RXADVANCE
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Clinical Policy Title:	dasatinib
Policy Number:	RxA.470
Drug(s) Applied:	Sprycel®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Dasatinib (Sprycel®) is a kinase inhibitor.
It is indicated in adults 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
  It is indicated in pediatric patients 1 year of age and older for the treatment of:
- Ph+ CML in chronic phase
- newly diagnosed Ph+ ALL in combination with chemotherapy

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
dasatinib (Sprycel®)	Chronic myelogenous leukemia	<u>Adults:</u> • Chronic phase: 100:140 mg/day orally • Accelerated, myeloid phase, or lymphoid blast phase: 140 - 180 mg/day orally <u>Pediatrics:</u> Initial weight-based orally once daily: • 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 orally once daily: • Starting dose 40 mg can be escalated to 50 mg • Starting dose 60 mg can be escalated to 70 mg	Adults: 180 mg/day Pediatrics: 120 mg/day

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
		• Starting dose 70 mg can be escalated to 90 mg • Starting dose 100 mg can be escalated to 120 mg	
dasatinib (Sprycel®)	Acute lymphoblastic leukemia	Adults: 140 - 180 mg/day orally Pediatrics: Weight-based dosing orally once daily • 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

Dosage Forms

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

Clinical Policy

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

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 mentioned in Dosing Information section;
   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
Commercial : 6 months
Medicaid: 6 months

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

1. Diagnosis of unresectable or metastatic gastrointestinal stromal tumor (GIST; a soft tissue sarcoma);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Failure of single agent therapy with imatinib (Gleevec®), Sutent® and Stivarga®, unless contraindicated or clinically significant adverse effects are experienced;
   *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).

Approval duration
Commercial : 6 months
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).

Approval duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving the medication that has been authorized by RxAdvance or member has met initial approval criteria listed in this policy; 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 weight: based dosing mentioned in Dosing Information section ;
   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
Commercial: 6 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

ALL: Acute lymphoblastic leukemia
CML: Chronic myelogenous leukemia
FDA: Food and Drug Administration
Ph+: Positive Philadelphia chromosome
GIST: Gastrointestinal Stromal Tumor

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose

Gastrointestinal Stromal Tumors		
imatinib (Gleevec®)	400 mg orally once daily to 400 mg orally twice a day	800 mg/day
Sutent® (sunitinib)	50 mg orally once daily	50 mg/day
Stivarga® (regorafenib)	160 mg orally once daily for the first 21 days of each 28:day cycle	160 mg/day
CML or ALL		
Tasigna (nilotinib)	Refer to prescribing information of the product	Varies
imatinib (Gleevec)	Refer to prescribing information of the product	Varies
Bosulif (bosutinib)	Refer to prescribing information of the product	600 mg/day
Iclusig (ponatinib)	45 mg orally once daily	45 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

- Contraindication(s):
  - None

- Boxed Warning(s):
  - None

References

1. Sprycel Prescribing Information. Princeton, NJ: Bristol:Myers Squibb Company; December 2018. Available at: https://www.sprycel.com/. Accessed October 14, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed October 13, 2020.
3. National Comprehensive Cancer Network. Chronic Myeloid Leukemia Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed October 14, 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 October 13, 2020.
5. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2020 May 28, 2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed October 13, 2020.
6. National Comprehensive Cancer Network. Bone Cancer Version 1.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf. Accessed October 13, 2020.
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.
9. National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic Leukemia Version 2.2021 October 22, 2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed October 26, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical policy title updated. 2. Line of Business Policy Applies to was updated to “All lines of business”. 3. Dosing Regimen Abbreviated forms QD and PO is replaced with once daily and by mouth. 4. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance”. 5. Commercial approval duration was updated for initial and continued therapy criteria and HIM deleted. 6. Appendix B Therapeutic Alternatives language rephrased and abbreviated form BID changed to twice a day. 7. References were reviewed and updated. 8. Adjusted language for initial therapy criteria for GIST per NCCN recommendation 9. Added therapeutic alternatives for other indication of dasatinib.	10/14/2020	12/07/2020