

PHARMACY PRE-AUTHORIZATION CRITERIA



DRUG (S)	Jakafi (ruxolitinib)
POLICY #	22132
INDICATIONS	<p>For treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis.</p> <p>For treatment of polycythemia vera in patients who have had an inadequate response to, or are intolerant of, hydroxyurea.</p> <p>For the treatment of steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older.</p>
CRITERIA	<p>ConnectiCare considers Jakafi medically necessary when:</p> <ul style="list-style-type: none"> • Patient has clinically documented primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis. <p>AND</p> <ul style="list-style-type: none"> • Patient has intermediate or high risk disease as defined by possessing TWO or more of the following criteria: <ul style="list-style-type: none"> ➤ Age > 65 ➤ Documented Hemoglobin < 10g / dL ➤ Documented WBC > 25 x 10⁹ / L ➤ Circulating Blasts ≥ 1% ➤ Presence of Constitutional Symptoms (weight loss > 10% from baseline or unexplained fever or excessive sweats persisting for more than 1 month) <p>AND</p> <ul style="list-style-type: none"> • Baseline complete blood count (CBC) with platelet count of at least 50 X 10⁹ / L prior to initiating therapy <p>AND</p> <ul style="list-style-type: none"> • Patient will be using Jakafi (ruxolitinib) as monotherapy (excludes medically necessary supportive agents) <p>OR</p> <ul style="list-style-type: none"> • Patient has a diagnosis of polycythemia vera and has had an inadequate response to or are intolerant of hydroxyurea <p>OR</p> <ul style="list-style-type: none"> • Patient has a diagnosis of acute graft-versus-host disease despite previous steroid use <p>Members on concomitant tyrosine kinase inhibitors or immunomodulatory medications (example: Revlimid/lenalidomide) will not be approved.</p>

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LIMITATIONS	<p>Initial authorization will be given for 3 months if the above criteria are met. Subsequent approval will be based on current progress notes from the physician documenting efficacy, if:</p> <ul style="list-style-type: none">• The member has achieved a reduction from pretreatment baseline of at least 50% in palpable spleen length or a 35% in spleen volume as measured by CT or MRI <p>OR</p> <ul style="list-style-type: none">• The member has achieved a 50% or greater reduction in the Total Symptom Score from baseline as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF) <p>Medication will be discontinued after 6 months if no spleen reduction or symptom improvement.</p> <p>Continuation coverage duration: up to 3 years</p> <p>Quantity limit- Sixty (60) tablets per month based on twice daily dosing for all strengths. Complete blood counts (CBC's) will be required for dosage changes that require additional tablets.</p>
REFERENCES	<ol style="list-style-type: none">1. Jakafi full prescribing information. Wilmington, DE, Incyte Corporation.
P&T REVIEW HISTORY	12/11, 10/12, 10/13, 10/14, 11/15, 5/16, 5/17, 5/18, 5/19
REVISION RECORD	4/15, 5/17, 6/19, 7/19