Cigna National Formulary Coverage Policy

Effective Date..... 4/1/2023
Next Review Date..... 4/1/2024

Drug Quantity Management – Per Rx Oncology – Sprycel® (dasatinib tablets)

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Product Identifier(s)

Effective 1/1/23 to 3/21/23: 108901

Effective 3/22/23: 21035

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

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.

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

Cigna covers quantities as medically necessary when the following criteria are met:

Sprycel 20 mg tablets

1. If the individual 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 individual 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.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

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]

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.

Revision History

Type of Revision	Summary of Changes	Approval Date
Early Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. Approval duration was changed from 3 years to 1 year.	02/15/2023