

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Asciminib (Scemblix)

Notes:

- Quantity Limits: Yes
- Take on an empty stomach – avoid food consumption for at least two hours before and one hour after taking asciminib.
- ^ Adequate trial is defined as three months treatment
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- + Appropriate second-line TKIs are dependent on mutation profile. Refer to the Kaiser National Oncology CML Treatment Pathway

Initiation (new start) criteria: Non-formulary **asciminib (Scemblix)** will be covered on the prescription drug benefit for 36 months when the following criteria are met:

- Patient is 18 years of age or older **AND**
- Medication is ordered by a hematologist/oncologist **AND**
- Patient has a diagnosis of: Philadelphia chromosome-positive, chronic phase chronic myeloid leukemia (CML) **WITHOUT** a T315I mutation **AND**
 - Patient failed an adequate trial[^] of imatinib or has an allergy or intolerance to imatinib **AND** BCR-ABL is $\geq 10\%$
 - Patient failed an adequate trial[^] of an appropriate second-line tyrosine kinase inhibitor⁺ (e.g., dasatinib, nilotinib, or bosutinib) or has an allergy or intolerance to second-line treatment options

OR

- Patient has a diagnosis of Philadelphia chromosome-positive, chronic phase chronic myeloid leukemia (CML) **WITH** a T315I mutation
 - Patient failed an adequate trial[^] of ponatinib or has an allergy or intolerance to ponatinib
 - Patient does not have a A337T or P465S mutation

Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously: Non-formulary **asciminib (Scemblix)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Patient is 18 years of age or greater

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- Medication is prescribed by hematology/oncology
- Patient has a diagnosis Philadelphia chromosome-positive CML
- Patient is not a candidate for TKI discontinuation OR patient refuses to discontinue TKI

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **asciminib (Scemblix)** will 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 hematology/oncology
- Patient has a diagnosis Philadelphia chromosome-positive CML

Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication: Non-formulary **asciminib (Scemblix)** will continue to be covered on the prescription drug benefit for 12 months when all of 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 CML
- Patient is not a candidate for TKI discontinuation OR patients refuses to discontinue TKI