Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

TASIGNA® (nilotinib)

GPI CODING:

215340600001**

DESCRIPTION:

Tasigna is an oral tyrosine kinase inhibitor indicated for the treatment of chronic myelogenous leukemia in adults who have resistance or intolerance to previous treatment that included Gleevec (imatinib).

APPROVAL DURATION:

Approval duration: 1 year

CRITERIA FOR TASIGNA

I. Treatment of newly diagnosed adult patients with chronic myelogenous leukemia (CML) in chronic phase
   A. Cytogenetic and/or molecular testing to detect Ph chromosome or BCR-ABL gene was performed and result was positive

OR

II. Treatment of chronic phase and accelerated phase Ph+ CML in adult patients resistant or intolerant to prior therapy that included imatinib
   A. T315I mutation testing was performed and result was negative

Compendial Uses

I. Treatment of patients with advanced phase CML (accelerated or blast phase) **OR**
II. Follow-up therapy for CML patients in relapse after hematopoietic stem cell transplant (HSCT) **OR**
III. Follow-up therapy for CML patients resistant to primary therapy with dasatinib and T315I mutation testing was negative **OR**
IV. CML patients with severe nonhematologic toxicity due to dasatinib and T315I mutation testing was negative **OR**
V. Relapsed/refractory Ph+ acute lymphoblastic leukemia (ALL) **OR**
VI. Gastrointestinal stromal tumor (GIST) in patients with disease progression on imatinib or sunitinib **OR**
VII. Off label uses for oncology drugs if considered medically acceptable in one or more of the following compendia (i.e., Micromedex DrugDex, AHFS, Clinical Pharmacology, and NCCN.) A use is identified by a compendium as medically accepted if the:
   A. Indication is a Category 1 or 2A in NCCN,
   B. Indication is a Class I, Class IIa or Class IIb in DrugDex,
   C. Narrative text in AHFS or Clinical Pharmacology is supportive; or
   D. The use is supported by clinical research in 2 or more peer-reviewed medical journals

Additional Criteria

I. Age 18 years or older **AND**

II. Patient does not have hypokalemia/hypomagnesemia or hypokalemia/hypomagnesemia will be corrected prior to Tasigna administration **AND**
III. ECG will be monitored at baseline, 7 days after initiation and periodically during treatment **AND**
IV. Patient does not have long QT syndrome **AND**
V. Patient is not receiving any drugs known to prolong the QT interval or any strong CYP3A4 inhibitors **AND**
VI. Patient has been instructed to take Tasigna 1 hour before or 2 hours after a meal **AND**
VII. If patient has hepatic impairment, prescriber will consider a lower starting dose **AND**

Authorizations for continued use in second-line CML therapy ≥ 12 months duration (chronic phase): no evidence of disease progression.
Authorizations for continued use in first-line CML therapy ≥ 12 to 24 months duration (chronic phase): complete or partial cytogenetic response has been achieved AND for continuation of therapy ≥ 24 months duration (chronic phase): no evidence of disease progression