

# Criteria-Based Consultation Prescribing Program

## CRITERIA FOR DRUG COVERAGE

### Nilotinib (Tasigna)

#### Notes:

- Quantity Limits: Yes
- ^ Adequate trial is defined as three months duration
- \* Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- + Initial approval for 36 months
- \*\* Approval for 12 months
- \*\* continued use criteria is not required for diagnoses other than chronic-phase CML

**Initiation (new start) criteria:** Formulary **nilotinib (Tasigna)** will be covered on the prescription drug benefit when the following criteria are met:

- Patient is 18 years of age or older
  - Medication is ordered by a hematologist/oncologist
  - Patient has diagnosis of:
    - Chronic-phase chronic myeloid leukemia (CML)<sup>+</sup>
      - Patient failed an adequate trial<sup>^</sup> of imatinib and dasatinib or has an allergy or intolerance\* to imatinib and dasatinib
      - Absence of the following mutations: T315I, Y253H, E255K, E255V, F359V, F359C, or F359I
- OR-
- Accelerated-phase chronic myeloid leukemia (CML)
    - Patient failed an adequate trial<sup>^</sup> of dasatinib or has an allergy or intolerance\* to dasatinib
    - Absence of the following mutations: T315I, Y253H, E255K, E255V, F359V, F359C, or F359I
- OR-
- Blast-phase chronic myeloid leukemia (CML)
    - Patient failed an adequate trial<sup>^</sup> of dasatinib or has an allergy or intolerance\* to dasatinib
    - Absence of the following mutations: T315I, Y253H, E255K, E255V, F359V, F359C, or F359I

-OR-

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# Criteria-Based Consultation Prescribing Program

## CRITERIA FOR DRUG COVERAGE

### Nilotinib (Tasigna)

- Philadelphia chromosome-positive acute lymphoblastic leukemia (ALL)
  - Patient failed an adequate trial^ of treatment regimen that included dasatinib or has an allergy or intolerance\* to dasatinib
  - Absence of the following mutations: T315I, Y253H, G250E, E255K, E255V, F359V, F359C, or F359I

-OR-

- Unresectable, progressive, or metastatic gastrointestinal stromal tumor (GIST)
  - Patient failed previous treatment with imatinib, sunitinib, regorafenib, and ripretinib

**Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:** Formulary **nilotinib (Tasigna)**

will be covered on the prescription drug benefit when the following criteria are met:

- Patient is 18 years of age or greater
- Medication is prescribed by hematology/oncology
- Patient has a diagnosis of one of the following:
  - Chronic-phase chronic myeloid leukemia (CML)\*\*
  - Accelerated-phase chronic myeloid leukemia (CML)
  - Blast-phase chronic myeloid leukemia (CML)
  - Philadelphia chromosome-positive acute lymphoblastic leukemia
  - Unresectable, progressive, or metastatic gastrointestinal stromal tumor

**Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication**<sup>±</sup>: Formulary **nilotinib (Tasigna)** will continue to

be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Patient is 18 years of age or greater
- Medication is prescribed by a hematologist/oncologist
- Patient has a diagnosis of Chronic-phase chronic myeloid leukemia (CML)
- Patient is not a candidate for TKI discontinuation OR patients refuses to discontinue TKI