CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Jakafi (ruxolitinib)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Jakafi, a janus kinase inhibitor (JAK1 and JAK2), is approved for use in both acute and chronic graft-versus-host disease (GVHD), myelofibrosis, and polycythemia vera. JAK1 and JAK2 mediate signaling of cytokines and growth factors important for hematopoiesis and immune function. Prominent side effects of Jakafi are thrombocytopenia and anemia.
GVHD is a common complication following allogenic hematopoietic stem cell transplant (HSCT). It occurs when immune cells transplanted from a non-identical donor (graft) recognize the transplant recipient (host) as foreign, initiating an immune response. Acute GVHD typically occurs within the first 100 days and mainly affects the skin, gastrointestinal system, and liver. Chronic GVHD affects a wider variety of systems and is less well understood. Steroids are the mainstay of treatment but are only effective for about 50% of patients.

Jakafi (ruxolitinib) will be considered for coverage when the following criteria are met:

Acute Graft-Versus-Host Disease (aGVHD)

For **initial** authorization:
1. Member is at least 12 years of age; AND
2. Medication must be prescribed by or in consultation with a transplant or hematology/oncology specialist; AND
3. Member has a documented diagnosis of grade II-IV acute graft-versus host disease following allogeneic hematopoietic cell transplantation (HCT); AND
4. Member is refractory to treatment with glucocorticoid (such as methylprednisolone 2mg/kg/day), defined as progression by day 3-5, non-response by day 7, or inability to taper.
5. **Dosage allowed/Quantity limit**: Starting dose is 5 mg orally twice daily; consider increasing to 10 mg twice daily. (60 tablets per 30 days).

If all the above requirements are met, the medication will be approved for 30 days.

For **reauthorization**:
1. Member is being monitored for side effects (e.g., cytopenias) and has not experienced any life-threatening adverse events; AND
2. Chart notes must demonstrate improved signs and symptoms of disease.

If all the above requirements are met, the medication will be approved for an additional 6 months.

Chronic Graft-Versus-Host Disease (cGVHD)

For **initial** authorization:
1. Member is at least 12 years of age; AND
2. Medication must be prescribed by or in consultation with a transplant or hematology/oncology specialist; AND

3. Member has a documented diagnosis of moderate to severe cGVHD; AND
4. Member's condition is steroid refractory or dependent (with or without a calcineurin inhibitor): Lack of response or disease progression after at least 1 week (e.g., on prednisone 1mg/kg/day), persistence without improvement after at least 4 weeks, or at least 2 failed taper attempts.
5. **Dosage allowed/Quantity limit:** 10 mg twice daily. (60 tablets per 30 days).

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show improvement of signs and symptoms of disease in at least 1 organ/site, without progression in any other organ/site.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Myelofibrosis

Any request for cancer must be submitted through NantHealth/Eviti portal.

Polycythemia Vera

Any request for cancer must be submitted through NantHealth/Eviti portal.

CareSource considers Jakafi (ruxolitinib) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
06/08/2020	New policy for Jakafi for acute GVHD.
09/30/2021	Transferred to new template. New section added for chronic GVHD. Reviewed aGVHD section: Changed "progression by day 3" to "progression by day 3-5."

References:

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3. Zeiser R, Bubnoff NV, Butler J, et al. Ruxolitinib for Glucocorticoid-Refractory Acute Graft-versus-Host Disease. *New England Journal of Medicine*. 2020;382(19):1800-1810. doi:10.1056/nejmoa1917635
4. Zeiser R, Burchert A, Lengerke C, et al. Ruxolitinib in corticosteroid-refractory graft-versus-host disease after allogeneic stem cell transplantation: a multicenter survey. *Leukemia*. 2015;29(10):2062-2068. doi:10.1038/leu.2015.212
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6. Zeiser R, Burchert A, Lengerke C, et al. Long-Term Follow-up of Patients with Corticosteroid-Refractory Graft-Versus-Host Disease Treated with Ruxolitinib. *Blood*. 2016;128(22):4561-4561. doi:10.1182/blood.v128.22.4561.4561
7. Zeiser R, Polverelli N, Ram R, et al. Ruxolitinib for Glucocorticoid-Refractory Chronic Graft-versus-Host Disease. *N Engl J Med*. 2021;385(3):228-238. doi:10.1056/NEJMoa2033122
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10. Penack O, Marchetti M, Ruutu T, et al. Prophylaxis and management of graft versus host disease after stem-cell transplantation for haematological malignancies: updated consensus recommendations of the European Society for Blood and Marrow Transplantation. *Lancet Haematol*. 2020;7(2):e157-e167. doi:10.1016/S2352-3026(19)30256-X

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