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## NOW APPROVED

The first and only FDA-approved drug to treat Polycythemia vera (PV) patients who have had an inadequate response to or are intolerant of hydroxyurea

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### Healthcare Professional & Office Staff Tips

Prior to payers updating their prior authorization policies, you may want to consider providing the following information to payers to assist patients in obtaining prescription coverage for Jakafi for the treatment of PV:

- Documentation of FDA approval (e.g., prescribing information)
- Documentation of PV diagnosis and patient history
- ICD-9 code for PV diagnosis (238.4)
- Supporting lab results—CBC
- Previous PV treatment history

#### Indications and Usage

Jakafi (ruxolitinib) is indicated for treatment of patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea.

#### Important Safety Information

- Treatment with Jakafi can cause thrombocytopenia, anemia and neutropenia, which are each dose-related effects. 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
- Manage thrombocytopenia 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

*(Continued on reverse)*

**Important Safety Information (continued)**

- Severe neutropenia (ANC <0.5 X 10<sup>9</sup>/L) was generally reversible by withholding Jakafi until recovery
- Serious bacterial, mycobacterial, fungal and viral infections have occurred. Delay starting Jakafi until active serious infections have resolved. Observe patients receiving Jakafi for signs and symptoms of infection and manage promptly
- Tuberculosis (TB) infection has been reported. Observe patients taking Jakafi for signs and symptoms of active TB and manage promptly. Prior to initiating Jakafi, evaluate patients for TB risk factors and test those at higher risk for latent infection. Consult a physician with expertise in the treatment of TB before starting Jakafi in patients with evidence of active or latent TB. Continuation of Jakafi during treatment of active TB should be based on the overall risk-benefit determination
- Progressive multifocal leukoencephalopathy (PML) has occurred with ruxolitinib treatment for myelofibrosis. If PML is suspected, stop Jakafi and evaluate
- Advise patients about early signs and symptoms of herpes zoster and to seek early treatment
- When discontinuing Jakafi, myeloproliferative neoplasm-related symptoms may return within one week. After discontinuation, some patients with myelofibrosis have experienced fever, respiratory distress, hypotension, DIC, or multi-organ failure. If any of these occur after discontinuation or while tapering Jakafi, evaluate and treat any intercurrent illness and consider restarting or increasing the dose of Jakafi. Instruct patients not to interrupt or discontinue Jakafi without consulting their physician. When discontinuing or interrupting Jakafi for reasons other than thrombocytopenia or neutropenia, consider gradual tapering rather than abrupt discontinuation
- Non-melanoma skin cancers including basal cell, squamous cell, and Merkel cell carcinoma have occurred. Perform periodic skin examinations
- The three most frequent non-hematologic adverse reactions (incidence >10%) were bruising, dizziness and headache
- A dose modification is recommended when administering Jakafi with strong CYP3A4 inhibitors or fluconazole or in patients with renal or hepatic impairment. Patients should be closely monitored and the dose titrated based on safety and efficacy
- Use of Jakafi during pregnancy is not recommended and should only be used if the potential benefit justifies the potential risk to the fetus. Women taking Jakafi should not breast-feed

**Please see accompanying Full Prescribing Information for Jakafi.**



For more information, contact IncyteCARES **Monday through Friday, 8 AM – 8 PM ET**, by calling **1-855-Jakafi (1-855-452-5234)** or fax the enrollment form to **1-855-525-7207**. Learn more at [www.IncyteCARES.com](http://www.IncyteCARES.com).

