

## Clinical Policy: Dasatinib (Sprycel)

Reference Number: CP.PHAR.72

Effective Date: 06.01.12

Last Review Date: 02.19

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Dasatinib (Sprycel®) is a kinase inhibitor.

### FDA Approved Indication(s)

Sprycel is indicated for the treatment of:

- Newly diagnosed adults with Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in chronic phase
- Adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib
- Adults with Ph+ acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy
- Pediatric patients 1 year of age and older with Ph+ CML in chronic phase
- Pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Sprycel is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Chronic Myeloid Leukemia and Acute Lymphoblastic Leukemia (must meet all):

1. Diagnosis of Ph+ (i.e., BCR-ABL1 positive) CML or ALL;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age  $\geq$  1 year;
4. Dose does not exceed:
  - a. Pediatrics age < 18 years: weight-based dosing in Section V;
  - b. Adults age  $\geq$  18 years: 180 mg per day;
  - c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

##### Approval duration:

**Medicaid/HIM** – 6 months

**Commercial** – Length of Benefit

**B. Gastrointestinal Stromal Tumor (off-label) (must meet all):**

1. Diagnosis of gastrointestinal stromal tumor (GIST) (a soft tissue sarcoma);
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Failure of imatinib (Gleevec<sup>®</sup>), Sutent<sup>®</sup>, or Stivarga<sup>®</sup>, unless contraindicated or clinically significant adverse effects are experienced;  
*\*Prior authorization is required for imatinib, Sutent, and Stivarga*
5. Request meets one of the following (a or b):
  - a. Dose does not exceed 180 mg per day;
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration:**

**Medicaid/HIM** – 6 months

**Commercial** – Length of Benefit

**C. Bone Cancer (off-label) (must meet all):**

1. Diagnosis of metastatic chondrosarcoma or recurrent chordoma;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  13 years;
4. Request meets one of the following (a or b):
  - a. Dose does not exceed 180 mg per day;
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration:**

**Medicaid/HIM** – 6 months

**Commercial** – Length of Benefit

**D. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

**II. Continued Approval**

**A. All Indications in Section I (must meet all):**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Sprycel for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b, or c):
  - a. Adults age  $\geq$  18 years, bone cancer, or GIST: New dose does not exceed 180 mg per day;
  - b. Pediatrics age  $<$  18 years for CML or ALL: New dose does not exceed weight-based dosing in Section V;

- c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration:**

**Medicaid/HIM - 6 months**

**Commercial - Length of Benefit**

**B. Other diagnoses/indications (must meet 1 or 2):**

- 1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 6 months (whichever is less); or**

- 2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

ALL: acute lymphoblastic leukemia

CML: chronic myelogenous leukemia

FDA: Food and Drug Administration

Ph+: positive Philadelphia chromosome

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
imatinib (Gleevec®)	<b>GIST</b> 400 mg PO QD to 400 mg PO BID	800 mg/day
Sutent® (sunitinib)	<b>GIST</b> 50 mg PO QD	50 mg/day
Stivarga® (regorafenib)	<b>GIST</b> 160 mg PO QD for the first 21 days of each 28-day cycle	160 mg/day

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

None reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
CML	<p>Adults:</p> <ul style="list-style-type: none"> <li>Chronic phase: 100-140 mg/day PO</li> <li>Accelerated, myeloid phase, or lymphoid blast phase: 140-180 mg/day PO</li> </ul> <p>Pediatrics:</p> <p>Initial weight-based dosing PO QD:</p> <ul style="list-style-type: none"> <li>Weight 10 to &lt; 20 kg: 40 mg</li> <li>Weight 20 to &lt; 30 kg: 60 mg</li> <li>Weight 30 to &lt; 45 kg: 70 mg</li> <li>Weight ≥ 45 kg: 100 mg</li> </ul> <p>Dose escalation PO QD:</p> <ul style="list-style-type: none"> <li>Starting dose 40 mg can be escalated to 50 mg</li> <li>Starting dose 60 mg can be escalated to 70 mg</li> <li>Starting dose 70 mg can be escalated to 90 mg</li> <li>Starting dose 100 mg can be escalated to 120 mg</li> </ul>	<p>Adults: 180 mg/day</p> <p>Pediatrics: 120 mg/day</p>
ALL	<p>Adults: 140-180 mg/day PO</p> <p>Pediatrics: Weight-based dosing PO QD</p> <ul style="list-style-type: none"> <li>Weight 10 to &lt; 20 kg: 40 mg</li> <li>Weight 20 to &lt; 30 kg: 60 mg</li> <li>Weight 30 to &lt; 45 kg: 70 mg</li> <li>Weight ≥ 45 kg: 100 mg</li> </ul>	<p>Adults: 180 mg/day</p> <p>Pediatrics: 100 mg/day</p>

**VI. Product Availability**

Tablets: 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, 140 mg

**VII. References**

1. Sprycel Prescribing Information. Princeton, NJ: Bristol-Myers Squibb Company; December 2018. Available at: [https://packageinserts.bms.com/pi/pi\\_sprycel.pdf](https://packageinserts.bms.com/pi/pi_sprycel.pdf). Accessed January 2, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [http://www.nccn.org/professionals/drug\\_compendium](http://www.nccn.org/professionals/drug_compendium). Accessed January 2, 2019.
3. National Comprehensive Cancer Network. Chronic Myeloid Leukemia Version 1.2019. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/cml.pdf](https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf). Accessed January 2, 2019.
4. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia Version 1.2018. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/all.pdf](https://www.nccn.org/professionals/physician_gls/pdf/all.pdf). Accessed January 2, 2019.
5. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 1.2019. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/sarcoma.pdf](https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf). Accessed January 2, 2019.

6. National Comprehensive Cancer Network. Bone Cancer Version 1.2019. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/bone.pdf](https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf). Accessed January 2, 2019.
7. Schuetze SM, Bolejack V, Choy E, et al. Phase 2 study of dasatinib in patients with alveolar soft part sarcoma, chondrosarcoma, chordoma, epithelioid sarcoma, or solitary fibrous tumor. *Cancer* 2017;123(1):90-97. doi: 10.1002/cncr.30379. Epub 2016 Oct 3.
8. Trent JC, Wathen K, von Mehren M, et al. A phase 2 study of dasatinib for patients with imatinib-resistant gastrointestinal stromal tumor (GIST). *Journal of Clinical Oncology* 2011;29(15):Abstract 10006.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Reworked narrative for CML and ALL per NCCN guidelines. Removed requests for documentation from all algorithms. Resistance (Appendix B) used in Figures 1 and 2. Combined Figures 2 and 3 (CML); modified monitoring per NCCN guidelines – see corresponding narrative and Appendix C. Restructured safety section into list per package insert.	06.15	07.15
Policy converted to new template. Age removed under FDA approved use per new oncology template guidelines (but retained if specified in the NCCN recommended uses). Criteria specifying “Ph+” for ALL and “Ph+ and/or BCRABL1 positive” for CML follows NCCN compendial recommendations. Detailed resistance and therapeutic response criteria removed. NCCN compendial uses for CML and ALL added if not considered covered by the CML/ALL FDA approved uses. The remaining NCCN compendial use for GIST is added.	06.16	07.16
No significant changes: converted to new template; FDA indication update for pediatric extension of Ph+ CML.	02.09.18	
2Q 2018 annual review: HIM and Commercial lines of business added; off-label GIST added; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; added continuity of care statement; references reviewed and updated.	02.13.18	05.18
Criteria added for new FDA indication: pediatric use in newly diagnosed Ph+ ALL; added criteria for new NCCN-supported indication: chondrosarcoma/chordoma; added hematologist as a prescriber specialist option to CML/ALL; added age requirement for FDA uses; added pediatric-specific max dose requirements to CML/ALL; references reviewed and updated.	01.15.19	02.19

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical

policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**For Health Insurance Marketplace members**, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

©2012 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.