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

<u>Initiation (new start) criteria</u>: 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)⁺
 - Patient failed an adequate trial[^] 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[^] of dasatinib or has an allergy or intolerance^{*} to dasatinib
 - Absence of the following mutations: T315I, Y253H, E255K, E255V, F359V, F359C, or F359I

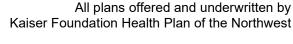
-OR-

- Blast-phase chronic myeloid leukemia (CML)
 - Patient failed an adequate trial[^] 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 **: 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

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