Reference number
1782-A

SPECIALTY GUIDELINE MANAGEMENT

SPRYCEL (dasatinib)
PHYRAGO (dasatinib)
dasatinib (generic)

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. Phyrago and Sprycel are indicated for newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase
2. Phyrago and Sprycel are indicated for adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib
3. Phyrago and Sprycel are indicated for adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy
4. Sprycel is indicated for pediatric patients 1 year of age and older with Ph+ CML in chronic phase
5. Sprycel is indicated for 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. Additional therapy for CML patients after hematopoietic stem cell transplant (HSCT)
3. Ph+ B-cell acute lymphoblastic leukemia or lymphoblastic lymphoma (Ph+ B-ALL/LL)
4. Maintenance therapy for Ph+ B-ALL/LL patients after HSCT
5. Relapsed or refractory Ph+ B-ALL/LL
6. Relapsed or refractory T-cell ALL/LL with ABL-class translocation
7. Induction or consolidation therapy for Ph-like B-ALL/LL with ABL-class kinase fusion
8. Consolidation therapy for Ph-like B-ALL/LL and CRLF2- with ABL-class kinase fusion
9. Metastatic and widespread chondrosarcoma
10. Recurrent chordoma
11. Gastrointestinal stromal tumor (GIST)
12. Myeloid/lymphoid neoplasms with eosinophilia and ABL1 rearrangement in chronic or blast phase
13. Cutaneous Melanoma

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

II. 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 exon 18 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
G. For treatment of melanoma: results of molecular testing or analysis confirming c-KIT activating mutations

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: 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: T315I/A, F317L/V/I/C, and V299L

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

1. Authorization of 12 months may be granted for treatment of ALL/LL when both of the following criteria are met:
   i. The member has any of the following:
      a. Ph+ ALL/LL that has been confirmed by detection of the Ph chromosome or BCR::ABL gene by cytogenetic and/or molecular testing
      b. Ph-like B-ALL/LL with ABL-class kinase fusion that has been confirmed by cytogenetic and/or molecular testing
      c. T-cell ALL/LL with ABL-class translocation that has been confirmed by cytogenetic and/or molecular testing and the disease is relapsed or refractory
   ii. The member meets any of the following:
      a. Member has not received prior therapy with a TKI (e.g., bosutinib, imatinib, nilotinib, ponatinib)
      b. Member experienced toxicity or intolerance to prior therapy with a TKI
      c. Member experienced resistance to prior therapy with a TKI and results of BCR::ABL1 mutational testing are negative for all of the following: T315I/A, F317L/V/I/C, and V299L

2. Authorization of 12 months may be granted for members who have received HSCT for Ph+ ALL/LL and results of BCR::ABL1 mutation testing are negative for all of the following: T315I/A, F317L/V/I/C, and V299L

C. Gastrointestinal Stromal Tumor (GIST)

Authorization of 12 months may be granted for treatment of GIST when all of the following criteria are met:

1. Member has residual, unresectable, recurrent/progressive, or metastatic/tumor rupture disease
2. The disease harbors a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation
3. Member has received prior therapy with avapritinib
4. The requested medication will be used as a single agent

D. Bone Cancer
Authorization of 12 months may be granted for treatment of widespread 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.

F. Cutaneous Melanoma
Authorization of 12 months may be granted for treatment of cutaneous melanoma when all of the following criteria are met:
1. The disease is metastatic or unresectable
2. The tumor has c-KIT activating mutations
3. The requested medication will be used as subsequent therapy
4. Member has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy
5. The requested medication will be used as a single agent

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 and 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/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. Member has Ph+ ALL/LL that has been confirmed by detection of Ph chromosome or BCR::ABL gene by cytogenetic and/ or molecular testing.
2. Member has Ph-like B-ALL/LL with ABL-class kinase fusion that has been confirmed by cytogenetic and/or molecular testing.
3. Member has T-cell ALL/LL with ABL-class translocation that has been confirmed by cytogenetic testing and/or molecular testing.
4. Member has received HSCT for ALL/LL

C. GIST, Bone Cancer, Myeloid/Lymphoid Neoplasms with Eosinophilia, or Cutaneous Melanoma
Authorization of 12 months may be granted for continued treatment of GIST, chondrosarcoma, chordoma, myeloid/lymphoid neoplasms with eosinophilia, or cutaneous melanoma 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; February 2023.
2. Phyrago [package insert]. New Brighton, MN: Nanocopoeia, LLC; December 2023.
3. dasatinib [package insert]. Weston, FL: Apotex Corp.; September 2024.
4. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 26, 2024.
5. NCCN Clinical Practice Guidelines in Oncology® Chronic Myeloid Leukemia (Version 2.2024). © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 15, 2024.
6. NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 4.2023). © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 15, 2024.
7. NCCN Clinical Practice Guidelines in Oncology® Gastrointestinal Stromal Tumors (Version 1.2024). © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 15, 2024.