Clinical Policy Title:	ruxolitinib
Policy Number:	RxA.805
Drug(s) Applied:	Jakafi
Original Policy Date:	12/07/2021
Last Review Date:	6/14/2024
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 ≥ 50×10^9/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:

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: 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: 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

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