Reference number
1999-A

SPECIALTY GUIDELINE MANAGEMENT

JAKAFI (ruxolitinib)

POLICY

I. INDICATIONS

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.

A. FDA-Approved Indications
1. Jakafi is indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis.
2. Jakafi is indicated for treatment of patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea.

B. Compendial Uses
1. Symptomatic low-risk or intermediate-risk 1 myelofibrosis
2. Accelerated phase or blast phase myelofibrosis
3. Polycythemia vera in patients with inadequate response or loss of response to interferon therapy
4. Steroid-refractory acute or chronic graft versus host-disease (GVHD)
5. B-cell Acute Lymphoblastic (Lymphocytic) Leukemia (ALL)

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

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

B. Polycythemia Vera
Authorization of 12 months may be granted for the treatment of polycythemia vera to members who have had an inadequate response or intolerance to hydroxyurea or interferon therapy (ie, interferon alfa-2b, peginterferon alfa-2a, or peginterferon alfa-2b).

C. Steroid-refractory acute or chronic graft versus host-disease (GVHD)
Authorization of 12 months may be granted for the treatment of steroid-refractory acute or chronic graft versus host-disease (GVHD).

D. B-cell Acute Lymphoblastic (Lymphocytic) Leukemia (ALL)
Authorization of 12 months may be granted for the treatment of B-cell Acute Lymphoblastic (Lymphocytic) Leukemia for members with either a cytokine receptor-like factor 2 (CRLF2) mutation or a Janus kinase (JAK) mutation.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

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4. Ruxolitinib. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed August 24, 2018.
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8. Raetz Elizabeth, Loh Mignon. A Phase 2 Study of the JAK1/JAK2 Inhibitor Ruxolitinib with Chemotherapy in Children with De Novo High-Risk CRLF2-Rearranged and/or JAK Pathway-Mutant Acute Lymphoblastic Leukemia. *American Society of Hematology.* 2016: 13(3).
9. Ding YY, Stern JW, Jubelirer TF, et al. Clinical efficacy of Ruxolitinib and chemotherapy in a child with Philadelphia chromosome-like acute lymphoblastic leukemia with GOLGAS-JAK2 fusion and induction failure. *Haematologica.* 2018 Sep;103(9):e427-e431. doi: 10.3324/haematol.2018.192088. Epub 2018 May 17