Clinical Policy: Ponatinib (Iclusig)

Reference Number: ERX.SPA.17
Effective Date: 07.01.16
Last Review Date: 05.20
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Iclusig is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Myelogenous Leukemia (must meet all)**:**

1. Diagnosis of Ph+ (BCR-ABL1-positive) 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

B. Acute Lymphoblastic Leukemia (must meet all)**:**

1. Diagnosis of Ph+ (BCR-ABL1-positive) 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

C. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Iclusig for a covered indication and has received this medication for at least 30 days;
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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. 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

V. Dosage and Administration

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

VI. Product Availability

Tablets: 15 mg, 45 mg

VII. References

1. Iclusig Prescribing Information. Cambridge, MA: Ariad Pharmaceuticals, Inc.; January 2020. Available at http://www.iclusig.com/pi. Accessed February 10, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 10, 2020.
3. National Comprehensive Cancer Network Guidelines. Chronic Myeloid Leukemia Version 3.2020. Available at www.nccn.org. Accessed February 10, 2020.
4. National Comprehensive Cancer Network Guidelines. Acute Lymphoblastic Leukemia Version 1.2020. Available at www.nccn.org. Accessed February 10, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	05.16	06.16
Increased approval durations from 3/6 months to 6/12 months.	04.17	05.17
2Q 2018 annual review: specialist involvement in care added; age (CML) added, COC statement added; NCCN and FDA approved uses summarized for improved clarity; approval durations increased to length of benefit; references updated.	02.13.18	05.18
2Q 2019 annual review: Ph+ designation added to CML; hematologist added to CML/ALL criteria; references reviewed and updated.	02.19.19	05.19
2Q 2020 annual review: no significant changes; added Medicaid line of business with 6/12 month approval durations; references reviewed and updated.	02.11.20	05.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.