PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Dasatinib Products Prior Authorization 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:[1,10]

- **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.

Guidelines

Dasatinib is addressed in guidelines from National Comprehensive Cancer Network (NCCN):

- **ALL:** NCCN guidelines for adults and adolescents (version 2.2025 – June 27, 2025) recommend dasatinib for Ph+ disease in many different clinical circumstances (e.g., induction, consolidation therapy, maintenance, or relapsed or refractory disease) [category 2A].[2] NCCN guidelines for pediatric ALL (version 1.2026 – August 11, 2025) feature dasatinib prominently in a variety of clinical scenarios (mainly category 2A recommendations). The guidelines state to consider TKI-based regimen for *ABL*-class translocation for relapsed or refractory T-ALL (category 2A).[3]
- **Bone Cancer:** NCCN guidelines (version 2.2026 – December 19, 2025) recommend dasatinib for metastatic and widespread chondrosarcoma as "other recommended regimens" (category 2A).[4] Dasatinib is also recommended for recurrent conventional or chondroid chordoma as "other recommended regimens" (category 2A).
- **CML:** NCCN guidelines (version 1.2026 – July 16, 2025) recommend dasatinib as a "Preferred" primary treatment for newly diagnosed chronic phase Ph+ or *BCR::ABL1*-positive CML with a low-, intermediate-, or high-risk score (category 1).[5] Dasatinib is also recommended as an alternative TKI treatment (after primary treatment with imatinib, Bosulif® [bosutinib capsules and tablets], nilotinib, or Scemblix® [asciminib tablets]) [category 2A]. Dasatinib is also recommended in a variety of other situations, including post-allogeneic hematopoietic stem cell transplant (category 2A).
- **Gastrointestinal Stromal Tumor:** NCCN guidelines (version 1.2026 – January 13, 2026) recommend dasatinib as a second-line therapy as "other recommended regimens" for unresectable, progressive or metastatic disease in patients with platelet-derived growth factor receptor alpha *[PDGFRA]* exon 18 mutations that are insensitive to imatinib (including the *PDGFRA* D842V mutation) [category 2A]. First-line therapy in this setting is Ayvakit (avapritinib tablets).[6]
- **Melanoma: Cutaneous**: NCCN guidelines (version 1.2026 – February 17, 2026) recommend dasatinib as "useful in certain circumstances" for metastatic or unresectable disease with an activating *KIT* mutation as second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of progression with *BRAF*-targeted therapy (category 2A).[7]
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions:** NCCN guidelines (version 1.2026 – October 3, 2025) list dasatinib as a "Preferred" therapy for chronic phase or blast phase disease with an *ABL1* rearrangement (category 2A).[8,9] It is also recommended as treatment in combination with ALL- or acute myeloid leukemia-type induction chemotherapy followed by allogeneic hematopoietic stem cell transplantation (HCT) [if eligible] for lymphoid, myeloid or mixed lineage neoplasms with eosinophilia and *ABL1* rearrangement in blast phase (category 2A).[9]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of dasatinib products. All approvals are provided for the duration noted below.

- **Phyrago® (dasatinib tablets – Handa)**
- **Sprycel® (dasatinib tablets - Bristol-Myers Squibb; generic)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Acute Lymphoblastic Leukemia.** Approve for 1 year if the patient meets ONE of the following (A or B):
   A) Patient has Philadelphia chromosome-positive acute lymphoblastic leukemia; OR
   B) Patient has *ABL*-class translocation.

2. **Chronic Myeloid Leukemia.** Approve for 1 year if the patient meets ONE of the following (A or B):
   A) Patient has Philadelphia chromosome-positive chronic myeloid leukemia; OR
   B) Patient has *BCR::ABL1*-positive chronic myeloid leukemia.

Other Uses with Supportive Evidence

3. **Bone Cancer.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has chondrosarcoma or chordoma.

4. **Gastrointestinal Stromal Tumor.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried Ayvakit (avapritinib tablets).

5. **Melanoma, Cutaneous.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has metastatic or unresectable disease; AND
   C) Patient has an activating *KIT* mutation; AND
   D) Patient has tried at least one systemic regimen.
   Note: Examples of a systemic regimen include: Opdivo (nivolumab intravenous infusion) + Yervoy (ipilimumab intravenous infusion), Opdualag (nivolumab/relatlimab-rmbw intravenous infusion), Keytruda (pembrolizumab intravenous infusion), Opdivo, Tafinlar (dabrafenib capsules and oral tablets for suspension) + Mekinist (trametinib tablets and oral solution), Zelboraf (vemurafenib tablets) + Cotellic (cobimetinib tablets), Braftovi (encorafenib capsules) + Mektovi (binimetinib tablets).

6. **Myeloid/Lymphoid Neoplasms with Eosinophilia.** Approve for 1 year if the patient meets BOTH of the following (A and B):

A) Patient is ≥ 18 years of age; AND
B) The tumor has an *ABL1* rearrangement.

CONDITIONS NOT COVERED

- **Phyrago® (dasatinib tablets – Handa)**
- **Sprycel® (dasatinib tablets - Bristol-Myers Squibb; generic)**

is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Sprycel® tablets [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; July 2024.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2026 – August 11, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 19, 2026.
3. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2026 – August 11, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 19, 2026.
4. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 2.2026 – December 19, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 19, 2026.
5. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 1.2026 – July 16, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 18, 2026.
6. The NCCN Gastrointestinal Stromal Tumors Guidelines in Oncology (version 1.2026 – January 13, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 19, 2026.
7. The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 1.2026 – February 17, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 19, 2029.
8. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Clinical Practice Guidelines in Oncology (version 1.2026 – October 3, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 19, 2026.
9. The NCCN Drugs and Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Search term: dasatinib. Accessed on March 18, 2026.
10. 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.	05/01/2024
Selected Revision	Sprycel is available as generic dasatinib. Generic was added to the policy and changed brand "Sprycel" to "dasatinib" throughout the policy. Also changed document name to "Oncology – Dasatinib PA Policy."	10/02/2024
Annual Revision	**Acute Lymphoblastic Leukemia:** The following option for approval was added, "patient has *ABL*-class translocation." **Chronic Myeloid Leukemia:** The following option for approval was added, "patient has *BCR::ABL1*-positive chronic myeloid leukemia." **Melanoma, Cutaneous:** The following example of systemic regimen in the Note was modified from Opdivo + Opdualag	03/26/2025

	(nivolumab/relatlimab-rmbw intravenous infusion) to Opdualag (nivolumab/relatlimab-rmbw intravenous infusion).	
Selected Revision	Phyrago was added to the policy with the same criteria applied as those for the other dasatinib products. **Policy Title**: The name of the policy was changed from Oncology – Dasatinib PA (Prior Authorization) to Oncology – Dasatinib Products PA.	10/15/2025
Annual Revision	**Gastrointestinal Stromal Tumor:** Trial of "imatinib" was removed from the requirement that previously stated the patient has tried imatinib or Ayvakit (avapritinib tablets).	03/25/2026