SPECIALTY GUIDELINE MANAGEMENT

SPRYCEL (dasatinib)

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. Treatment of newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase
2. Treatment of adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib
3. Treatment of adults with Ph+ acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy
4. Treatment of pediatric patients with Ph+ CML in chronic phase

B. Compendial Uses
1. Treatment of patients with advanced phase CML (accelerated phase or blast phase)
2. Follow-up therapy for CML patients after hematopoietic stem cell transplant (HSCT)
3. Follow-up therapy for CML patients resistant or intolerant to primary treatment with another tyrosine kinase inhibitor (TKI)
4. Ph+ ALL as a single agent or in combination with chemotherapy or corticosteroids
5. Gastrointestinal stromal tumor (GIST) in patients with PDGFRA D842V mutation and disease progression on imatinib, sunitinib, or regorafenib

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

II. CRITERIA FOR INITIAL APPROVAL

A. Chronic Myelogenous Leukemia, Chronic Phase (CP-CML)
Authorization of 12 months may be granted for members initiating Sprycel for the treatment of CP-CML when all of the following criteria are met:
1. Diagnosis of CML was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing.
2. Member meets ANY of the following criteria:
   a. Member is less than or equal to 21 years of age.
   b. Member has a high or intermediate risk score according to the Sokal or Hasford scoring methodology.
   c. Member has a low risk score according to the Sokal or Hasford scoring methodology AND meets EITHER of the following:
      i. Member has experienced resistance to prior therapy with imatinib or an alternate TKI AND results of mutational testing are negative for T315I mutation.
      ii. Member has experienced toxicity or intolerance to prior therapy with imatinib or an alternate TKI.

B. Chronic Myelogenous Leukemia, Accelerated Phase (AP-CML) or Blast Phase (BP-CML)
Authorization of 12 months may be granted for members initiating Sprycel for the treatment of AP-CML or BP-CML when diagnosis was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing.

C. CML, Post-Hematopoietic Stem Cell Transplant (HSCT)
Authorization of 12 months may be granted for members who are initiating treatment with Sprycel and have received a HSCT for CML when diagnosis was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing.

D. Ph+ Acute Lymphoblastic Leukemia (ALL)
Authorization of 12 months may be granted for members who are prescribed Sprycel for the treatment of ALL when diagnosis was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing.

E. Gastrointestinal stromal tumor (GIST)
Authorization of 12 months may be granted for members who are prescribed Sprycel for the treatment of GIST and have experienced disease progression on imatinib, sunitinib, or regorafenib.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL diagnosis-specific authorization criteria below:

A. Chronic Myelogenous Leukemia (CML)
Authorization of up to 12 months may be granted for members continuing treatment with Sprycel for CML when ALL of the following criteria are met:
1. Diagnosis of CML was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing.
2. Member meets ANY of the following criteria:
    a. Authorization of up to 12 months for members with chronic phase CML if receiving benefit from Sprycel therapy (i.e., achieved or maintained a cytogenic or molecular response to therapy).
    b. Authorization of 12 months for members with accelerated or blast phase CML.
    c. Authorization of 12 months for members who have received a HSCT for CML (any phase).

B. Ph+ Acute Lymphoblastic Leukemia (ALL)
All members (including new members) requesting authorization for continuation of Sprycel therapy for Ph+ ALL must meet ALL initial authorization criteria.

C. GIST
All members (including new members) requesting authorization for continuation of Sprycel therapy for GIST must meet ALL initial authorization criteria.

IV. REFERENCES

1. Sprycel [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; November 2017.
2. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 6, 2017.
3. The NCCN Clinical Practice Guidelines in Oncology® Chronic Myelogenous Leukemia (Version 2.2017). © 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 5, 2017.
4. The NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 2.2016). © 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 3, 2017.