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 1 year of age and older with Ph+ CML in chronic phase
5. Pediatric patients 1 year of age and older 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+ acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LL)
4. Induction or consolidation therapy for pediatric Ph+ B-ALL/LL
5. Relapsed or refractory pediatric Ph+ B-ALL/LL
6. Relapsed or refractory pediatric T-cell ALL/LL with ABL-class translocation
7. Induction or consolidation therapy for pediatric Ph-like B-ALL/LL with ABL-class translocation
8. Consolidation therapy for pediatric Ph-like B-ALL/LL and CRLF2- with ABL-class translocation
9. Metastatic chondrosarcoma
10. Recurrent chordoma
11. Unresectable, recurrent, or metastatic gastrointestinal stromal tumor (GIST)
12. Myeloid/lymphoid neoplasms with eosinophilia and ABL1 rearrangement in chronic phase
13. Lymphoid, myeloid or mixed lineage neoplasms with eosinophilia and ABL1 rearrangement in blast phase

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

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:
A. For treatment of CML or Ph+ ALL/LL: results of cytogenetic and/or molecular testing for detection of the Ph chromosome or the BCR-ABL gene
B. For treatment of Ph-like B-ALL/LL: results of cytogenetic and/or molecular testing confirming ABL-class kinase fusion
C. For treatment of T-cell ALL/LL: results of cytogenetic and/or molecular testing confirming ABL-class translocation

D. For members requesting initiation of therapy with the requested medication for treatment of CML or ALL/LL after experiencing resistance to prior tyrosine kinase inhibitor (TKI) therapy: results of BCR-ABL1 mutation testing for T315I/A, F317L/V/I/C, and V299L mutations
E. For treatment of GIST: PDGFRA D842V mutation testing (where applicable)
F. For members requesting initiation of therapy with the requested medication for treatment of myeloid and/or lymphoid neoplasms with eosinophilia: results of testing or analysis confirming ABL1 rearrangement

III. CRITERIA FOR INITIAL APPROVAL

A. Chronic Myeloid Leukemia (CML)

Authorization of 7 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 BCR-ABL1 mutational testing are negative for all of the following mutations: T315I/A, F317L/V/I/C, and V299L
4. Member has received HSCT for CML and results of BCR-ABL1 mutational testing are negative for all of the following mutations: T315I/A, F317L/V/I/C, and V299L

B. Acute Lymphoblastic Leukemia (ALL)/Lymphoblastic Lymphoma (LL)

Authorization of 12 months may be granted for treatment of ALL or LL when both of the following criteria are met:

1. The member has any of the following:
   i. Ph+ ALL or LL that has been confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing
   ii. Ph-like B-ALL or LL with ABL-class kinase fusion that has been confirmed by cytogenetic and/or molecular testing
   iii. T-cell ALL or LL with ABL-class translocation that has been confirmed by cytogenetic and/or molecular testing and the disease is relapsed or refractory
2. The member meets any of the following:
   i. Member has not received prior therapy with a TKI (e.g., bosutinib, imatinib, nilotinib, ponatinib)
   ii. Member experienced toxicity or intolerance to prior therapy with a TKI
   iii. Member experienced resistance to prior therapy with a TKI and results of BCR-ABL1 mutational testing are negative for all of the following mutations: T315I/A, F317L/V/I/C, and V299L

C. Gastrointestinal Stromal Tumor (GIST)

Authorization of 12 months may be granted for treatment of unresectable, recurrent, or metastatic GIST as a single agent when either of the following criteria are met:

1. The disease has progressed on imatinib in members with PDGFRA D842V mutation
2. The member has failed at least four FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib)

D. Bone Cancer

Authorization of 12 months may be granted for treatment of metastatic chondrosarcoma or recurrent chordoma when the requested medication is used as a single agent.

E. Myeloid/Lymphoid Neoplasms with Eosinophilia

Authorization of 12 months may be granted for treatment of myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase.

IV. CONTINUATION OF THERAPY

A. CML

Authorization 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 either of the following criteria is met:

1. Authorization of 12 months may be granted when any of the following criteria is met:
   i. BCR-ABL1 is less than or equal to 10% and there is no evidence of disease progression or unacceptable toxicity while on the current regimen for members who have been receiving the requested medication for 6 months or greater
   ii. Member has received HSCT when there is no evidence of unacceptable toxicity or disease progression while on the current regimen
2. Authorization of up to 7 months may be granted when the member has completed less than 6 months of therapy with the requested medication.

B. Acute Lymphoblastic Leukemia or Lymphoblastic Lymphoma (ALL/LL)

Authorization of 12 months may be granted for continued treatment of ALL or LL when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and any of the following criteria is met:

1. The member has Ph+ ALL or LL that has been confirmed by detection of Ph chromosome or BCR-ABL gene by cytogenetic and/ or molecular testing.
2. The member has Ph-like B-ALL or LL with ABL-class kinase fusion that has been confirmed by cytogenetic and/or molecular testing.
3. The member has T-cell ALL or LL with ABL-class translocation that has been confirmed by cytogenetic testing and/or molecular testing.

C. GIST, Bone Cancer, and Myeloid/Lymphoid Neoplasms with Eosinophilia

Authorization of 12 months may be granted for continued treatment of GIST, metastatic chondrosarcoma, recurrent chordoma, or myeloid/lymphoid neoplasms with eosinophilia when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Sprycel [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; March 2021.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 31, 2021.
3. NCCN Clinical Practice Guidelines in Oncology® Chronic Myeloid Leukemia (Version 3.2021). © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 1, 2021.
4. NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 2.2020). © 2020 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 1, 2021.