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 a new diagnosis of Philadelphia chromosome positive (Ph+) Chronic Myelogenous Leukemia (CML) in chronic phase (Label, NCCN 2A);

OR

II. Individual has a diagnosis of chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib (Label);

OR

III. Individual has a diagnosis of chronic phase Ph+ CML disease and using Sprycel (dasatinib) as alternative treatment after primary treatment of imatinib, bosutinib, or nilotinib; **AND**

IV. 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

V. Individual has a diagnosis of Ph+ Acute Lymphoblastic Leukemia (ALL) with resistance (i.e. relapse/refractory) or intolerance to prior therapy (Label, NCCN 2A); **AND**

VI. 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

VII. Individual has Philadelphia-like or positive ALL and using Sprycel (dasatinib) as a component of induction and/or consolidation therapy (NCCN 2A);

OR

VIII. Individual has a diagnosis of Soft Tissue Sarcoma – Gastrointestinal Stromal Tumors (GIST) (NCCN 2A); **AND**

IX. Individual has confirmed PDGFRA D842V mutation; **AND**

X. Individual is using in treatment after disease progression after single agent therapy with imatinib, sunitinib and regorafenib;

OR

XI. Individual has a diagnosis of Ph+ CML in chronic phase in children and adolescents weighing at least 10 kg (22 pounds);

OR

XII. Individual has a new diagnosis of Ph+ ALL; **AND**
XIII. Individual is a child or adolescent weighing at least 10 kg (22 pounds); **AND**
XIV. Individual is using in combination with chemotherapy;

OR

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

OR

XVI. Individual has a diagnosis Chondrosarcoma (NCCN 2A): **AND**
XVII. 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

XVIII. 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

XIX. Individual has a diagnosis for myeloid/lymphoid neoplasm chronic or blast phase with eosinophilia (NCCN 2A); **AND**
XX. Individual has ABL1 rearrangement;

OR

XXI. Individual has a diagnosis of relapsed or refractory pediatric T-ALL; **AND**
XXII. Individual has ABL-class translocation; **AND**
XXIII. Individual is using as part of a TKI-based regimen;

AND

XXIV. 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

XXV. 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

XXVI. Individual has resistance, intolerance, 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

XXVII. Individual has intermediate or high Sokal score (0.8 or higher);

OR

XXVIII. Individual is diagnosed with genetic variants associated with high risk CML.

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.: 2024. 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.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Updated periodically.
   a. Acute Lymphoblastic Leukemia. V3.2023. Revised October 9, 2023.
   b. Bone Cancer. V1.2024. Revised August 7, 2023.
   c. Chronic Myeloid Leukemia. V2.2024. Revised December 5, 2023.
   d. Gastrointestinal Stromal Tumors. V1.2023. Revised March 13, 2023.
   e. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes. V2.2023. Revised July 14, 2023.
6. Pediatric Acute Lymphoblastic Leukemia. V3.2024. Revised October 31, 2023.
7. 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
8. Accessed January 16, 2023.
9. 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.
10. 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