



DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Dasatinib – Drug Quantity Management Policy – Per Rx

- Sprycel® (dasatinib tablets – Bristol-Myers Squibb, generic)

REVIEW DATE: 02/19/2025

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Dasatinib, 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 dasatinib 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 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 has not been achieved at the recommended starting dosage.

The recommended initial dosing of dasatinib in pediatric patients is based on body weight (Table 1). A dose escalation up to 120 mg QD may be considered in pediatric patients with CML. Dose escalation is not recommended in pediatric patients with Ph+ ALL, where dasatinib is administered in combination with chemotherapy.

Table 1. Dasatinib Recommended Pediatric Dosing.¹

Body Weight	Initial Daily Dose	Escalated Daily Dose (CML only)
10 kg to < 20 kg	40 mg	50 mg
20 kg to < 30 kg	60 mg	70 mg
30 kg to < 45 kg	70 mg	90 mg
≥ 45 kg	100 mg	120 mg

CML – Chronic myeloid leukemia.

Cytochrome P450 (CYP)3A4 inhibitors may increase dasatinib plasma concentrations.¹ Dasatinib should not be taken concomitantly with strong CYP3A4 inhibitors or grapefruit juice. If they must be administered together, consider a dose reduction as outlined below:

- 40 mg QD for patients taking 140 mg QD
- 20 mg QD for patients taking 100 mg QD
- 20 mg QD for patients taking 70 mg QD
- Consider interrupting dasatinib until the inhibitor is discontinued in patients taking dasatinib 60 mg or 40 mg QD.

CYP3A4 inducers may decrease dasatinib plasma concentrations.¹ Concomitant use of dasatinib and strong CYP3A4 inducers or St. John's wort. If dasatinib is given with a strong CYP3A4 inducer, consider a dasatinib dose increase.

The dasatinib dose may also need to be decreased for neutropenia, thrombocytopenia, or other toxicities.¹

Off-Label Dosing

Treatment of gastrointestinal stromal tumor (GIST) has been studied at a dose of 70 mg twice daily (BID).² Treatment of chondrosarcoma or chordoma (bone cancer) 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 Dasatinib has also been studied at doses of 70 mg BID for the treatment of cutaneous melanoma.⁵⁻⁷

Availability

Dasatinib 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 dasatinib (Xeloda, generic). 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, generic)	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

Oncology – Dasatinib – Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Dasatinib 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.

Dasatinib 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.

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

No overrides recommended.

REFERENCES

1. Sprycel tablets [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; February 2023.
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.
5. Kluger HM, Dudek AZ, McCann C, et al. A phase 2 trial of dasatinib in advanced melanoma. *Cancer*. 2011;117(10):2202-2208.
6. Kalinsky K, Lee S, Rubin KM, et al. A phase 2 trial of dasatinib in patients with locally advanced or stage IV mucosal, acral, or vulvovaginal melanoma: a trial of the ECOG-ACRIN Cancer Research Group (E2607). *Cancer*. 2017;123(14):2688-2697.
7. Storkus WJ, Maurer D, Lin Y, et al. Dendritic cell vaccines targeting tumor blood vessel antigens in combination with dasatinib induce therapeutic immune responses in patients with checkpoint-refractory advance melanoma. *J Immunother Cancer*. 2021;9(11):e003675.

HISTORY

Type of Revision	Summary of Changes	Review 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
Annual Revision	No criteria changes.	02/20/2024
Annual Revision	Sprycel is available as generic dasatinib. Generic was added to the policy and changed brand "Sprycel" to "dasatinib" throughout the policy. The name of the policy was changed to "Oncology – Dasatinib DQM Policy – Per Rx".	02/19/2025

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