

# Criteria-Based Consultation Prescribing Program

## CRITERIA FOR DRUG COVERAGE

### Ponatinib (Iclusig)

#### 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:** Non-formulary **ponatinib (Iclusig)** 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 or has an allergy or intolerance<sup>\*</sup> to imatinib
    - Presence of T315I mutation
  - OR-
  - Accelerated-phase chronic myeloid leukemia (CML)
    - Patient failed an adequate trial<sup>^</sup> of dasatinib, nilotinib, or bosutinib or has an allergy or intolerance<sup>\*</sup> to dasatinib, nilotinib, or bosutinib
    - Presence of T315I mutation
  - OR-
  - Blast-phase chronic myeloid leukemia (CML)
    - Patient failed an adequate trial<sup>^</sup> of imatinib, dasatinib, nilotinib, or bosutinib or has an allergy or intolerance<sup>\*</sup> to imatinib, dasatinib, nilotinib, or bosutinib
    - OR-
    - Presence of T315I mutation
  - OR-
  - Philadelphia chromosome-positive acute lymphoblastic leukemia (ALL)

# Criteria-Based Consultation Prescribing Program

## CRITERIA FOR DRUG COVERAGE

### Ponatinib (Iclusig)

- Patient failed an adequate trial<sup>^</sup> of treatment regimen that included dasatinib or has an allergy or intolerance\* to dasatinib  
-OR-
- Per oncologist judgment, patient is younger and without cardiovascular risk factors  
-OR-
- Presence of T315I mutation

**Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:** Non-formulary ponatinib (Iclusig) 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

**Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication\*\*:** Non-formulary ponatinib (Iclusig) 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