Clinical Policy: Ponatinib (Iclusig)

Reference Number: PA.CP.PHAR.112
Effective Date: 01/18
Last Review Date: 04/19 Revision Log

Description
Ponatinib (Iclusig®) is a kinase inhibitor.

FDA Approved Indication(s)
Iclusig is indicated for:

- Treatment of adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) or Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) for whom no other tyrosine kinase inhibitor (TKI) therapy is indicated.
- Treatment of adult patients with T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Ph+ ALL.

Limitation(s) of use: Iclusig is not indicated and is not recommended for the treatment of patients with newly diagnosed chronic phase CML.

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness that Iclusig is **medically necessary** when one of the following criteria are met:

I. Initial Approval Criteria

A. Chronic Myelogenous Leukemia (must meet all):

1. Diagnosis of Ph+ (BCR-ABL1-positive) chronic myelogenous leukemia (CML);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a or b):
   a. Dose does not exceed 45 mg per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration: 6 months

B. Acute Lymphoblastic Leukemia (must meet all):

1. Diagnosis of Ph+ (BCR-ABL1-positive) acute lymphoblastic leukemia (ALL);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Request meets one of the following (a or b):
   a. Dose does not exceed 45 mg per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration: 6 months

C. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 45 mg per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PMN.53

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALL: acute lymphoblastic leukemia
CML: chronic myelogenous leukemia
FDA: Food and Drug Administration
Ph+: Philadelphia chromosome-positive

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): arterial occlusion, venous thromboembolism, heart failure, hepatotoxicity

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Ph+ CML and Ph+ ALL	Starting dose 45 mg PO QD	45 mg/day

V. Product Availability

Tablets: 15 mg, 45 mg

VI. References

1. Iclusig Prescribing Information. Cambridge, MA: Ariad Pharmaceuticals, Inc.; October 2018. Available at http://www.iclusig.com/pi. Accessed February 5, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 5, 2019.
3. National Comprehensive Cancer Network Guidelines. Chronic Myeloid Leukemia Version 1.2019. Available at www.nccn.org. Accessed February 5, 2019.
4. National Comprehensive Cancer Network Guidelines. Acute Lymphoblastic Leukemia Version 1.2018. Available at www.nccn.org. Accessed February 5, 2019.

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: no significant changes;; added age (CML), added COC statement; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; references reviewed and updated.	02.13.18	
2Q 2019 annual review: Ph+ designation added to CML; hematologist added to CML/ALL criteria; references reviewed and updated.	04/19	