myeloid leukemia. *Clin Lyphoma Myeloma Leuk*. 2014;15(3):171-176.

HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date
Annual revision	No criteria changes.	01/25/2017
Annual revision	No criteria changes	02/14/2018
Annual revision	No criteria changes	02/27/2019
Selected revision	1. Graft Versus Host Disease, Acute: This condition was added based on a new FDA-approved indication. Criteria are to approve for 1 year if the patient has tried one systemic corticosteroid.	06/05/2019

* For a further summary of criteria changes, refer to respective TAC minutes available at: http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx; TAC – Therapeutic Assessment Committee.