

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

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

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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- 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).

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. 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>.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Updated periodically. Accessed on January 23, 2020
 - a. Acute Lymphoblastic Leukemia. V1.2020. Revised January 15, 2020.
 - b. Bone Cancer. V1.2020. Revised August 12, 2019.
 - c. Chronic Myeloid Leukemia. V2.2020. Revised September 25, 2019.
 - d. Pediatric Acute Lymphoblastic Leukemia. V2.2020. Revised November 25, 2019.
 - e. Soft Tissue Sarcoma. V4.2019. Revised September 12, 2019.