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 criteria listed above applies to Fallon Health Plan and its subsidiaries.
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 indicating that sufficient evidence exists to support use.

¹Reference: 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.
Reviewed: 11/28/17 – for peer reviewed literature, replaced “determined by Fallon” with “indicating”

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