CVS Caremark®

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| Reference number(s) |
| 1782-A |

# Specialty Guideline Management dasatinib products

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Sprycel | dasatinib |
| Phyrago | dasatinib |

## 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.

### FDA-approved Indications

* Phyrago and Sprycel are indicated for newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase
* 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
* Phyrago and Sprycel are indicated for adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy
* Sprycel is indicated for pediatric patients 1 year of age and older with Ph+ CML in chronic phase
* Sprycel is indicated for pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy

### Compendial Uses

* Primary treatment of advanced phase CML (accelerated phase or blast phase)
* Additional therapy for CML patients after hematopoietic stem cell transplant (HSCT)
* Ph+ B-cell acute lymphoblastic leukemia or lymphoblastic lymphoma (Ph+ B-ALL/LL)
* Maintenance therapy for Ph+ B-ALL/LL patients after HSCT
* Relapsed or refractory Ph+ B-ALL/LL
* Relapsed or refractory T-cell ALL/LL with ABL-class translocation
* Induction or consolidation therapy for Ph-like B-ALL/LL with ABL-class kinase fusion
* Consolidation therapy for Ph-like B-ALL/LL and CRLF2- with ABL-class kinase fusion
* Metastatic and widespread chondrosarcoma
* Recurrent chordoma
* Gastrointestinal stromal tumor (GIST)
* Myeloid/lymphoid neoplasms with eosinophilia and ABL1 rearrangement in chronic or blast phase
* Cutaneous Melanoma

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

## Documentation

The following information is necessary to initiate the prior authorization review:

* 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
* For treatment of Ph-like B-ALL/LL: results of cytogenetic and/or molecular testing confirming ABL-class kinase fusion
* For treatment of T-cell ALL/LL: results of cytogenetic and/or molecular testing confirming ABL-class translocation
* 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
* For treatment of GIST: PDGFRA exon 18 mutation testing (where applicable)
* 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
* For treatment of melanoma: results of molecular testing or analysis confirming c-KIT activating mutations

## Coverage Criteria

### 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:

* Member has not received prior therapy with a TKI (e.g., bosutinib, imatinib, nilotinib, ponatinib)
* Member experienced toxicity or intolerance to prior therapy with a TKI
* 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
* 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

### Acute Lymphoblastic Leukemia (ALL)/Lymphoblastic Lymphoma (LL)

* Authorization of 12 months may be granted for treatment of ALL/LL when both of the following criteria are met:
  + The member has any of the following:
    - Ph+ ALL/LL that has been confirmed by detection of the Ph chromosome or BCR::ABL gene by cytogenetic and/or molecular testing
    - Ph-like B-ALL/LL with ABL-class kinase fusion that has been confirmed by cytogenetic and/or molecular testing
    - 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
  + The member meets any of the following:
    - Member has not received prior therapy with a TKI (e.g., bosutinib, imatinib, nilotinib, ponatinib)
    - Member experienced toxicity or intolerance to prior therapy with a TKI
    - 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
* 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

### Gastrointestinal Stromal Tumor (GIST)

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

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

### 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.

### 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.

### Cutaneous Melanoma

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

* The disease is metastatic or unresectable
* The tumor has c-KIT activating mutations
* The requested medication will be used as subsequent therapy
* Member has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy
* The requested medication will be used as a single agent

## Continuation of Therapy

### 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:

* Authorization of 12 months may be granted when any of the following criteria is met:
  + 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
  + Member has received HSCT and there is no evidence of unacceptable toxicity or disease progression while on the current regimen
* Authorization of up to 7 months may be granted when the member has completed less than 6 months of therapy with the requested medication.

### 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:

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

### 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.

## 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. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 26, 2024.
4. 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.
5. NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 4.2023).

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1. NCCN Clinical Practice Guidelines in Oncology® Gastrointestinal Stromal Tumors (Version 1.2024).

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