DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Sprycel – Drug Quantity Management Policy – Per Rx
- Sprycel® (dasatinib tablets – Bristol-Myers Squibb)

REVIEW DATE: 02/15/2023

OVERVIEW

Sprycel, a tyrosine kinase inhibitor (TKI), is indicated for the following uses:[1]

- **Acute lymphoblastic leukemia** (ALL) in:
  - Philadelphia chromosome positive (Ph+) adults with resistance or intolerance to prior therapy.
  - Ph+, newly diagnosed pediatric patients ≥ 1 year of age in combination with chemotherapy.
- **Chronic myeloid leukemia** (CML) in:
  - Ph+, newly diagnosed adults, in chronic phase.
  - Ph+, chronic phase, accelerated, or myeloid or lymphoid blast phase, in adults with resistance or intolerance to prior therapy that included imatinib.
  - Ph+, chronic phase, in pediatric patients ≥ 1 year of age.

Dosing

The recommended starting dose of Sprycel for chronic phase CML in adults is 100 mg once daily (QD).[1] The recommended starting dose for accelerated phase CML, myeloid or lymphoid blast phase CML, or Ph+ ALL in adults is 140 mg QD.[1] Treatment of gastrointestinal stromal tumor (GIST) has been studied at a dose of 70 mg twice daily (BID).[2] Treatment of chondrosarcoma or chordoma has been studied at a dose of 70 mg BID.[3] Dose and schedule adjustments were allowed for toxicity (50 mg BID and then 100 mg QD). Treatment of myeloid neoplasms have been studied at standard doses.[4]

Prescribers may choose to escalate the dose to 140 mg QD in chronic phase CML and Ph+ ALL, or to 180 mg QD in advanced phase CML and Ph+ ALL when a hematologic or cytogenetic response at the recommended starting dosage has not been achieved.[1]

The recommended starting dosage for pediatrics is based on body weight shown in Table 1.

Table 1. Sprycel Recommended Starting Dose for Pediatrics.[1]

Body Weight	Sprycel Daily Dose
10 kg to < 20 kg	40 mg
20 kg to < 30 kg	60 mg
30 kg to < 45 kg	70 mg
≥ 45 kg	100 mg

The Sprycel dose may need to be decreased for neutropenia, thrombocytopenia, other toxicities, and when used concomitantly with cytochrome P450 (CYP)3A4 inhibitors.[1] CYP3A4 inducers may decrease Sprycel plasma concentrations.

Availability

Sprycel is available as 20 mg (60 count bottle), 50 mg (60 count bottle), 70 mg (60 count bottle), 80 mg (30 count bottle), 100 mg (30 count bottle), and 140 mg tablets (30 count bottle).[1]

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Sprycel. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Sprycel® (dasatinib tablets)	20 mg tablets	90 tablets	270 tablets
	50 mg tablets	30 tablets	90 tablets
	70 mg tablets	60 tablets	180 tablets
	80 mg tablets	30 tablets	90 tablets
	100 mg tablets	30 tablets	90 tablets
	140 mg tablets	30 tablets	90 tablets

CRITERIA

Sprycel 20 mg tablets

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (i.e., the dose requires multiple tablets of the same strength be used OR would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed a total of 270 tablets per dispensing at retail or 810 tablets per dispensing at home delivery.

Sprycel 50 mg tablets

1. If the patient requires a dose reduction to 50 mg twice daily, approve 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery.

Sprycel 70 mg, 80 mg, 100 mg, and 140 mg tablets

No overrides recommended.

REFERENCES

1. Sprycel tablets [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; June 2021.
2. Trent JC, Wathen K, von Mehren M, et al. A phase II study of dasatinib for patients with imatinib-resistant gastrointestinal stromal tumor (GIST). *J Clin Oncol*, 2011 ASCO Annual Meeting Proceedings (Post-Meeting Edition): 29(15).suppl (May 20 Supplement), 2011: 10006.
3. Schuetze SM, Bolejack V, Choy E, et al. Phase 2 study of dasatinib in patients with alveolar soft part sarcoma, chondrosarcoma, chordoma, epithelioid sarcoma, or solitary fibrous tumor. *Cancer.* 2017; 123(1):90-97.
4. Schwaab J, Naumann N, Luebke, et al. Response to tyrosine kinase inhibitors in myeloid neoplasms associated with PCM1-JAK2, BCR-JAK2 and ETV6-ABL1 fusion genes. *Am J Hematol.* 2020; 95(7):824-833.