PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Sprycel Prior Authorization Policy
- Sprycel® (dasatinib tablets – Bristol-Myers Squibb)

REVIEW DATE: 05/04/2022; selected revision 06/22/2022

OVERVIEW

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

- **Acute lymphoblastic leukemia (ALL)** in:
  - Philadelphia chromosome positive (Ph+) adults with resistance or intolerance to prior therapy.
  - Ph+, newly diagnosed pediatric patients ≥ 1 year of age in combination with chemotherapy.
- **Chronic myeloid leukemia (CML)** in:
  - Ph+ with newly diagnosed adults, in chronic phase.
  - Ph+, chronic phase, accelerated, or myeloid or lymphoid blast phase, in adults with resistance or intolerance to prior therapy that included imatinib.
  - Ph+, chronic phase, in pediatric patients ≥ 1 year of age.

Guidelines

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

- **ALL:** The NCCN guidelines for ALL (version 1.2022 – April 4, 2022) [adults] recommend Sprycel as an option for patients with relapsed or refractory ALL (category 2A) and in many different clinical circumstances (e.g., induction therapy).[2] The NCCN guidelines for pediatric ALL (version 1.2022 – October 21, 2021) feature Sprycel prominently in a variety of clinical scenarios (mainly category 2A recommendations).[3]
- **Bone Cancer:** The NCCN guidelines on bone cancer (version 2.2022 – October 8, 2021) recommend Sprycel for patients with chondrosarcoma as an other recommended regimen for a patient with metastatic and widespread disease (category 2A).[4] Sprycel is also an other recommended regimen for chordoma (category 2A).
- **CML:** NCCN guidelines for CML (version 3.2022 – January 27, 2022) state that for patients with chronic phase CML with a low-risk score, the primary treatment recommended includes a first-generation TKI (imatinib [brand or generic] [category 1]), or a second-generation TKI (Bosulif® [bosutinib tablets], Sprycel [category 1], or Tasigna® [nilotinib capsules] {all category 1}).[5] For patients with chronic phase CML with an intermediate- or high-risk score, a second-generation TKI is preferred (Bosulif [category 1], Sprycel [category 1], or Tasigna [category 1]). A first-generation TKI (imatinib [brand or generic]) is an alternative (category 2A). Iclusig® (ponatanib tablets) is an option for patients with a T315I mutation and/or chronic phase CML with resistance or intolerance to at least two prior TKIs or for patients with accelerated-phase CML or blast-phase CML for whom no other TKI is indicated (category 2A). Scemblix® (asciminib tablets) is a treatment option for chronic phase CML in patients with the T315I mutation and/or chronic phase CML with resistance or intolerance to at least two prior TKIs (category 2A).
- **Gastrointestinal Stromal Tumor:** According to the NCCN guidelines (version 1.2022 – January 21, 2022), Sprycel is recommended as a preferred second-line therapy after treatment with imatinib (category 1) or Ayvakit® (avapritinib tablets) [category 2A] {both first-line therapies} 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).[6] Sprycel reintroduction may be considered for symptom palliation as supportive care.

- **Myeloid/Lymphoid Neoplasms with Eosinophilia:** The NCCN guidelines for myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes (version 1.2022 – April 14, 2022) note that Sprycel is a TKI with activity against *ABL1* rearrangements (category 2A) and it may have a role for use in patients with this condition.[7]

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

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

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

Other Uses with Supportive Evidence

3. **Chondrosarcoma or Chordoma.** Approve for 1 year if the patient is ≥ 18 years of age.

4. **Gastrointestinal Stromal Tumor.** Approve for 1 year if the patient meets the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried imatinib or Ayvakit (avapritinib tablets).

5. **Myeloid/Lymphoid Neoplasms with Eosinophilia.** Approve for 1 year if the patient meets the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) The tumor has an *ABL1* rearrangement.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Sprycel is not recommended in the following situations:

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

REFERENCES

1. Sprycel® tablets [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; June 2021.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 2.2022 – April 4, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 28, 2022.

3. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2022 – October 1, 2021). © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 28, 2022.
4. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – October 8, 2021). © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 28, 2022.
5. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 3.2022 – January 27, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 28, 2022.
6. The NCCN Gastrointestinal Stromal Tumors Guidelines in Oncology (version 1.2022 – January 21, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 28, 2022.
7. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 1.2022 – April 14, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 28, 2022.