PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Dasatinib Prior Authorization Policy
- Sprycel® (dasatinib tablets – Bristol-Myers Squibb; generic)

REVIEW DATE: 03/26/2025

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]

- **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 3.2024 – December 20, 2024) recommend dasatinib for Ph+ disease in many different clinical circumstances (e.g., induction, consolidation therapy, maintenance, or relapsed or refractory disease) [category 2A].[2] TKIs in combination with other

agents (e.g., chemotherapy or corticosteroids) are recommended for induction therapy for Ph+ ALL. TKIs have also been incorporated into consolidation and maintenance therapy, as well as in the relapsed/refractory setting (category 2A). TKI options include: Bosulif® (bosutinib tablets), dasatinib, imatinib, Tasigna (nilotinib capsules), or Iclusig® (ponatinib tablets) [category 2A]. NCCN panel notes that not all TKIs have been directly studied within the context of each specific regimen and there are limited data for Bosulif in Ph+ ALL. Use of a specific TKI should account for anticipated/prior TKI intolerance, dose used, *BCR::ABL1* mutations, and disease-related features. For adults and adolescents, Iclusig has activity against T315I mutations and/or in whom no other TKI is indicated (category 2A). NCCN guidelines for pediatric ALL (version 3.2025 – March 17, 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 2.2025 – February 28, 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 3.2025 – November 27, 2024) 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 tablets], Tasigna® [nilotinib capsules], 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 2.2024 – July 31, 2024) 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].[6]
- **Melanoma: Cutaneous**: NCCN guidelines (version 2.2025 – January 28, 2025) 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 1.2025 – February 21, 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. All approvals are provided for the duration noted below.

- **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 imatinib or 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), 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

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

is(are) considered experimental, investigational or unproven 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 3.2024 – December 20, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 18, 2025.
3. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 3.2025 – March 17, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 18, 2025.
4. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – February 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 18, 2025.
5. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 3.2025 – November 27, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 18, 2025.
6. The NCCN Gastrointestinal Stromal Tumors Guidelines in Oncology (version 2.2024 – July 31, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 18, 2025.
7. The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 2.2025 – January 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 18, 2025.
8. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Clinical Practice Guidelines in Oncology (version 1.2025 – February 21, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 18, 2025.
9. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Search term: dasatinib. Accessed on March 18, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Bone Cancer**: The condition of approval of chondrosarcoma or chordoma was reworded to bone cancer and criterion was added which states that patient has chondrosarcoma or chordoma. **Melanoma, Cutaneous:** This new condition of approval was added to "Other Uses With Supportive Evidence" section based on NCCN guideline recommendations.	05/31/2023
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	10/02/2024

	policy. Also changed document name to "Oncology – Dasatinib PA Policy."	
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 (nivolumab/relatlimab-rmbw intravenous infusion) to Opdualag (nivolumab/relatlimab-rmbw intravenous infusion).	03/26/2025