

**Generic Name:** Dasatinib

**Applicable Drugs:** Sprycel®

**Preferred:** N/A

**Non-preferred:** N/A

**Date of Origin:** 2/1/2013

**Date Last Reviewed / Revised:** 10/24/2023

## PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met)

- I. Documented diagnosis of one of the following indications A through F AND must meet criteria listed under applicable diagnosis and respective age group (where applicable):
  - A. Chondrosarcoma
    - i. Age  $\geq$  18 years old with metastatic and widespread disease.
  - B. Chordoma
    - i. Age  $\geq$  18 years old with recurrent disease.
  - C. Gastrointestinal stromal tumor (GIST)
    - i. Age  $\geq$  18 years old with unresectable, recurrent, or metastatic disease
    - ii. Meets one of the following criteria:
      1. Documented intolerance or treatment failure to imatinib.
      2. Documentation of the presence of PDGFRA exon 18 mutation insensitive to imatinib (such as D842V), and documented intolerance or treatment failure to avapritinib.
  - D. Myeloid/Lymphoid neoplasms with eosinophilia and tyrosine kinase gene fusions (MLNE)
    - i. Documented ABL1 rearrangement.
    - ii. Age  $\geq$  18 years old with one of the following (1 or 2):
      1. Chronic phase disease.
      2. Blast phase myeloid, mixed lineage, or lymphoid disease.
  - E. Philadelphia chromosome-positive (Ph+) or BCR-ABL1 kinase positive chronic myeloid leukemia (CML)
    - i. Age  $\geq$  1 to < 18 years old with chronic phase Ph+ CML.
    - ii. Age  $\geq$  18 years old with one of the following (1 or 2):
      1. Newly diagnosed with chronic phase Ph+ CML.

2. Chronic, accelerated, myeloid or lymphoid blast phase Ph+ CML with documented resistance or intolerance to prior therapy (including imatinib).
    - a. In cases of tyrosine kinase inhibitor failure, provision of a BCR-ABL 1 kinase domain mutational analysis showing sensitivity to dasatinib is required.
- F. Ph+ or BCR-ABL1 kinase positive acute lymphoblastic leukemia (ALL)
- i. Age ≥ 1 to < 18 years old with newly diagnosed Ph+ ALL or Ph-Like ALL in combination with chemotherapy.
  - ii. Age ≥ 18 years old with Ph+ ALL AND resistance or intolerance to prior therapy.
    1. In cases of tyrosine kinase inhibitor failure, provision of a BCR-ABL 1 kinase domain mutational analysis showing sensitivity to dasatinib is required.
- II. Prescriber is an oncologist or a hematologist.
- III. Medication is prescribed in accordance with FDA labeling or current clinical practice guidelines.

### EXCLUSION CRITERIA

- BCR-ABL-1 kinase domain mutational analysis showing T315I/A, F317L/V/I/C, or V299L mutations.

### OTHER CRITERIA

- N/A

### QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantity is limited to sufficient tablets to fulfill a 30-day supply.

### APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated progress notes showing current medical necessity criteria are met and that the medication is effective with acceptable toxicity.

### APPENDIX

**Table 1. Sprycel dosage by indication<sup>1-13</sup>**

Indication	Dosage <sup>a</sup>
ALL <sup>b</sup>	<ul style="list-style-type: none"> <li>• ≥1 to &lt;18 years old:                             <ul style="list-style-type: none"> <li>○ 10 to &lt; 20 kg: 40 mg orally once daily</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>○ 20 to &lt; 30 kg: 60mg orally once daily</li> <li>○ 30 to &lt; 45 kg: 70 mg orally once daily</li> <li>○ ≥ 45 kg: 100 mg orally once daily</li> <li>● ≥ 18 years old: 140 mg to 180 mg orally once daily</li> </ul>
Chondrosarcoma or Chordoma <sup>c</sup>	50 to 100 mg orally twice daily
CML <sup>b</sup>	<p>Chronic Phase:</p> <ul style="list-style-type: none"> <li>● ≥ 1 to &lt; 18 years old: <ul style="list-style-type: none"> <li>○ 10 to &lt; 20 kg: 40 to 50 mg orally once daily</li> <li>○ 20 to &lt; 30 kg: 60mg to 70 mg orally once daily</li> <li>○ 30 to &lt; 45 kg: 70 to 90 mg orally once daily</li> <li>○ ≥ 45 kg: 100 mg to 120 mg orally once daily</li> </ul> </li> <li>● ≥ 18 years old: 100 mg to 140 mg orally once daily</li> </ul> <p>Chronic, accelerated, myeloid or lymphoid blast phase CML with documented resistance or intolerance to prior therapy:</p> <ul style="list-style-type: none"> <li>● ≥ 18 years old: 140 mg to 180 mg orally once daily</li> </ul>
GIST <sup>c</sup>	<ul style="list-style-type: none"> <li>● 70 mg orally twice daily</li> </ul>
MLNE <sup>c</sup>	<ul style="list-style-type: none"> <li>● Up to 180 mg orally once daily<sup>d</sup></li> </ul>

<sup>a</sup> See prescribing information for detailed information about recommendations for dosage modifications to manage adverse reactions, dose escalation, and dosage adjustment for drug-drug interactions for FDA-labeled indications.

<sup>b</sup>FDA-labeled indications.

<sup>c</sup>Off-label NCCN recommended indication.

<sup>d</sup>Per Schwaab J, et al. (doi: 10.1002/ajh.25825), patient treated with standard dose.

Abbreviations: acute lymphoblastic leukemia, ALL; chronic myeloid leukemia, CML; gastrointestinal stromal tumor, GIST.

## REFERENCES

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**DISCLAIMER:** Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.