

Generic Name: Nilotinib

Therapeutic Class or Brand Name: Tasigna®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 11/9/2023

PRIOR AUTHORIZATION CRITERIA

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

- I. Documented diagnosis of Philadelphia chromosome-positive (Ph+) Chronic Myelogenous Leukemia (CML) AND fulfills ONE of following patient criteria A through C:
 - A. Adult or pediatric patient 1 year of age or older who is newly diagnosed and in chronic phase.
 - B. Adult patient both chronic phase (CP) and accelerated phase (AP) Ph+ CML with documented resistance or intolerance to imatinib.
 - C. Pediatric patient 1 year of age or older with chronic phase (CP) and accelerated phase (AP) Ph+ CML and documented resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy.
- 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 (T315I, Y253H, E255K/V, F359V/C/I)
- Documentation of peripheral arterial occlusive disease.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantities of up to 112 capsules per 28 days.

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 (NCCN) Guidelines Chronic Myeloid Leukemia. Version 1.2024, updated September 6, 2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cml_blocks.pdf
2. Tasigna® [Package Insert]. East Hanover, NJ: Novartis. November 2021. Available at: <http://www.pharma.us.novartis.com/product/pi/pdf/tasigna.pdf> .

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.