Clinical Policy: Dasatinib (Sprycel)

Reference Number: CP.PHAR.72
Effective Date: 06.01.12
Last Review Date: 05.18
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 with Ph+ CML in chronic phase.

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 (must meet all):

1. Diagnosis of Ph+ (i.e., BCR-ABL1 positive) CML;
2. Prescribed by or in consultation with an oncologist;
3. Dose does not exceed 180 mg/day.

Approval duration:
Medicaid/HIM - 6 months
Commercial - Length of Benefit

B. Acute Lymphoblastic Leukemia (must meet all):

1. Diagnosis of Ph+ (i.e., BCR-ABL1 positive) ALL;
2. Prescribed by or in consultation with an oncologist;
3. Dose does not exceed 180 mg/day.

Approval duration:
Medicaid/HIM - 6 months
Commercial - Length of Benefit

C. 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 ≥ 18 years;
4. Failure of imatinib, sunitinib, or regorafenib unless contraindicated or clinically significant adverse effects are experienced;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 180 mg/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 all covered indications 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 or b):
   a. New dose does not exceed 180 mg/day;
   b. 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®)	GIST 400 mg PO QD to 800 PO BID	800 mg/day
Sutent® (sunitinib)	GIST 50 mg PO QD	50 mg/day
Stivarga® (regorafenib)	GIST 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.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CML	100-140 mg/day for chronic phase 140-180 mg/day for accelerated, myeloid phase, or lymphoid blast phase	180 mg/day
ALL	140-180 mg/day	180 mg/day

VI. Product Availability

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

VII. References

1. Sprycel Prescribing Information. Princeton, NJ: Bristol-Myers Squibb Company; November 2017. Available at: https://packageinserts.bms.com/pi/pi_sprycel.pdf. Accessed February 2018.
2. Dasatinib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 2018.
3. Chronic myelogenous leukemia (Version 4.2018). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 2018.
4. Acute lymphoblastic leukemia (Version 5.2017). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 2018.
5. Soft tissue sarcoma (Version 1.2018). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Annual Clinical Review Updated approval timeframe in Figure 1 algorithm Added cytogenetic response question Figure 2 and 3 algorithms Added to and updated background	07.14	07.14
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

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.