Tasigna (nilotinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Tasigna (nilotinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Tasigna (nilotinib) may be approved if the following criteria are met**:**

I. Individual is 1 year of age or older (Label, NCCN 2A); **AND**
II. Individual has newly diagnosed, low risk, chronic phase (CP) Philadelphia chromosome positive Chronic Myeloid Leukemia (Ph+CML); **AND**
III. Individual does not have any of the following mutations:
   A. T315I; **OR**
   B. Y253H; **OR**
   C. E255K/V; **OR**
   D. F359V/C/I; **OR**
   E. G250E;

AND

1. Individual has been receiving and is maintained on a stable dose of Tasigna. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

OR

2. Individual has had a trial and inadequate response or intolerance to generic imatinib. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

OR

3. Individual has resistance, contraindication or warning to generic imatinib due to current clinical conditions, including but not limited to pulmonary arterial hypertension, pleural or pericardial effusion, or cardiac abnormalities;

OR

IV. Individual is 1 year of age or older (Label, NCCN 2A); **AND**
V. Individual has newly diagnosed, intermediate or high risk, chronic phase (CP) Philadelphia chromosome positive Chronic Myeloid Leukemia (Ph+CML); **AND**
VI. Individual does not have any of the following mutations:

A. T315I; **OR**
B. Y253H; **OR**
C. E255K/V; **OR**
D. F359V/C/I; **OR**
E. G250E;

OR

VII. Individual has newly diagnosed, accelerated phase (AP) or blast phase (BP) Philadelphia chromosome positive Chronic Myeloid Leukemia (Ph+CML) (NCCN 2A); **AND**

VIII. Individual does not have any of the following BCR-ABL1 mutations:
A. T315I; **OR**
B. Y253H; **OR**
C. E255K/V; **OR**
D. F359V/C/I; **OR**
E. G250E;

OR

IX. Individual has a diagnosis of chronic phase (CP), accelerated phase (AP), or blast phase (BP) Philadelphia chromosome positive Chronic Myeloid Leukemia (Ph+ CML) and is using as alternate treatment after prior treatment with asciminib, imatinib, bosutinib, or nilotinib (Label, NCCN 2A); **AND**

X. Individual does not have any of the following mutations:
A. T315I; **OR**
B. Y253H; **OR**
C. E255K/V; **OR**
D. F359V/C/I; **OR**
E. G250E;

OR

XI. Individual has a diagnosis of Philadelphia chromosome positive Chronic Myeloid Leukemia (Ph+CML) and is using as maintenance or continuation of therapy (NCCN 2A);

OR

XII. Individual has a diagnosis of Philadelphia chromosome positive Acute Lymphoblastic Leukemia (Ph+ ALL) and is using in maintenance therapy; **AND**

XIII. Individual is using in combination with vincristine and prednisone with or without methotrexate and mercaptopurine;

OR

XIV. Individual has a diagnosis of Philadelphia chromosome positive Acute Lymphoblastic Leukemia (Ph+ALL); **AND**

XV. Individual is using post-hematopoietic stem cell transplant;

OR

XVI. Individual has a diagnosis of Philadelphia chromosome positive Acute Lymphoblastic Leukemia (Ph+ALL) and is using in relapsed/refractory disease; **AND**

XVII. Individual does not have any of the following mutations (NCCN 2A):

A. T315I; **OR**
B. Y253H; **OR**
C. E255K/V; **OR**
D. F359V/C/I; **OR**
E. G250E;

OR

XVIII. Individual has a diagnosis of Philadelphia chromosome positive Acute Lymphoblastic Leukemia (Ph+ALL) and is using Tasigna (nilotinib HCl) as a component of either induction therapy or in induction/consolidation therapy (NCCN 2A); **AND**

A. T315I; **OR**
B. Y253H; **OR**
C. E255K/V; **OR**
D. F359V/C/I; **OR**
E. G250E;

OR

XIX. Individual has a diagnosis of Gastrointestinal Stromal Tumors (GIST) (NCCN 2A); **AND**

XX. Individual is no longer receiving benefit from imatinib, sunitinib, and regorafenib (NCCN 2A);

OR

XXI. Individual has a diagnosis of metastatic or unresectable cutaneous melanoma (NCCN 2A); **AND**

XXII. Individual has activating mutations of KIT; **AND**

XXIII. Individual is using as a single agent;

OR

XXIV. Individual has a diagnosis of pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT) (NCCN 2A); **AND**

XXV. Individual is using as a single agent;

OR

XXVI. Individual has a diagnosis for myeloid/lymphoid neoplasm chronic or blast phase with eosinophilia (NCCN 2A); **AND**

XXVII. Individual has ABL1 rearrangement.

Note:
Tasigna (nilotinib) has black box warnings for QT prolongation and sudden death. ECGs to monitor the QTc, should be performed at baseline, seven days after initiation, following any dose adjustments, and periodically thereafter. The use of concomitant drugs known to prolong

the QT interval and strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin, atazanavir, indinavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, voriconazole) should be avoided. Therapy should not be administered to individuals with hypokalemia, hypomagnesium, or long QT syndrome. Prior to administration and periodically during therapy, hypokalemia and hypomagnesemia should be monitored for and deficiencies corrected if occurs.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2025. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. 2025. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. 2025. Updated periodically.
    a. Acute Lymphoblastic Leukemia. V3.2024. Revised December 20, 2024.
    b. Chronic Myeloid Leukemia. V3.2025. Revised November 27, 2024.
    c. Gastrointestinal Stromal Tumors (GIST). V2.2024. Revised July 31, 2024.
    d. Melanoma: Cutaneous. V1.2025. Revised December 20, 2024.
    e. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes. V2.2024. Revised June 19, 2024.
    f. Soft Tissue Sarcoma. V4.2024. Revised November 21, 2024.
6. Schwaab J, Naumann N, Luebke J, et. al. Response to tyrosine kinase inhibitors in myeloid neoplasms associated with PCM1-JAK2, BCR-JAK2 and ETV6-ABL1 fusion genes. Am J. Hematol 2020;95:824-833. Accessed on January 15, 2021.
7. Kang YK, Ryu MH, Yoo C, et al. Resumption of imatinib to control metastatic or unresectable gastrointestinal stromal tumours after failure of imatinib and sunitinib (RIGHT): a randomised, placebo-controlled, phase 3 trial. *Lancet Oncol*. 2013;14(12):1175-1182. doi:10.1016/S1470-2045(13)70453-4. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4347867/pdf/nihms665683.pdf Accessed January 16, 2023.
8. Gelderblom H, Cropet C, Chevreau C, et al. Nilotinib in locally advanced pigmented villonodular synovitis: a multicentre, open-label, single-arm, phase 2 trial. *Lancet Oncol*. 2018;19(5):639-648. doi:10.1016/S1470-2045(18)30143-8

Spierenburg G, Grimison P, Chevreau C, et al. Long-term follow-up of nilotinib in patients with advanced tenosynovial giant cell tumours: Long-term follow-up of nilotinib in TGCT. *Eur J Cancer*. 2022;173:219-228. doi:10.1016/j.ejca.2022.06.028

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