COMMON GROUND
HEALTHCARE COOPERATIVE

PHARMACY POLICY STATEMENT
Common Ground Healthcare Cooperative (CGHC)

DRUG NAME	**Jakafi (ruxolitinib)**
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Jakafi, approved by the FDA in 2011, is a janus kinase inhibitor (JAK1 and JAK2) 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 allogeneic 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 stem cell transplantation (HSCT); AND
4. Member is refractory to or dependent on steroid (progression within 3-5 days of prednisone 2mg/kg/day or greater, non-response within 5-7 days, incomplete response after more than 28 days, or inability to taper).
5. **Dosage allowed/Quantity limit**: Starting dose is 5 mg orally twice daily; may consider increasing to 10 mg twice daily.
   QL: 60 tablets per 30 days

If all the above requirements are met, the medication will be approved for 2 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 6 months.

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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 cGVHD following allogeneic hematopoietic stem cell transplantation (HSCT); AND
4. Member's condition is steroid refractory or dependent (progression while on prednisone 1 mg/kg/day or greater after at 1-2 weeks, or at least 2 unsuccessful taper attempts separated by at least 8 weeks).
5. **Dosage allowed/Quantity limit:** 10 mg twice daily.
   QL: 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, 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."
03/11/2024	Updated references. Updated definitions of steroid refractoriness and dependence (NCCN). aGVHD: Extended initial auth duration from 1 mo to 2 mo. Removed side effect monitoring from reauth, changed response definition to match cGVHD (and NCCN). cGVHD: Added "following allogeneic hematopoietic stem cell transplantation (HSCT)." Removed "moderate to severe."

References:

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3. 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
4. Jagasia M, Perales M-A, Schroeder MA, et al. Ruxolitinib for the treatment of steroid-refractory acute GVHD (REACH1): a multicenter, open-label phase 2 trial. *Blood*. 2020;135(20):1739-1749. doi:10.1182/blood.2020004823
5. 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
6. 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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8. National Comprehensive Cancer Network. Hematopoietic Cell Transplantation (HCT). Version 3.2023. https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf. Accessed March 8, 2024.
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