

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Dasatinib Prior Authorization Policy

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

REVIEW DATE: 05/01/2024; selected revision 10/02/2024

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 4.2023 – February 5, 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 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 5.2024 – April 3, 2024) feature dasatinib prominently in a variety of clinical scenarios (mainly category 2A recommendations).³
- **Bone Cancer:** NCCN guidelines (version 2.2024 – March 12, 2024) recommend dasatinib for patients with chondrosarcoma as “other recommended regimens” for a patient with metastatic and widespread disease (category 2A).⁴ Dasatinib is also recommended for recurrent conventional or chondroid chordoma as “other recommended regimens” (category 2A).
- **CML:** NCCN guidelines (version 2.2024 – December 5, 2023) recommend dasatinib as a “preferred” primary treatment for newly diagnosed chronic phase Ph+ 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], or Tasigna® [nilotinib capsules]) (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 1.2024 – March 8, 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 2.2024 – April 3, 2024) 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 1.2024 – December 21, 2023) 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of dasatinib is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Acute Lymphoblastic Leukemia.** Approve for 1 year if the patient has Philadelphia chromosome-positive acute lymphoblastic leukemia.
2. **Chronic Myeloid Leukemia.** Approve for 1 year if the patient has Philadelphia chromosome-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), Opdivo + Opdualag (nivolumab/relatlimab-rmbw intravenous infusion), Keytruda (pembrolizumab intravenous infusion), Opdivo, Tafenlar (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 RECOMMENDED FOR APPROVAL

Coverage of dasatinib is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Sprycel® tablets [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; February 2023.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 4.2023 – February 5, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on April 29, 2024.
3. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 5.2024 – April 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on April 29, 2024.
4. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 2.2024 – March 12, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on April 29, 2024.
5. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 2.2024 – December 5, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on April 29, 2024.
6. The NCCN Gastrointestinal Stromal Tumors Guidelines in Oncology (version 1.2024 – March 8, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on April 29, 2024.
7. The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 2.2024 – April 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on April 29, 2024.
8. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on April 29, 2024.
9. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Search term: dasatinib. Accessed on April 29, 2024.

