PRIOR AUTHORIZATION POLICY

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

DATE REVIEWED: 04/01/2020

OVERVIEW

Sprycel, a tyrosine kinase inhibitor (TKI), is indicated for the treatment of adults with: newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase (CP); chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib; and Ph+ acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy.[1] Additionally, Sprycel is indicated for the treatment of pediatric patients ≥ 1 year of age with Ph+ CML in CP and newly diagnosed Ph+ ALL in combination with chemotherapy. Currently, there are four other TKIs approved for the treatment of CP Ph+ CML: imatinib, Sprycel® (dasatinib tablets), Bosulif® (bosutinib tablets), Tasigna® (nilotinib capsules), and Iclusig® (ponatinib tablets).[2-5] These agents are indicated for the treatment of CP Ph+ CML in various phases; some TKIs are indicated after resistance or intolerance to prior therapy. Iclusig is approved for patients with T315I-positive CML and in adult patients with CML for whom no other TKI therapy is indicated.[5] Imatinib also has indications related to use in ALL.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for CML (version 3.2020 – January 30, 2020) state that for patients with CP CML with a low-risk score, the primary treatment recommended includes a first-generation TKI (Gleevec or generic imatinib 400 mg QD [Category 1]), or a second-generation TKI (Bosulif 400 mg QD [Category 1], Sprycel 100 mg QD [Category 1], or Tasigna 300 mg BID [Category 1]).[6] For patients with CP CML with an intermediate- or high-risk score, a second-generation TKI is preferred (Bosulif 400 mg QD [Category 1], Sprycel 100 mg QD [Category 1], or Tasigna 300 mg BID [Category 1]). A first-generation TKI (Gleevec or generic imatinib 400 mg QD) is an alternative [Category 2A]. Iclusig is an option for patients with a T315I mutation and for with disease that has not responded to multiple TKIs or in whom another TKI is not indicated.

The NCCN guidelines for ALL (version 1.2020 – January 15, 2020)[7] and Pediatric ALL (version 1.2020 – November 25, 2019)[8] recommend Sprycel in a variety of clinical scenarios including induction therapy, maintenance, relapsed or refractory ALL and for use in specific mutations.

The NCCN soft tissue sarcoma guidelines (version 6.2019 – February 10, 2020) indicate that Sprycel is a treatment option for patients with GIST as an additional option for patients who are no longer experiencing benefit from imatinib, Sutent® (sunitinib capsules), or Stivarga® (regorafenib tablets).[9] It is noted that data are limited with Sprycel (e.g., unpublished, Phase II, small numbers, retrospective). However, it was suggested that Sprycel may be a more effective option for patients with the D842V mutation.[8]

The NCCN guidelines on bone cancer (version 1.2020 – August 12, 2019) recommend Sprycel for patients with chondrosarcoma or chordoma.[10]

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Sprycel. All approvals are provided for 3 years in duration.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Acute Lymphoblastic Leukemia (ALL) That is Philadelphia Chromosome Positive (Ph+).** Approve for 3 years.

2. **Chronic Myeloid Leukemia (CML) That is Philadelphia Chromosome Positive (Ph+).** Approve for 3 years.

Other Uses with Supportive Evidence

3. **Gastrointestinal Stromal Tumor (GIST).** Approve for 3 years if the patient meets the following criteria (A, B, and C):
   A) Patient has tried imatinb; AND
   B) Patient has tried Sutent® (sunitinib capsules); AND
   C) The patient has tried Stivarga® (regorafenib tablets).

4. **Chondrosarcoma or chordoma.** Approve for 3 years.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Sprycel has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

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; December 2018.
2. Gleevec® tablets [prescribing information]. East Hanover, NJ: Novartis; July 2018.
3. Tasigna® capsules [prescribing information]. East Hanover, NJ: Novartis; September 2019.
4. Bosulif® tablets [prescribing information]. New York, NY: Pfizer Inc; October 2019.
5. Iclusig® tablets [prescribing information]. Cambridge, MA: Ariad Pharmaceuticals; January 2020.
6. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (Version 3.2020 – January 30, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 17, 2020.
7. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (Version 1.2020 – January 15, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 17, 2020.
8. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (Version 2.2020 – November 25, 2019). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 17, 2020.
9. The NCCN Soft Tissue Sarcoma Practice Guidelines in Oncology (Version 6.2019 – February 10, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 17, 2020.
10. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (Version 1.2020 – August 12, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 17, 2020.