Prior Authorization Approval Criteria

Tasigna (Nilotinib)

**Generic name:** Nilotinib

**Brand name:** Tasigna

**Medication class:** Antineoplastic agent (Tyrosine kinase inhibitor)

**FDA-approved uses:**
- Newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.
- Chronic phase and accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia resistant to or intolerant to prior therapy that included imatinib.

**Criteria for approval (bullet points below are all inclusive unless otherwise noted):**
- Must be prescribed by an oncologist or hematologist
- Must be 18 years of age or older.
- Must not have hypokalemia, hypomagnesemia, or long QT syndrome
- Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.

**Or**
- Clinically diagnosed with chronic phase or accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia and
- Failure/intolerance/contraindication to imatinib

**Criteria for continuation of therapy:**
- Patient’s therapy has been re-evaluated within the last 12 months, unless a re-evaluation is not clinically appropriate for the patient’s condition at this time.
- Patient is tolerating treatment
- Patient has disease stabilization or improvement in disease (as defined by standard parameters for the patient’s condition)

**Special Considerations:**
- FDA’s approval of Tasigna includes a black box warning for possible life-threatening heart problems that may lead to an irregular heartbeat and possible sudden death.

**Approval Duration:**
- Initial 6 months
- Renewal 12 months

**Benefit Type:**
- Pharmacy

**Off-label Use:**
Fallon may authorize coverage of the requested medication for use in other cancer diagnoses with submitted documentation that the drug is recognized as a “Medically Accepted Indication” according to...
the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium as indicated by a Category 1 or 2A for quality of evidence and level of consensus.

If the requested off-label use is not acknowledged by the NCCN Drugs and Biologics Compendium, Fallon will abide by the Centers for Medicare and Medicaid Services (CMS) guidance or Massachusetts regulations¹ accepting documentation of recommended off-label use of the requested medication in any one of the following:

1. One of the following standard reference compendia:
   - American Hospital Formulary Service – Drug information (AHFS-DI)
   - Thomson Micromedex DrugDex
   - Clinical Pharmacology (Gold Standard)
   - Wolters Kluwer Lexi-Drugs

2. Peer-reviewed published medical literature determined by Fallon that sufficient evidence exists to support use.

¹Reference:  [https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter175/Section47K](https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter175/Section47K)
accessed 7/7/2017

Adopted: 12/10/14
Reviewed: 2/10/15, 9/13/17: updated criteria for approval; added contraindication, updated continuation of therapy, approval duration, and benefit type.