

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Sprycel Prior Authorization Policy

- Sprycel® (dasatinib tablets – Bristol-Myers Squibb)

REVIEW DATE: 05/01/2024

OVERVIEW

Sprycel, a tyrosine kinase inhibitor (TKI), is indicated for the following uses:¹

Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia (ALL):

In adults with resistance or intolerance to prior therapy.

In newly diagnosed pediatric patients ≥ 1 year of age in combination with chemotherapy.

Ph+ chronic myeloid leukemia (CML):

Chronic phase in newly diagnosed adults.

Chronic phase, accelerated, or myeloid or lymphoid blast phase, in adults with resistance or intolerance to prior therapy including imatinib.

Chronic phase, in pediatric patients ≥ 1 year of age.

Guidelines

Sprycel is addressed in guidelines from National Comprehensive Cancer Network (NCCN):

ALL: NCCN guidelines for adults and adolescents (version 4.2023 – February 5, 2024) recommend Sprycel for Ph+ disease in many different clinical circumstances (e.g., induction, consolidation therapy, maintenance, or relapsed or refractory disease) [category 2A].² TKIs in combination with other agents (e.g., chemotherapy or corticosteroids) are recommended for induction therapy for Ph+ ALL. TKIs have also been incorporated into consolidation and maintenance therapy, as well as in the relapsed/refractory setting (category 2A). TKI options include: Bosulif® (bosutinib tablets), Sprycel, imatinib, Tasigna (nilotinib capsules), or Iclusig® (ponatinib tablets) [category 2A]. NCCN panel notes that not all TKIs have been directly studied within the context of each specific regimen and there are limited data for Bosulif in Ph+ ALL. Use of a specific TKI should account for anticipated/prior TKI intolerance and disease-related features. For adults and adolescents, Iclusig has activity against T315I mutations and/or in whom no other TKI is indicated (category 2A). NCCN guidelines for pediatric ALL (version 5.2024 – April 3, 2024) feature Sprycel prominently in a variety of clinical scenarios (mainly category 2A recommendations).³

Bone Cancer: NCCN guidelines (version 2.2024 – March 12, 2024) recommend Sprycel for patients with chondrosarcoma as “other recommended regimens” for a patient with metastatic and widespread disease (category 2A).⁴ Sprycel is also recommended for recurrent conventional or chondroid chordoma as “other recommended regimens” (category 2A).

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CML: NCCN guidelines (version 2.2024 – December 5, 2023) recommend Sprycel as a “preferred” primary treatment for newly diagnosed chronic phase Ph+ CML with a low-, intermediate-, or high-risk score (category 1).⁵ Sprycel is also recommended as an alternative TKI treatment (after primary treatment with imatinib, Bosulif® [bosutinib tablets], or Tasigna® [nilotinib capsules]) (category 2A). Sprycel is also recommended in a variety of other situations, including post-allogeneic hematopoietic stem cell transplant (category 2A).

Gastrointestinal Stromal Tumor: NCCN guidelines (version 1.2024 – March 8, 2024) recommend Sprycel as a second-line therapy as “other recommended regimens” for unresectable, progressive or metastatic disease in patients with platelet-derived growth factor receptor alpha [PDGFRA] exon 18 mutations that are insensitive to imatinib (including the PDGFRA D842V mutation) [category 2A].⁶

Melanoma: Cutaneous: NCCN guidelines (version 2.2024 – April 3, 2024) recommend Sprycel as “useful in certain circumstances” for metastatic or unresectable disease with an activating KIT mutation as second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy (category 2A).⁷

Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions: NCCN guidelines (version 1.2024 – December 21, 2023) list Sprycel as a “preferred” therapy for chronic phase or blast phase disease with an ABL1 rearrangement (category 2A).^{8,9} It is also recommended as treatment in combination with ALL- or acute myeloid leukemia-type induction chemotherapy followed by allogeneic hematopoietic stem cell transplantation (HCT) (if eligible) for lymphoid, myeloid or mixed lineage neoplasms with eosinophilia and ABL1 rearrangement in blast phase (category 2A).⁹

Policy Statement

Prior Authorization is recommended for prescription benefit coverage of Sprycel. All approvals are provided for the duration noted below.

Automation: None.

Recommended Authorization Criteria

Coverage of Sprycel is recommended in those who meet one of the following criteria:

FDA-Approved Indications

Acute Lymphoblastic Leukemia. Approve for 1 year if the patient has Philadelphia chromosome-positive acute lymphoblastic leukemia.

Chronic Myeloid Leukemia. Approve for 1 year if the patient has Philadelphia chromosome-positive chronic myeloid leukemia.

Other Uses with Supportive Evidence

Bone Cancer. Approve for 1 year if the patient meets BOTH of the following (A and B):

Patient is ≥ 18 years of age; AND

Patient has chondrosarcoma or chordoma.

Gastrointestinal Stromal Tumor. Approve for 1 year if the patient meets BOTH of the following (A and B):

Patient is ≥ 18 years of age; AND

Patient has tried imatinib or Ayvakit (avapritinib tablets).

Melanoma, Cutaneous. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

Patient is ≥ 18 years of age; AND

Patient has metastatic or unresectable disease; AND

Patient has an activating KIT mutation; AND

Patient has tried at least one systemic regimen.

Note: Examples of a systemic regimen include: Opdivo (nivolumab intravenous infusion) + Yervoy (ipilimumab intravenous infusion), Opdivo + Opdualag (nivolumab/relatlimab-rmbw intravenous infusion), Keytruda (pembrolizumab intravenous infusion), Opdivo, Tafinlar (dabrafenib capsules and oral tablets for suspension) + Mekinist (trametinib tablets), Zelboraf (vemurafenib tablets) + Cotellic (cobimetinib tablets), Braftovi (encorafenib capsules) + Mektovi (binimetinib tablets).

Myeloid/Lymphoid Neoplasms with Eosinophilia. Approve for 1 year if the patient meets BOTH of the following (A and B):

Patient is ≥ 18 years of age; AND

The tumor has an ABL1 rearrangement.

Conditions Not Recommended for Approval

Coverage of Sprycel is not recommended in the following situations:

Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

References

Sprycel® tablets [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; February 2023.

The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 4.2023 – February 5, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on April 29, 2024.

The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 5.2024 – April 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on April 29, 2024.

The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 2.2024 – March 12, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on April 29, 2024.

The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 2.2024 – December 5, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on April 29, 2024.

The NCCN Gastrointestinal Stromal Tumors Guidelines in Oncology (version 1.2024 – March 8, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on April 29, 2024.

The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 2.2024 – April 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on April 29, 2024.

The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on April 29, 2024.

The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Search term: dasatinib. Accessed on April 29, 2024.

