Clinical Policy: Dasatinib (Sprycel)

Reference Number: ERX.SPA.76
Effective Date: 03.01.14
Last Review Date: 05.20
Line of Business: Commercial, 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:

- Adults with newly diagnosed 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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+ (BCR-ABL1-positive) CML or Ph+ (BCR-ABL1-positive) ALL;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 1 year;
4. Request meets one of the following (a, b, or c):*
   a. Pediatrics age < 18 years: Dose does not exceed the weight-based dosing in Section V;
   b. Adults age ≥ 18 years: Dose does not exceed 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

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 ≥ 18 years;
4. Failure of imatinib (Gleevec®), Sutent®, or Stivarga®, unless clinically significant adverse effects are experienced or all are contraindicated;

**Prior authorization may be required for imatinib, Sutent, and Stivarga*

5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

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 ≥ 13 years;
4. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

D. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, 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 ≥ 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 the 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*).
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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+: Philadelphia chromosome-positive

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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
imatinib (Gleevec)	GIST: 400 mg PO QD to 400 mg 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.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CML	Adults: • Chronic phase: 100-140 mg/day PO • Accelerated, myeloid phase, or lymphoid blast phase: 140-180 mg/day PO Pediatrics: Initial weight-based dosing PO QD: • Weight 10 to < 20 kg: 40 mg • Weight 20 to < 30 kg: 60 mg • Weight 30 to < 45 kg: 70 mg • Weight ≥ 45 kg: 100 mg Dose escalation PO QD: • Starting dose 40 mg can be escalated to 50 mg • Starting dose 60 mg can be escalated to 70 mg • Starting dose 70 mg can be escalated to 90 mg • Starting dose 100 mg can be escalated to 120 mg	Adults: 180 mg/day Pediatrics: 120 mg/day
ALL	Adults: 140-180 mg/day PO Pediatrics: Weight-based dosing PO QD • Weight 10 to < 20 kg: 40 mg • Weight 20 to < 30 kg: 60 mg • Weight 30 to < 45 kg: 70 mg • Weight ≥ 45 kg: 100 mg	Adults: 180 mg/day Pediatrics: 100 mg/day

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. Accessed February 10, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 10, 2020.
3. National Comprehensive Cancer Network. Chronic Myeloid Leukemia Version 3.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed February 10, 2020.

4. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia Version 1.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed February 10, 2020.
5. National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic Leukemia Version 2.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed February 10, 2020.
6. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 6.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed February 10, 2020.
7. National Comprehensive Cancer Network. Bone Cancer Version 1.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf. Accessed February 10, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy converted to new template. Removed age restrictions, requests for documentation, cytogenic response criteria, and safety criteria. Changed all approval durations to 3 months for initial and 6 months for re-auth. Updated criteria to specify "Ph+" for ALL and "Ph+ and/or BCRABL1 positive" for CML per NCCN compendial recommendations. Added all other NCCN compendial uses.	08.16	09.16
Converted to new template. Age added for CML and ALL. CML NCCN: 1) "myeloid" is inserted to describe blast phase CML; 2) "In combination with steroids as primary treatment for CML in lymphoid blast phase" is added; 3) "for relapse" is deleted from "post stem cell transplant therapy" to incorporate history of responsive CML; 4) CML positive for a Y253H, E255K/V, or F359V/C/I mutation is added; 5) continuing treatment with Sprycel is deleted with the assumption that this would fall under the continuation criteria. ALL NCCN: 1) Sprycel may or may not be used with various regimens as part of induction/consolidation therapy – regimens are therefore deleted; 2) "After complete response to induction therapy is achieved following transplantation" is replaced with "maintenance therapy post stem cell transplant"; 3) "with or without methotrexate and mercaptopurine" is added to the maintenance vincristine regimen; 4) mutation history is separated from the "relapsed/refractory disease" heading and moved below it. Maximum dose added. Dosing guidance added for off-label use. All off-label uses are referred to the off-label use policy. Approval periods are lengthened from 3/6 to 6/12 months.	07.17	08.17
2Q 2018 annual review: new FDA labeled pediatric CML and off-label GIST added; NCCN and FDA approved uses summarized for improved clarity; specialist involvement in care added; continuity of care statement added; approval durations increased to length of benefit; 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
2Q 2019 annual review: no significant changes; references reviewed and updated.	02.19.19	05.19
2Q 2020 annual review: no significant changes; added Medicaid line of business with 6 month approval durations; references reviewed and updated.	02.11.20	05.20

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.