BlueCross BlueShield Federal Employee Program

JAKAFI
(ruxolitinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Jakafi (ruxolitinib) is a Janus Associated Kinase (JAK) 1 and 2 inhibitor indicated for the treatment of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis. It is also indicated in patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea, and for the treatment of chronic graft-versus-host disease and steroid-refractory acute graft-versus-host disease. JAK1 and JAK2 mediate the signaling of a number of cytokines and growth factors that are important in hematopoiesis and immune function. Myelofibrosis (MF) and polycythemia vera (PV) are myeloproliferative neoplasms (MPN) known to be associated with dysregulated JAK1 and JAK2 signaling. Inhibition of this overactivity results in a decrease in the inflammatory cytokine signaling and a decrease in overproduction of cells. JAK signaling involves recruitment of signal transducers and activators of transcription (STATs) to cytokine receptors, activation, and subsequent localization of STATs to the nucleus leading to modulation of gene expression. JAK-STAT signaling pathways play a role in regulating the development, proliferation, and activation of several immune cell types important for graft-versus-host disease GVHD pathogenesis (1).

Regulatory Status

FDA-approved indications: Jakafi is a kinase inhibitor indicated for treatment of: (1)

- Intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis in adults.
- Polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea.
- Steroid-refractory acute graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older.
- Chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

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Treatment with Jakafi can cause thrombocytopenia, anemia, and neutropenia. Thrombocytopenia should be managed by reducing the dose or temporarily interrupting Jakafi. Platelet transfusions may be necessary. Patients developing anemia may require blood transfusions and or dose modifications of Jakafi. A complete blood count (CBC) must be performed before initiating therapy, every 2 to 4 weeks until dose is stabilized, and then as clinically indicated. CBC with differential, palpable spleen length or spleen volume by magnetic resonance imaging (MRI) or computed tomography (CT) should be performed to monitor disease progression. Patients should be assessed for signs and symptoms of infection. Serious infections should have resolved before starting therapy. Lipid elevations have been reported and lipid levels should be assessed 8 to12 weeks from start of therapy and treated as needed (1).

The safety and effectiveness of Jakafi for the treatment of myelofibrosis or polycythemia vera in pediatric patients have not been established. The safety and effectiveness of Jakafi for the treatment of chronic GVHD and steroid-refractory acute GVHD have been established for the treatment of pediatric patients 12 years of age and older (1).

Summary

Jakafi (ruxolitinib) is a kinase inhibitor indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, post-essential thrombocythemia myelofibrosis, and polycythemia vera in patients who have had an inadequate response to or are intolerant of hydroxyurea. It is also indicated for the treatment of graft-versus-host disease (GVDH). Thrombocytopenia, anemia, and neutropenia can occur and can be managed by dose reduction, or interruption or transfusion. The safety and effectiveness of Jakafi for the treatment of myelofibrosis or polycythemia vera in pediatric patients have not been established. The safety and effectiveness of Jakafi for the treatment of chronic GVHD and steroid-refractory acute GVHD have been established for the treatment of children 12 years and older (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Jakafi while maintaining optimal therapeutic outcomes.

References

1. Jakafi [package insert]. Wilmington, DE: Incyte Co.; January 2023.
2. NCCN Drugs & Biologics Compendium® Ruxolitinib 2024. National Comprehensive Cancer Network, Inc. Accessed on April 24, 2024.