

Clinical Policy Title:	ruxolitinib
Policy Number:	RxA.805
Drug(s) Applied:	Jakafi
Original Policy Date:	12/07/2021
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Myelofibrosis (must meet all):

1. Diagnosis of MF (includes primary MF, post-PV MF, post-ET MF);
2. Prescribed by or in consultation with a hematologist or oncologist;
3. Documentation of a recent (within the last 30 days) platelet count of $\geq 50 \times 10^9/L$.

Approval Duration

All lines of business (except Medicare): 12 months, Split-fill

B. Polycythemia Vera (must meet all):

1. Diagnosis of PCV;
2. Prescribed by or in consultation with a hematologist or oncologist;
3. Trial and failure of hydroxyurea, peginterferon, or interferon, unless clinically significant adverse effects are experienced, or all are contraindicated.

Approval Duration

All Lines of Business (except Medicare) : 12 months, Split-fill

C. Graft-Versus-Host Disease (must meet all):

1. Diagnosis of steroid-refractory acute or chronic GVHD post hematopoietic cell transplantation;
2. Prescribed by or in consultation with an oncologist, hematologist, or bone marrow transplant specialist;
3. For acute GVHD, trial and failure of a systemic corticosteroid (e.g., oral prednisone or intravenous methylprednisolone dose equivalent), unless contraindicated or clinically significant adverse effects are experienced;
4. For chronic GVHD, member meets one of the following (a or b):
 - a. Trial and failure of a systemic corticosteroid at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
 - b. Trial and failure of a systemic immunosuppressant at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 12 months, Split-fill

II. Continued Therapy Approval

A. All indications:

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Pardanani A, Harrison C, Cortes JE, et al. Safety and Efficacy of Fedratinib in Patients with Primary or Secondary Myelofibrosis – A Randomized Clinical Trial. JAMA Oncol. 2015;1(5): 643-51. Available at: <https://pubmed.ncbi.nlm.nih.gov/26181658/>. Accessed June 14, 2024.
2. Leukemia and Lymphoma Society. Polycythemia vera facts. Available at: https://www.lls.org/sites/default/files/file_assets/FS13_PolycythemiaVera_FactSheet_final5.1.15.pdf. Accessed June 14, 2024

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	12/07/2021	12/07/2021
Policy was reviewed: <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.5: Updated to include new combination therapy criteria “Opzelura™ is not prescribed concurrently with biologic disease-modifying antirheumatic drugs (e.g., Humira, Enbrel, Taltz, Stelara), JAK inhibitors (e.g., Xeljanz, Rinvoq, Olumiant), or potent immunosuppressants (e.g., azathioprine, cyclosporine)”. 2. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, Nonsegmental vitiligo. 3. Continued Therapy Approval Criteria, II.B: Updated to include approval criteria for indication, Nonsegmental vitiligo. 4. References were reviewed and updated. 	9/6/2022	10/19/2022
Policy was reviewed: <ol style="list-style-type: none"> 1. Clinical Policy Title, Drug(s) Applied: Updated to include new drug Jakafi®. 2. Initial Approval Criteria, I.C: Updated to include approval criteria for indication, Myelofibrosis. 3. Initial Approval Criteria, I.D: Updated to include approval criteria for indication, Polycythemia Vera. 4. Initial Approval Criteria, I.E: Updated to include approval criteria for indication, Graft-Versus-Host Disease. 5. Initial Approval Criteria, I.F: Updated to include approval criteria for Off Label indication, Chronic Myelomonocytic Leukemia and Myelodysplastic/Myeloproliferative Neoplasms (MDS/MPN). 	03/17/2023	04/13/2023

<p>6. Initial Approval Criteria, I.G: Updated to include approval criteria for Off Label indication, Pediatric B-Cell Acute Lymphoblastic Leukemia.</p> <p>7. Initial Approval Criteria, I.H: Updated to include approval criteria for Off Label indication, Myeloid/Lymphoid Neoplasm with Eosinophilia.</p> <p>8. Initial Approval Criteria, I.I: Updated to include approval criteria for Off Label indication, Essential Thrombocythemia.</p> <p>9. Initial Approval Criteria, I.J: Updated to include approval criteria for Off Label indication, CAR T-Cell Related Toxicities.</p> <p>10. Continued Therapy Approval, II.C: Updated to include approval criteria for indication, Myelofibrosis, Polycythemia Vera and Graft-Versus-Host Disease.</p> <p>11. Continued Therapy Approval, II.D: Updated to include approval criteria for indication, CAR T-cell-related toxicities.</p> <p>12. References were reviewed and updated.</p>		
Policy was reviewed.	10/19/2023	10/19/2023
Removed Opzelura criteria and off label use	2/1/2024	2/1/2024
<p>Policy was reviewed:</p> <p>1. Approval Duration Update.</p> <p>2. Continuation criteria updated.</p> <p>3. References were reviewed and Updated.</p>	6/14/2024	6/14/2024
Policy was reviewed.	12/05/2024	N/A
Policy reviewed.	12/11/2025	12/11/2025