

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Dasatinib (Sprycel)

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 **dasatinib (Sprycel)** 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 a diagnosis of:
 - Philadelphia chromosome-positive acute lymphoblastic leukemia
 - OR-
 - Unresectable, progressive, or metastatic gastrointestinal stromal tumor
 - Patient failed previous treatment with imatinib or avapritinib
 - Tumor with PDGFRA exon 18 mutation (excluding PDGFR D842V mutation) that is insensitive to imatinib
 - OR-
 - Chronic-phase chronic myeloid leukemia (CML)+
 - Patient failed an adequate trial[^] of imatinib or has an allergy or intolerance to imatinib
 - BCR-ABL is 10% or greater
 - Absence of T315I mutation
 - OR-
 - Accelerated-phase chronic myeloid leukemia (CML)
 - De novo AND absence of the following mutations: F317C, F317I, F317L, F317V, T315A, T315I, V299L
 - OR-
 - Blast-phase chronic myeloid leukemia (CML)
 - Administered in combination with intensive chemotherapy AND absence of the following mutations: F317C, F317I, F317L, F317V, T315A, T315I, V299L

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- Not a candidate for intensive chemotherapy and given as monotherapy or with a steroid AND absence of the following mutations: F317C, F317I, F317L, F317V, T315A, T315I, V299L

Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously: Formulary **dasatinib (Sprycel)** will be covered on the prescription drug benefit for 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:
 - Philadelphia chromosome-positive acute lymphoblastic leukemia
 - Unresectable, progressive, or metastatic gastrointestinal stromal tumor
 - Chronic-phase chronic myeloid leukemia (CML)**
 - Accelerated-phase chronic myeloid leukemia (CML)
 - Blast-phase chronic myeloid leukemia (CML)

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Formulary **dasatinib (Sprycel)** will be covered on the prescription drug benefit for when the following criteria are met:

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

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Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication:** Formulary **dasatinib (Sprycel)** 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 chronic myeloid leukemia (CML)
- Patient is not a candidate for TKI discontinuation OR patients refuses to discontinue TKI