AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Jakafi	Page:	1 of 5
Effective Date:	6/9/2025	Last Review Date:	5/19/2025
Applies to:	☐Florida Kids ☒Michigan	☒New Jersey ☒Pennsylvania Kids	☒Maryland ☒Virginia

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Jakafi under the patient's prescription drug benefit.

Description:

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- Jakafi is indicated for treatment of intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF in adults.
- Jakafi is indicated for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea.
- Jakafi is indicated for treatment of steroid-refractory acute graft-versus-host disease (aGVHD) in adult and pediatric patients 12 years and older.
- Jakafi is indicated for treatment of chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

Compendial Uses

- Symptomatic lower risk myelofibrosis
- Myelofibrosis-associated anemia
- Accelerated/blast phase myeloproliferative neoplasms
- Polycythemia vera in patients with inadequate response or loss of response to interferon therapy
- Polycythemia vera in patients with high-risk disease
- Philadelphia chromosome (Ph-like) B-cell Acute Lymphoblastic Leukemia (ALL)/Lymphoblastic lymphoma (LL)
- Chronic myelomonocytic leukemia (CMML)-2
- T-cell lymphomas - T-cell large granular lymphocytic leukemia and T-cell prolymphocytic leukemia
- Myelodysplastic/Myeloproliferative Neoplasms (MDS/MPN) with neutrophilia
- Essential Thrombocythemia
- Myeloid/lymphoid neoplasms with eosinophilia and JAK2 rearrangement in blast phase or chronic phase
- CAR T-cell-related toxicities - Cytokine release syndrome (CRS)
- Immune checkpoint inhibitor-related toxicities
  - Concomitant myositis and myocarditis
  - Hemophagocytic lymphohistiocytosis-like syndrome

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Jakafi

Policy/Guideline:

Documentation:
Submission of the following information is necessary to initiate the prior authorization review:

- For Ph-like B-cell acute lymphoblastic leukemia/lymphoblastic lymphoma (LL), medical record documentation confirming either a cytokine receptor-like factor 2 (CRLF2) mutation or a mutation associated with activation of the Janus kinase/signal transducers and activators of transcription (JAK/STAT) pathway.
- For myelodysplastic/myeloproliferative neoplasms (MDS/MPN) with neutrophilia: Testing or analysis confirming JAK2 mutation or CSF3R mutation
- For myeloid and/or lymphoid neoplasms with eosinophilia: Testing or analysis confirming JAK2 rearrangement

Criteria for Initial Approval:

Myelofibrosis
Authorization of 12 months may be granted for the treatment of myelofibrosis.

Accelerated/Blast Phase Myeloproliferative Neoplasms
Authorization of 12 months may be granted for the treatment of symptomatic accelerated phase or blast phase myeloproliferative neoplasms when used as a single agent or in combination with azacitidine or decitabine.

Polycythemia Vera
Authorization of 12 months may be granted for the treatment of polycythemia vera when ANY of the following criteria are met:

- Member has had an inadequate response, loss of response or intolerance to cytoreductive treatment (e.g., hydroxyurea, peginterferon alfa-2a)
- Member has high risk disease

Acute Graft-versus-Host Disease (aGVHD) or Chronic Graft-versus-Host Disease (cGVHD)
Authorization of 12 months may be granted for the treatment of graft-vs-host disease when used in combination with systemic corticosteroids and ANY of the following criteria are met:

- Member has steroid-refractory acute GVHD (e.g., progressed within 3 days or did not improve within 7 consecutive days of treatment with prednisone 2 mg/kg/day or equivalent) or
- Member has chronic GVHD and has failed at least one prior line of systemic therapy

Acute Lymphoblastic Leukemia (ALL)/Lymphoblastic Lymphoma (LL)
Authorization of 12 months may be granted for the treatment of Ph-like B-cell acute lymphoblastic leukemia/lymphoblastic lymphoma for members with EITHER a cytokine receptor-like factor 2 (CRLF2) mutation or a mutation associated with activation of the Janus kinase/signal transducers and activators of transcription (JAK/STAT) pathway.

Chronic Myelomonocytic Leukemia (CMML)-2
Authorization of 12 months may be granted for the treatment of symptomatic chronic myelomonocytic leukemia (CMML)-2 in combination with a hypomethylating agent (e.g., azacitidine, decitabine).

T-Cell Large Granular Lymphocytic Leukemia or T-Cell Prolymphocytic Leukemia
Authorization of 12 months may be granted for the subsequent treatment of T-cell large granular lymphocytic leukemia or symptomatic T-cell prolymphocytic leukemia, as a single agent.

Myelodysplastic/Myeloproliferative Neoplasms (MDS/MPN) with Neutrophilia
Authorization of 12 months may be granted for the treatment of MDS/MPN with neutrophilia when ALL the following are met:

- Requested medication will be used as a single agent or in combination with a hypomethylating agent, AND
- Member is JAK2 mutation or CSF3R mutation positive.

Essential Thrombocythemia
Authorization of 12 months may be granted for the treatment of essential thrombocythemia in members who have had an inadequate response or loss of response to hydroxyurea, peginterferon alfa-2a, or anagrelide.

Myeloid/Lymphoid Neoplasms with Eosinophilia
Authorization of 12 months may be granted for the treatment of myeloid and/or lymphoid neoplasms with eosinophilia and JAK2 rearrangement in the chronic phase or blast phase.

Cytokine Release Syndrome
Authorization of 1 month may be granted for treatment of chimeric antigen receptor (CAR) T-cell-induced cytokine release syndrome that is refractory to high-dose corticosteroids and anti-IL-6 therapy.

Immune Checkpoint Inhibitor-Related Toxicities
Authorization of 1 month may be granted for treatment of immune checkpoint inhibitor-related concomitant myositis and myocarditis when requested agent is used in combination with abatacept.

Authorization of 1 month may be granted for treatment of hemophagocytic lymphohistiocytosis-like syndrome if member has not responded to five days of corticosteroids.

Continuation of Therapy:

Myelofibrosis, Accelerated/Blast Phase Myeloproliferative Neoplasms, Polycythemia Vera, Acute GVHD, Chronic GVHD, and Essential Thrombocythemia
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization who have improvement in symptoms and no unacceptable toxicity.

Acute Lymphoblastic Leukemia (ALL)/Lymphoblastic Lymphoma (LL), Myelodysplastic/Myeloproliferative Neoplasms (MDS/MPN) with Neutrophilia, Chronic Myelomonocytic Leukemia (CMML)-2, T-Cell Large Granular Lymphocytic Leukemia, and Myeloid/Lymphoid Neoplasms with Eosinophilia
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Cytokine Release Syndrome and Immune Checkpoint Inhibitor-Related Toxicities
All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria section.

Approval Duration and Quantity Restrictions:

Initial Approval:
Cytokine Release Syndrome: 1 month.
Immune Checkpoint Inhibitor-Related Toxicities: 1 month.
All other indications: 12 months.

Renewal Approval: 12 months.

Quantity Level Limit: 60 tablets per 30 days

References:

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4. 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
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8. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation (HCT). Available at: http://www.nccn.org. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf. Accessed January 28, 2025.