PHARMACY PRE-AUTHORIZATION CRITERIA

DRUG (S)	**Jakafi (ruxolitinib)**
POLICY #	**22132**
INDICATIONS	For treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis. For treatment of polycythemia vera in patients who have had an inadequate response to, or are intolerant of, hydroxyurea. For the treatment of steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older.
CRITERIA	ConnectiCare considers Jakafi medically necessary when: • Patient has clinically documented primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis. AND • Patient has intermediate or high risk disease as defined by possessing TWO or more of the following criteria: ➢ Age > 65 ➢ Documented Hemoglobin < 10g / dL ➢ Documented WBC > 25 x 10^9 / 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) AND • Baseline complete blood count (CBC) with platelet count of at least 50 X 10^9 / L prior to initiating therapy AND • Patient will be using Jakafi (ruxolitinib) as monotherapy (excludes medically necessary supportive agents) OR • Patient has a diagnosis of polycythemia vera and has had an inadequate response to or are intolerant of hydroxyurea OR • Patient has a diagnosis of acute graft-versus-host disease despite previous steroid use Members on concomitant tyrosine kinase inhibitors or immunomodulatory medications (example: Revlimid/lenalidomide) will not be approved.

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LIMITATIONS	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: • 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 OR • 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) Medication will be discontinued after 6 months if no spleen reduction or symptom improvement. Continuation coverage duration: up to 3 years **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.
REFERENCES	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