Clinical Policy: Dasatinib (Sprycel)

Reference Number: PA.CP.PHAR.72
Effective Date: 01/18
Last Review Date: 04/19

Revision Log

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
It is the policy of Pennsylvania Health and Wellness ® 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 IV;
   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).

Approval duration: 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, sunitinib, or regorafenib unless contraindicated or clinically significant adverse effects are experienced;

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*).

Approval duration: 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*).

Approval duration: 6 months

D. Other diagnoses/indications:

1. Refer to PA.CP.PMN.53

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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 weight-based dosing in Section IV;
   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: 6 months

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PMN.53

III. 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 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

IV. 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

V. Product Availability

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

VI. 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 4, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 4, 2019.
3. National Comprehensive Cancer Network. Chronic Myeloid Leukemia Version 1.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed February 4, 2019.
4. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia Version 1.2018. Available at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed February 4, 2019.
5. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 1.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed February 4, 2019.
6. National Comprehensive Cancer Network. Bone Cancer Version 1.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf. Accessed February 4, 2019.
7. Schuetze SM, Bolejack V, Choy E, et al. Phase 2 study of dasatinib in patients with alveolar soft part sarcoma, chondrosarcome, 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	Approval Date
2Q 2018 annual review: FDA indication update for pediatric extension of Ph+ CML; off-label GIST added; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; references reviewed and updated.	02.13.18	
2019 annual review: 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.	04/2019	