VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 04/14/2021; selected revision 06/23/21

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 1.2021 – April 6, 2021) [adults] recommend Sprycel as an option for patients with relapsed or refractory ALL (category 2A) in many different clinical circumstances.[2] Imatinib and Sprycel are preferred for induction therapy. The NCCN guidelines for pediatric ALL (version 2.2021 – October 22, 2020) feature Sprycel prominently (category 2A) in a variety of clinical scenarios.[3]
- **Bone Cancer:** The NCCN guidelines on bone cancer (version 1.2021 – November 20, 2020) 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 3.2021 – January 13, 2021) 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).
- **Gastrointestinal Stromal Tumor:** According to the NCCN guidelines (version 1.2021 – October 30, 2020), Sprycel is recommended as useful in certain circumstances (for patients with platelet-derived growth factor receptor alpha *[PDGFRA]* D842V mutation) after failure on approved therapies (category 2A).[6] Imatinib is a preferred regimen for first-line therapy (category 1). Ayvakit® (avapritinib tablets) is also a preferred regimen (category 2A) for patients with *PDGFRA* exon 18 mutations, including the *PDGFRA* D842V mutation. Sutent® (sunitinib capsules) is a preferred regimen (category 1) for second-line therapy (progressive disease after imatinib). Stivarga® (regorafenib tablets) is a preferred regimen (category 1) for third-line therapy (progressive disease after imatinib and Sutent). Qinlock™ (ripretinib tablets) is a preferred regimen

(category 1) for fourth-line therapy (progressive disease after imatinib, Sutent, and Stivarga). Besides Sprycel other additional options after failure on approved therapies that are useful in certain circumstances include Tasigna, Ayvakit, Nexavar® (sorafenib tablets), Votrient® (pazopanib tablets), and everolimus plus TKIs (all category 2A).

- **Myeloid/Lymphoid Neoplasms with Eosinophilia:** The NCCN guidelines for myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes (version 3.2021 – August 21, 2020) 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 the following criteria:

FDA-Approved Indications

1. **Acute Lymphoblastic Leukemia.** Approve for 3 years if the patient has Philadelphia chromosome-positive acute lymphoblastic leukemia.

2. **Chronic Myeloid Leukemia.** Approve for 3 years if the patient has Philadelphia chromosome-positive chronic myeloid leukemia.

Other Uses with Supportive Evidence

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

4. **Gastrointestinal Stromal Tumor.** Approve for 3 years if the patient meets the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried each of the following (i, ii, iii, and iv):
      i. Imatinib or Ayvakit (avapritinib tablets); AND
      ii. Sutent (sunitinib capsules); AND
      iii. Stivarga (regorafinib tablets); AND
      iv. Qinlock (ripretinib tablets).

5. **Myeloid/Lymphoid Neoplasms with Eosinophilia.** Approve for 3 years 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; March 2021.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2021 – April 6, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 9, 2021.
3. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 2.2021 – October 22, 2020). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 9, 2021.
4. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 1.2021 – November 20, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 9, 2021.
5. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 3.2021 – January 13, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 9, 2021.
6. The NCCN Gastrointestinal Stromal Tumors Guidelines in Oncology (version 1.2021 – October 30, 2020). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on June 14, 2021.
7. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 3.2021 – August 21, 2020). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 1, 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Acute Lymphoblastic Leukemia:** The condition of approval was changed to move the notation that the disease is "Philadelphia chromosome-positive" to the criteria section. **Chronic Myeloid Leukemia:** The condition of approval was changed to move the notation that the disease is "Philadelphia chromosome-positive" to the criteria section. **Gastrointestinal Stromal Tumor:** The requirement that the patient has tried Gleevec (imatinib tablets), Sutent (sunitinib capsules), and Stivarga (regorafenib tablets) was removed. The requirements that the patient is ≥ 18 years of age and that the patient has tried at least three other medications were added. The examples of medications are provided in a Note. **Myeloid/Lymphoid Neoplasms with Eosinophilia:** This was added as a new condition of approval.	4/14/2021
Selected Revision	**Chondrosarcoma or Chordoma:** The requirement that the patient is ≥ 18 years of age was added. **Gastrointestinal Stromal Tumor:** Patient has tried at least three other medications was reworded to "Patient has tried each of the following: imatinib or Ayvakit; Sutent (sunitinib capsules); Stivarga (regorafinib tablets); AND Qinlock (ripretinib tablets). The note of examples of medications was removed.	06/23/2021