Generic Name: Nilotinib

Therapeutic Class or Brand Name: Tasigna®, Danziten®

Applicable Drugs (if Therapeutic class): Tasigna (nilotinib), Danziten (nilotinib)

Preferred: Tasigna

Non-preferred: Danziten

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 4/17/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documentation of the following diagnoses A and must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Chronic Myelogenous Leukemia (CML)

1. Documentation of Philadelphia chromosome-positive (Ph+) CML AND fulfills ONE of following patient criteria a through c:

a) CML is newly diagnosed and in chronic phase

(1) Minimum age requirement if request is for Tasigna: 1 year old and older

(2) Minimum age requirement if request is for Danziten: 18 years old and older

b) CML is either chronic phase (CP) or accelerated phase (AP) with documented resistance or intolerance to imatinib.

(1) Minimum age requirement if request is for Tasigna: 1 year old and older

(2) Minimum age requirement if request is for Danziten: 18 years old and older

c) CML is either chronic phase (CP) or accelerated phase (AP) and documentation of resistance or intolerance to prior tyrosine-kinase inhibitor (TKI) therapy.

(1) Minimum age requirement: 1 year old and older

(2) Request is for Tasigna.

Other Uses With Supportive Evidence (Tasigna only)

B. Acute lymphoblastic leukemia

C. CML - post allogenic hematopoietic cell transplant (HCT)

D. Gastrointestinal stromal tumors

E. Melanoma: cutaneous

F. Myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase gene fusions

G. Soft tissue sarcoma (pigmented villonodular synovitis/tenosynovial giant cell tumor

II. Treatment must be prescribed by or in consultation with an oncologist or a hematologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Patients with hypokalemia, hypomagnesemia, or long QT syndrome.
- Documentation of the following BCR-ABL1 kinase domain mutation subtypes (T3151, Y253H, E255K/V, F359V/C/I)
- Documentation of peripheral arterial occlusive disease.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantities are limited to a 30-day supply
- Tasigna
    - Capsules: 50 mg, 150 mg, 200 mg
    - Adult dose
        - Newly diagnosed Ph+ CML-CP: maximum dose 300 mg orally twice daily
        - Resistant or intolerant Ph+ CML-CP and CML-AP: maximum dose 400 mg orally twice daily
    - Pediatric dose
        - Newly diagnosed Ph+ CML-CP or resistant or intolerant Ph+ CML-CP and CML-AP: 230 mg/m2 orally twice daily, rounded to the nearest 50 mg dose (maximum single dose of 400 mg)
- Danziten
    - Tablets: 71 mg, 95 mg
        - Newly diagnosed Ph+ CML-CP: maximum dose 142 mg orally twice daily
        - Resistant or intolerant Ph+ CML-CP and CML-AP: maximum dose 190 mg orally twice daily

Approval Length

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

Appendix

N/A

References

1. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Chronic Myeloid Leukemia. Version 3.2025. Updated November 27, 2024 Accessed April 10, 2025. https://www.nccn.org/professionals/physician_gls/pdf/cml_blocks.pdf
2. Tasigna. Prescribing Information. Novartis Pharmaceuticals Corporation. February 2024. Accessed April 10, 2025. www.accessdata.fda.gov/drugsatfda_docs/label/2024/022068s041lbl.pdf
3. Danziten. Prescribing Information. Azurity Pharmaceuticals. November 2024. Accessed April 10, 2025. www.accessdata.fda.gov/drugsatfda_docs/label/219293s000lbl.pdf
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Acute Lymphoblastic Leukemia. Version 3.2024. Updated December 20, 2024. Accessed April 10, 2025. www.nccn.org/professionals/physician_gls/pdf/all.pdf
5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Gastrointestinal Stromal Tumors. Version 2.2024. Updated July 31, 2024. Accessed April 10, 2025. www.nccn.org/professionals/physician_gls/pdf/gist.pdf
6. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Melanoma: Cutaneous. Version 2.2025. Updated January 28, 2025. Accessed April 10, 2025. www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf
7. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions. Version 2.2025. Updated April 4, 2025. Accessed April 10, 2025. www.nccn.org/professionals/physician_gls/pdf/mlne.pdf
8. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Soft Tissue Sarcoma. Version 5.2024. Updated March 10, 2025. Accessed April 10, 2025. www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf