Reference number
1782-A

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

B. Compendial Uses
1. Primary treatment of advanced phase CML (accelerated phase or blast phase)
2. Follow-up therapy for CML patients after hematopoietic stem cell transplant (HSCT)
3. Ph+ ALL as a single agent or in combination with chemotherapy or corticosteroids
4. Induction therapy for Ph+ ALL in adults aged ≥ 65 years
5. Metastatic chondrosarcoma
6. Recurrent chordoma
7. 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. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:
A. Prior to initiation of therapy for treatment of CML or Ph+ ALL: results of cytogenetic and/or molecular testing for detection of the Ph chromosome or the BCR-ABL gene
B. For members requesting initiation of Sprycel therapy for treatment of CML or ALL after experiencing resistance to prior tyrosine kinase inhibitor (TKI) therapy: results of T315I mutation testing

III. CRITERIA FOR INITIAL APPROVAL

A. Chronic Myeloid Leukemia (CML)
Authorization of 6 months may be granted for treatment of CML that has been confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing when any of the following criteria are met:
1. Member has not received prior therapy with a TKI (e.g., bosutinib, imatinib, nilotinib, ponatinib)
2. Member experienced toxicity or intolerance to prior therapy with a TKI

3. Member experienced resistance to prior therapy with a TKI and results of mutational testing are negative for T315I mutation
4. Member has received HSCT for CML

B. Ph+ Acute Lymphoblastic Leukemia (ALL)/Lymphoblastic Lymphoma (LL)
Authorization of 12 months may be granted for treatment of Ph+ ALL or LL that has been confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing when any of the following criteria are met:
1. Member has not received prior therapy with a TKI (e.g., bosutinib, imatinib, nilotinib, ponatinib)
2. Member experienced toxicity or intolerance to prior therapy with a TKI
3. Member experienced resistance to prior therapy with a TKI and results of mutational testing are negative for T315I mutation

C. Gastrointestinal Stromal Tumor (GIST)
Authorization of 12 months may be granted for treatment of GIST in members with PDGFRA D842V mutation who have experienced disease progression on imatinib, sunitinib, or regorafenib.

D. Bone Cancer
Authorization of 12 months may be granted for treatment of metastatic chondrosarcoma or recurrent chordoma.

IV. CONTINUATION OF THERAPY

A. CML
Authorization of 12 months may be granted for continued treatment of CML that has been confirmed by detection of Ph chromosome or BCR-ABL gene by cytogenetic and/ or molecular testing when any of the following criteria are met:
1. BCR-ABL1 ≤ 10% for members who have been receiving Sprycel for ≤ 12 months
2. No evidence of disease progression for members who have been receiving Sprycel for > 12 months
3. Member has received HSCT

B. Ph+ ALL/LL
Authorization of 12 months may be granted for continued treatment of Ph+ ALL or LL that has been confirmed by detection of Ph chromosome or BCR-ABL gene by cytogenetic and/ or molecular testing in members who have not experienced disease progression or an unacceptable toxicity.

C. GIST and Bone Cancer
Authorization of 12 months may be granted for continued treatment of GIST, metastatic chondrosarcoma, or recurrent chordoma in members who have not experienced disease progression or an unacceptable toxicity.

V. REFERENCES

1. Sprycel [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; December 2018.
2. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 18, 2019.
3. NCCN Clinical Practice Guidelines in Oncology® Chronic Myelogenous Leukemia (Version 1.2019). © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 16, 2019.
4. NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 1.2019).

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5. NCCN Clinical Practice Guidelines in Oncology® Soft Tissue Sarcoma (Version 2.2019). © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 18, 2019.
6. NCCN Clinical Practice Guidelines in Oncology® Bone Cancer (Version 2.2019). © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 18, 2019.