PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 05/31/2023

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

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 that included 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 1.2022 – April 4, 2022) 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 2.2023 – March 10, 2023) feature Sprycel prominently in a variety of clinical scenarios (mainly category 2A recommendations).[3]

- **Bone Cancer:** NCCN guidelines (version 3.2023 – April 4, 2023) 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 chordoma as "other recommended regimens" (category 2A).
- **CML:** NCCN guidelines (version 2.2023 – April 13, 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]) for BCR::ABL1 transcript levels (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 1.2023 – March 13, 2023) 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).[6]
- **Melanoma: Cutaneous**: NCCN guidelines (version 2.2023 – March 10, 2023) 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.[7]
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions:** NCCN guidelines (version 1.2023 –May 19, 2023) list Sprycel as a preferred therapy under "other recommended regimens" 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.

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

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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. **Bone Cancer.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has chondrosarcoma or chordoma.

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

5. **Melanoma, Cutaneous.** Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has metastatic or unresectable disease; AND
   C) Patient has an activating *KIT* mutation; AND
   D) 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) + Mekinist (trametinib tablets), Zelboraf (vemurafenib tablets) + Cotellic (cobimetinib tablets), Braftovi (encorafenib capsules) + Mektovi (binimetinib tablets).

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

CONDITIONS NOT COVERED

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

is(are) considered experimental, investigational or unproven for ANY other use(s).

REFERENCES

1. Sprycel® tablets [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; February 2023.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 2.2022 – April 4, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 10, 2023.
3. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 2.2023 – March 10, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 10, 2023.
4. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 3.2023 – April 4, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 10, 2023.
5. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 2.2023 – April 13, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 10, 2023.
6. The NCCN Gastrointestinal Stromal Tumors Guidelines in Oncology (version 1.2023 – March 13, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 10, 2023.
7. The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 2.2023 – March 10, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 10, 2023.
8. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Clinical Practice Guidelines in Oncology (version 1.2023 – May 19, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 10, 2023.
9. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Search term: dasatinib. Accessed on May 10, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Gastrointestinal Stromal Tumor:** Criteria changed from requiring that the patient has tried imatinib or Ayvakit (avapritinib tablets); Sutent (sunitinib capsules); Stivarga (regorafinib tablets); AND Qinlock (ripretinib tablets) to requiring only that the patient has tried imatinib or Ayvakit.	05/04/2022
Selected Revision	**Acute Lymphoblastic Leukemia:** The approval duration was changed from 3 years to 1 year. **Chronic Myeloid Leukemia:** The approval duration was changed from 3 years to 1 year. **Chondrosarcoma or Chordoma:** The approval duration was changed from 3 years to 1 year. **Gastrointestinal Stromal Tumor:** The approval duration was changed from 3 years to 1 year. **Myeloid/Lymphoid Neoplasms with Eosinophilia:** The approval duration was changed from 3 years to 1 year.	06/22/2022
Annual Revision	**Bone Cancer**: The condition of approval of chondrosarcoma or chordoma was reworded to bone cancer and criterion was added which states that patient has chondrosarcoma or chordoma.	05/31/2023

	Melanoma, Cutaneous: This new condition of approval was added to "Other Uses With Supportive Evidence" section based on NCCN guideline recommendations.	