



Drug Quantity Management – Per Rx Sprycel® (dasatinib tablets for oral use) Dispensing Limit

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Product Identifier(s)

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

Sprycel 20 mg tablets

Maximum quantity per RX = 90 tablets

Sprycel 70 mg tablets

Maximum quantity per RX = 60 tablets

Sprycel 50 mg, 80 mg, 100 mg, and 140 mg tablets

Maximum quantity per RX = 30 tablets

Criteria

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

All approvals are provided for 3 years in duration unless otherwise noted below.

Sprycel 20 mg tablets

1. Exceptions can be made when an individual is taking a dose that does not correspond to a commercially-available dosage form [that is, the dose requires multiple same strength tablets be used OR would otherwise require two (or more) strengths to be used]. Approve the quantity requested, not to exceed a total of 270 tablets per dispensing.

Sprycel 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg tablets

1. No overrides recommended.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Sprycel is available in 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg tablets. The recommended starting dose for chronic phase chronic myeloid leukemia (CML) in adults is 100 mg orally once daily. The recommended starting dose for accelerated phase CML, myeloid or lymphoid blast phase CML, or Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) in adults is 140 mg administered orally once daily.¹ Treatment of gastrointestinal stromal tumor (GIST) has been studied at a dose of 70 mg twice daily.²

Prescribers may choose to escalate the dose to 140 mg once daily in chronic phase CML and Ph+ ALL patients, or to 180 mg once daily in advanced phase CML and Ph+ ALL patients who do not achieve a hematologic or cytogenetic response at the recommended starting dosage.¹

The recommended starting dosage for pediatrics is based on body weight shown in the table below:

Body Weight (kg)	Sprycel Daily Dose (mg)
10 to less than 20	40 mg
20 to less than 30	60 mg
30 to less than 45	70 mg
At least 45	100 mg

Doses may require reduction for neutropenia, thrombocytopenia, other toxicities, and concomitant use with CYP3A4 inhibitors. CYP3A4 inducers may decrease dasatinib plasma concentrations.

References

1. Sprycel tablets [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; December 2018.
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

Revision History

Type of Revision	Summary of Changes	Date
Annual Revision	Reviewed by Clinical Specialists.	01/31/2020

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