Evolent Clinical Guideline 3111 for Tasigna™ (nilotinib)

Guideline Number:	Applicable Codes	
Evolent_CG_3111		
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Original Date:	**Last Revised Date:**	**Implementation Date:**
January 2012	June 2025	June 2025

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STATEMENT

Purpose

To define and describe the accepted indications for Tasigna (nilotinib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Acute Lymphoblastic Leukemia (ALL)

- The member has Philadelphia chromosome positive or BCR-ABL positive B-Cell ALL and Tasigna (nilotinib) may be used as a single agent or in combination with chemotherapy as induction, consolidation, maintenance, or subsequent therapy.

Chronic Myeloid Leukemia (CML)

- The member has CML (Philadelphia chromosome or BCR-ABL positive) and Tasigna (nilotinib) may be used as a single agent as initial or subsequent therapy.

CONTRAINDICATIONS/WARNINGS

- Contraindications
  - Tasigna (nilotinib) is contraindicated in patients with hypokalemia, hypomagnesemia, or long QT syndrome.
- US Boxed Warning
  - QT Prolongation and Sudden Deaths
    - Tasigna (nilotinib) prolongs the QT interval. Prior to Tasigna (nilotinib) administration and periodically, monitor for hypokalemia or hypomagnesemia and correct deficiencies. Obtain ECGs to monitor the QTc at baseline, 7 days

after initiation, and periodically thereafter, and following any dose adjustments. Sudden deaths have been reported in patients receiving nilotinib. Do not administer nilotinib to patients with hypokalemia, hypomagnesemia, or long QT syndrome. Avoid use of concomitant drugs known to prolong the QT interval and strong CYP3A4 inhibitors.

- Avoid food 2 hours before and 1 hour after taking a Tasigna (nilotinib) dose.

EXCLUSION CRITERIA

- The member has Philadelphia chromosome or BCR-ABL negative CML or ALL.
- Member has disease progression while taking Tasigna (nilotinib).
- Tasigna (nilotinib) is contraindicated for use in members with the following mutations of BCR-ABL1: T315I, Y253H, E255K/V, F359V/C/I or G250E.
- Dosing exceeds single dose limit of Tasigna (nilotinib) 400 mg.
- Treatment exceeds the maximum limit of 240 (50 mg), 112 (150 mg), or 112 (200 mg) capsules per month.
- Investigational use of Tasigna (nilotinib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
  - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
  - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
  - Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
  - Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
  - That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
  - That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
  - That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

CODING AND STANDARDS

Codes

- J8999 - nilotinib

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
June 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1199 Tasigna (nilotinib) • Updated indication section • Updated maximum dosage form quantities in exclusion criteria • Updated exclusion criteria • Updated references
June 2024	• Updated NCH verbiage to Evolent

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent

uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

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6. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2025.
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8. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: **https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf**.
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