Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

ICLUSIG® (ponatinib)

GPI CODING:

21534075100320
21534075100340

DESCRIPTION:

Ponatinib is a tyrosine kinase inhibitor Iclusig (ponatinib) is indicated for the treatment of adult patients with chronic phase, accelerated phase, or blast phase chronic myelogenous leukemia (CML) that is resistant or intolerant to prior tyrosine kinase inhibitor therapy or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) that is resistant or intolerant to prior tyrosine kinase inhibitor therapy.

APPROVAL DURATION:

Initial approvals and renewals: 12 months
Quantity limit: 2 tablets/day

CRITERIA FOR ICLUSIG:

I. Patient is 18 years of age or older

AND

II. Patient has a diagnosis of chronic myelogenous leukemia **AND**

III. Patient has tried and failed or had an intolerance to a first-line tyrosine kinase inhibitor (i.e. Gleevec [imatinib], Sprycel [dasatinib] or Tasigna [nilotinib]) OR patient has T3151 mutation

OR

IV. Patient has a diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) **AND**

V. Patient has tried and failed or had an intolerance to a previous tyrosine kinase inhibitor (i.e. Gleevec [imatinib] or Sprycel [dasatinib])

OR

VI. Off label uses for oncology drugs are approvable 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

Authorization for continued use shall be reviewed at least every 12 months to confirm the following: patient has experienced a measurable response to therapy.