



## DRUG QUANTITY MANAGEMENT POLICY – PER RX

- POLICY:** Oncology – Dasatinib Products Drug Quantity Management Policy – Per Rx
- Phyrago<sup>®</sup> (dasatinib tablets – Handa)
  - Sprycel<sup>®</sup> (dasatinib tablets – Bristol-Myers Squibb, generic)

**REVIEW DATE:** 02/04/2026

### **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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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.

### **CIGNA NATIONAL FORMULARY COVERAGE:**

#### **OVERVIEW**

Dasatinib products, such as Phyrago and Sprycel are tyrosine kinase inhibitor (TKI), is indicated for the following uses:<sup>1,8</sup>

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

## Dosing

The recommended starting dose of dasatinib for chronic phase CML in adults is 100 mg once daily (QD).<sup>1,8</sup> The recommended starting dose for accelerated phase CML, myeloid or lymphoid blast phase CML, or Ph+ ALL in adults is 140 mg QD.<sup>1</sup> 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.**<sup>1,8</sup>

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.<sup>1,8</sup> 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.<sup>1,8</sup> 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.<sup>1,8</sup>

### *Off-Label Dosing*

Treatment of gastrointestinal stromal tumor (GIST) has been studied at a dose of 70 mg twice daily (BID).<sup>2</sup> Treatment of chondrosarcoma or chordoma (bone cancer) has been studied at a dose of 70 mg BID.<sup>3</sup> 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.<sup>4</sup> Dasatinib has also been studied at doses of 70 mg BID for the treatment of cutaneous melanoma.<sup>5-7</sup>

## 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).<sup>1,8</sup>

## POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of dasatinib. 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
Phyrago® (dasatinib tablets)	100 mg tablets	30 tablets	90 tablets
	140 mg tablets	30 tablets	90 tablets

**EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.**

## CRITERIA

### Dasatinib (Sprycel, generic) and Phyrago 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 (Sprycel, generic) and Phyrago 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 (Sprycel, generic) and Phyrago 70 mg, 80 mg, 100 mg, and 140 mg tablets

No overrides recommended.

## REFERENCES

1. Sprycel tablets [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; July 2024.
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.
8. Phyrago® tablets [prescribing information]. San Jose, CA: Handa Therapeutics; August 2025.

## HISTORY

Type of Revision	Summary of Changes	Review Date
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
Annual Revision	<b>Policy Title:</b> The name of the policy was changed from Oncology – Dasatinib Drug Quantity Management Policy – Per Rx Policy to Oncology – Dasatinib Products Drug Quantity Management Policy – Per Rx Policy.  <b>Phyrago 20 mg, 50 mg, 70 mg, 80 mg, 100, mg, and 140 mg tablets:</b> Phyrago tablets were added to the policy. The same quantity limits and clinical overrides apply to Phyrago tablets as apply to Sprycel tablets.	02/04/2026

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