

Clinical Policy: Ponatinib (Iclusig)

Reference Number: PA.CP.PHAR.112

Effective Date: 01/18

Last Review Date: 04/18

[Revision Log](#)

Description

The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness[®] clinical policy for ponatinib (Iclusig[®]).

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 chronic myelogenous leukemia (CML);
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Prescribed dose of Iclusig does not exceed 45 mg once daily.

Approval duration: 6 months

B. Acute Lymphoblastic Leukemia (must meet all):

1. Diagnosis of Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia (ALL);
2. Prescribed by or in consultation with an oncologist;
- 3.
4. Prescribed dose of Iclusig does not exceed 45 mg once daily.

Approval duration: 6 months

C. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

A. Chronic Myelogenous Leukemia/Acute Lymphoblastic Leukemia (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. Documentation of positive response to therapy (e.g., no disease progression or unacceptable toxicity);
3. Prescribed dose of Iclusig does not exceed 45 mg once daily.

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.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:

Ponatinib is a kinase inhibitor. Ponatinib inhibited the *in vitro* tyrosine kinase activity of ABL and T315I mutant ABL with IC₅₀ concentrations of 0.4 and 2.0 nM, respectively. Ponatinib inhibited the *in vitro* activity of additional kinases with IC₅₀ concentrations between 0.1 and 20 nM, including members of the vascular endothelial growth factor receptor, platelet-derived growth factor receptor, fibroblast growth factor receptor, ephrin receptors and sarcoma families of kinases, and KIT, RET, TIE2, and FLT3. Ponatinib inhibited the *in vitro* viability of cells expressing native or mutant BCR-ABL, including T315I. In mice, treatment with ponatinib reduced the size of tumors expressing native or T315I mutant BCR-ABL when compared to controls.

Formulations:

Iclusig oral tablets: 15 mg, 45 mg

Appendices

Appendix A: Abbreviation Key

ALL: acute lymphoblastic leukemia
CML: chronic myelogenous leukemia

Ph+: Philadelphia chromosome positive
TKI: tyrosine kinase inhibitor

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	

References

1. Iclusig Prescribing Information. Cambridge, MA: Ariad Pharmaceuticals, Inc.; November 2016. Available at <http://www.iclusig.com/pi>. Accessed February 2018.
2. Ponatinib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed February 2018.
3. Chronic myelogenous leukemia (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed February 2018.
4. Acute lymphoblastic leukemia (Version 2.2016). In: National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed February 2018.