



PREFERRED SPECIALTY MANAGEMENT POLICY

- POLICY:** Oncology – Dasatinib Products Preferred Specialty Management Policy
- Phyrago® (dasatinib tablets – Handa)
 - Sprycel® (dasatinib tablets – Bristol-Myers Squibb, generic)

REVIEW DATE: 03/25/2026

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

- **Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia (ALL):**
 - In adults with resistance or intolerance to prior therapy.
 - In newly diagnosed pediatric patients ≥ 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 ≥ 1 year of age.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Product. For all medications (Preferred and Non-Preferred), the patient is required to meet the standard *Oncology – Dasatinib Products Prior Authorization Policy* criteria. The program also directs the patient to try the Preferred Product prior to the approval of the Non-Preferred Product. Requests for the Non-Preferred Product will also be reviewed using the exception criteria (below). If the patient meets the standard *Oncology – Dasatinib Products Prior Authorization Policy* criteria but has not tried a Preferred Product, approval for the Preferred Product will be authorized. All approvals are provided for the duration noted below.

Documentation: Documentation is required for previous use of the preferred drug as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information. All documentation must include patient-specific identifying information.

Preferred Product: generic dasatinib tablets
Non-Preferred Product: Phyrago, Sprycel

***Oncology – Dasatinib Products Preferred Specialty Management Policy* non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.**

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Phyrago	<p>1. Approve for 1 year if the patient meets BOTH of the following (A <u>and</u> B):</p> <ul style="list-style-type: none">A) Patient meets the standard <i>Oncology – Dasatinib Products Prior Authorization Policy</i> criteria; ANDB) Patient meets ONE of the following (i <u>or</u> ii):<ul style="list-style-type: none">i. Patient meets BOTH of the following (a <u>and</u> b):<ul style="list-style-type: none">a) Patient has tried generic dasatinib tablets [documentation required]; ANDb) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Non-Preferred and Preferred product which, according to the prescriber, would result in a significant allergy or

	<p>serious adverse reaction [documentation required]; OR</p> <p>ii. According to the prescriber, the patient requires co-administration with a histamine-2 (H2) antagonist or proton pump inhibitor (PPI). <u>Note:</u> Examples of H2 antagonists include famotidine, cimetidine, nizatidine. Examples of PPIs include omeprazole, esomeprazole, pantoprazole, rabeprazole.</p> <p>2. For a patient who has met the <i>Oncology – Dasatinib Products Prior Authorization Policy</i> criteria, but has not met exception criteria (1B) for brand Sprycel: approve generic dasatinib tablets.</p>
Sprycel	<p>1. Approve for 1 year if the patient meets ALL of the following (A, B, <u>and</u> C):</p> <p>A) Patient meets the standard <i>Oncology – Dasatinib Products Prior Authorization Policy</i> criteria; AND</p> <p>B) Patient has tried generic dasatinib tablets [documentation required]; AND</p> <p>C) Patient cannot continue to use the Preferred Product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction [documentation required].</p> <p>2. For a patient who has met the <i>Oncology – Dasatinib Products Prior Authorization Policy</i> criteria, but has not met exception criteria (1B) and (1C) for brand Sprycel: approve generic dasatinib tablets.</p>

REFERENCES

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

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	Effective date: 01/01/2025	10/02/2024
Annual Revision	No criteria changes.	10/01/2025
Selected Revision	Phyrago was added to policy as a non-preferred product. Phyrago: Exception criteria were added. Sprycel: The wording "between the brand and the bioequivalent generic product" was added to the following requirement, "Patient cannot continue to use the Preferred Product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.	11/19/2025
Selected Revision	Phyrago: For a patient who has tried dasatinib, the requirement that the patient cannot continue to use the Preferred Product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the preferred product which, per the prescriber, would result in a significant allergy or serious adverse reaction [documentation required] was removed. The option of approval which stated, "Patient is currently taking an H2 antagonist or proton pump inhibitor was revised to "according to the prescriber, the patient requires co-administration with a histamine-2 (H2) antagonist or proton pump inhibitor (PPI)."	12/03/2025
Early Annual Revision	The policy name was changed to as listed. Previously, it was Oncology – Dasatinib Preferred Specialty Management Policy. Phyrago: For a patient who has tried dasatinib, the requirement that the patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Non-Preferred and Preferred product which, according to the prescriber, would result in a significant allergy or serious adverse reaction [documentation required] was added.	03/25/2026

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