MEDICAL MUTUAL®

Drug Policy

Policy:	Sprycel (dasatinib)	Annual Review Date: 05/21/2020 Last Revised Date: 05/21/2020

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 Gleevec (imatinib tablets, generic); and Ph+ acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy. 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: Gleevec, Sprycel (dasatinib tablets), Bosulif (bosutinib tablets), Tasigna (nilotinib capsules), and Iclusig (ponatinib tablets). 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. Gleevec also has indications related to use in ALL.

POLICY STATEMENT

This policy involves the use of Sprycel. Prior authorization is recommended for pharmacy benefit coverage of Sprycel. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Sprycel as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Sprycel be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, this drug must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. **Philadelphia Chromosome Positive (Ph+) or BCR-ABL1 Positive Chronic Myeloid Leukemia (CML) Criteria.** *Approve.*

2. **Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL)**

Criteria. *Approve.*

3. **Gastrointestinal Stromal Tumor (GIST).**
   Criteria. *Approve if the patient meets the following criteria:*
   - **A.** Patient has experienced resistance, intolerance or is unable to receive treatment with Gleevec (imatinib); AND
   - **B.** Patient has experienced resistance, intolerance or is unable to receive treatment with Sutent (sunitinib); AND
   - **C.** Patient has experienced resistance, intolerance or is unable to receive treatment with Stivarga (regorafenib); AND
   - **D.** Patient has the D842V mutation.

4. **Chondrosarcoma**
   Criteria. *Approve if Sprycel will be used as single agent therapy for treatment of widespread metastatic disease*

5. **Chordoma**
   Criteria. *Approve if Sprycel will be used as single agent therapy for treatment of recurrent disease*

6. **Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
   Criteria. *Prescriber will provide specific diagnosis for documentation. Approve.*

7. **Patient has been started on Sprycel**
   Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Sprycel® tablets [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; December 2018.

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4. The NCCN Soft Tissue Sarcoma Practice Guidelines in Oncology (Version 1.2018 – October 31, 2017). © 2017 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 2, 2018.
5. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (Version 1.2019 – August 1, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 14, 2019.
6. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Practice Guidelines in Oncology (Version 4.2019 – March 15, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 20, 2019.
7. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2019 – January 18, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 12, 2019.
8. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2019 – March 6, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 12, 2019.
9. Dasatinib. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 19 May 2020. Accessed 21 May 2020.
10. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on 21 May 2020.