

ICLUSIG (ponatinib)

Pre - PA Allowance

None

Prior-Approval Require

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

- 1. T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
 - a. Used as monotherapy
- 2. Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
 - a. No other tyrosine kinase (TKI) therapy is indicated
 - b. Used as monotherapy
- 3. Newly-diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
 - a. Used in combination with chemotherapy
- 4. T315I-positive chronic myeloid leukemia (CML)a. At least 6 months prior to request for treatment
- 5. Chronic phase (CP) chronic myeloid leukemia (CML)a. Resistant or intolerant to at least two prior tyrosine kinase inhibitors
- Accelerated phase (AP) or blast phase (BP) chronic myeloid leukemia (CML)
 a. No other tyrosine kinase (TKI) therapy is indicated
- **AND ALL** of the following:
 - a. Prescriber agrees to monitor for evidence of thromboembolism and vascular occlusion
 - b. Cardiac function will be monitored
 - c. Hepatic function will be monitored
 - d. Complete blood count will be monitored
 - e. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Iclusig and for 3 weeks after the final dose



Prior - Approval Limits

Quantity 45 mg per day

Duration 12 months

Prior – Approval Renewal Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

- 1. T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
 - a. Used as monotherapy
- Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
 a. No other tyrosine kinase (TKI) therapy is indicated
 - b. Used as monotherapy
- Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
 a. Used in combination with chemotherapy
- 4. T315I-positive chronic myeloid leukemia (CML)
- 5. Chronic phase (CP) chronic myeloid leukemia (CML)a. Resistant or intolerant to at least two prior tyrosine kinase inhibitors
- Accelerated phase (AP) or blast phase (BP) chronic myeloid leukemia (CML)
 a. No other tyrosine kinase (TKI) therapy is indicated

AND NONE of the following:

- a. Thromboembolic events or vascular occlusions while being treated with Iclusig
- b. Heart failure while being treated with Iclusig
- c. Hepatotoxicity while being treated with Iclusig
- **AND ALL** of the following:
 - a. Complete blood count will be monitored



b. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Iclusig and for 3 weeks after the final dose

Prior - Approval Renewal Limits

Same as above