Sprycel (dasatinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Sprycel (dasatinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Sprycel (dasatinib) may be approved if the following criteria are met:

I. Individual has newly diagnosed low risk, chronic phase (CP) Philadelphia chromosome positive Chronic Myeloid Leukemia (Ph+CML) (Label, NCCN 2A); **AND**
II. Individual is a child or adolescent weighing at least 10 kg (22 pounds); **OR**
III. Individual does not have any of the following BCR-ABL1 mutations:
    A. T315I/A; **OR**
    B. F317L/V/I/C; **OR**
    C. V299L;

AND

1. Individual has been receiving and is maintained on a stable dose of dasatinib (Sprycel). Medication samples/coupons/discount cards are excluded from consideration as a trial.;

OR

2. Individual has had a trial and inadequate response or intolerance to generic imatinib. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

OR

3. Individual has resistance, contraindication or warning to generic imatinib due to current clinical conditions, including but not limited to pulmonary arterial hypertension, pleural or pericardial effusion, or cardiac abnormalities;

OR

IV. Individual has newly diagnosed, intermediate or high risk, chronic phase (CP) Philadelphia chromosome positive Chronic Myeloid Leukemia (Ph+CML) (Label, NCCN 2A); **AND**
V. Individual does not have any of the following BCR-ABL1 mutations:
    A. T315I/A; **OR**
    B. F317L/V/I/C; **OR**
    C. V299L;

OR

VI. Individual has newly diagnosed, accelerated phase (AP) or blast phase (BP) Philadelphia chromosome positive Chronic Myeloid Leukemia (Ph+CML) (NCCN 2A); **AND**

VII. Individual does not have any of the following BCR-ABL1 mutations:
- A. T315I/A; **OR**
- B. F317L/V/I/C; **OR**
- C. V299L;

OR

VIII. Individual has a diagnosis of chronic phase (CP), accelerated phase (AP), or blast phase (BP) Philadelphia chromosome positive Chronic Myeloid Leukemia (Ph+ CML) and is using as alternate treatment after prior treatment with asciminib, imatinib, bosutinib, or nilotinib (Label, NCCN 2A); **AND**

IX. Individual does not have any of the following BCR-ABL1 mutation profiles (NCCN 2A):
- A. T315I/A; **OR**
- B. F317L/V/I/C; **OR**
- C. V299L;

OR

X. Individual has a diagnosis of chronic phase (CP) Philadelphia chromosome positive Chronic Myeloid Leukemia (Ph+CML) in children and adolescents weighing at least 10 kg (22 pounds) and using as alternate treatment after prior treatment;

OR

XI. Individual has a diagnosis of Philadelphia chromosome positive Chronic Myeloid Leukemia (Ph+CML) and is using as maintenance or continuation of therapy (NCCN 2A);

OR

XII. Individual has a diagnosis of Philadelphia chromosome positive Acute Lymphoblastic Leukemia (Ph+ALL) (Label, NCCN 2A); **AND**

XIII. Individual is at least 1 year of age or older; **AND**

XIV. Individual does not have any of the following BCR-ABL 1 mutations:
- A. T315I/A; **OR**
- B. F317L/V/I/C; **OR**
- C. V299L;

OR

XV. Individual has a diagnosis of Gastrointestinal Stromal Tumors (GIST) (NCCN 2A); **AND**

XVI. Individual has mutations that are insensitive to imatinib; **AND**

XVII. Individual is using after treatment with avapritinib;

OR

XVIII. Individual has a diagnosis of recurrent Chordoma (NCCN 2A);

OR

XIX. Individual has a diagnosis Chondrosarcoma (NCCN 2A); **AND**

XX. Individual is using as a single-agent therapy for one of the following:

A. Treatment of metastatic disease at presentation; **OR**
B. Systemic recurrence of high grade (grade II or III), clear cell, or extracompartmental chondrosarcoma;

OR

XXI. Individual has a diagnosis of metastatic or unresectable cutaneous melanoma (NCCN 2A); **AND**
   A. Individual has activating mutations of KIT; **AND**
   B. Individual is using as a single agent;

OR

XXII. Individual has a diagnosis for myeloid/lymphoid neoplasm chronic or blast phase with eosinophilia (NCCN 2A); **AND**

XXIII. Individual has ABL1 rearrangement.

Requests for **brand** Sprycel must also meet the following criteria, in addition to the above Prior Authorization criteria:

I. Documentation is provided that individual has failed an adequate trial of one chemically equivalent generic dasatinib agent. Medication samples/coupons/discount cards are excluded from consideration as a trial.; **AND**
   A. Generic dasatinib had inadequate response; **OR**
   B. Generic dasatinib caused adverse outcome; **OR**
   C. The individual has a genuine allergic reaction to an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2025. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Updated periodically.
    a. Acute Lymphoblastic Leukemia. V3.2024. Revised December 20, 2024.
    b. Bone Cancer. V1.2025. Revised August 20, 2024.
    c. Chronic Myeloid Leukemia. V3.2025. Revised November 27, 2024.
    d. Gastrointestinal Stromal Tumors. V2.2024. Revised July 31, 2024.
    e. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes. V2.2024. Revised June 19, 2024.
    f. Pediatric Acute Lymphoblastic Leukemia. V2.2025. Revised December 16, 2024.
6. Kang YK, Ryu MH, Yoo C, et al. Resumption of imatinib to control metastatic or unresectable gastrointestinal stromal tumours after failure of imatinib and sunitinib (RIGHT): a randomised, placebo-controlled, phase 3 trial. *Lancet Oncol*. 2013;14(12):1175-1182. doi:10.1016/S1470-2045(13)70453-4. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4347867/pdf/nihms665683.pdf Accessed January 16, 2023.
7. Schwaab J, Naumann N, Luebke J, et. al. Response to tyrosine kinase inhibitors in myeloid neoplasms associated with PCM1-JAK2, BCR-JAK2 and ETV6-ABL1 fusion genes. Am J. Hematol 2020;95:824-833. Accessed on January 12, 2022.
8. Tasian SK, Loh ML, Hunger SP. Philadelphia chromosome-like acute lymphoblastic leukemia. Blood. 2017;130(19):2064-2072. doi:10.1182/blood-2017-06-743252

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.