MEDICATION POLICY:
Iclusig®

Generic Name: Ponatinib

Therapeutic Class or Brand Name: Iclusig®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/13/2013

Date Last Reviewed / Revised: 8/6/2023

PRIOR AUTHORIZATION CRITERIA

I. (May be considered medically necessary when criteria I through V are met)

II. Documented diagnosis of one of the following conditions A through B AND must meet one criterion listed under applicable diagnosis:

A. Chronic myeloid leukemia (CML)

1. Chronic phase (CP) and criterion a) is met:

a) Documented trial and failure of, intolerance to, or contraindication to at least 2 prior tyrosine kinase inhibitors (TKI).

2. Accelerated or blast phase and criterion a) is met:

a) Documentation that no other tyrosine kinase inhibitors (TKI) are indicated.

3. T315I-positive in chronic, accelerated, or blast phase.

B. Acute lymphoblastic leukemia (ALL)

1. Philadelphia chromosome-positive (Ph+) and criterion a) is met:

a) Documentation that no other tyrosine kinase inhibitors (TKI) are indicated.

2. Philadelphia chromosome-positive (Ph+) and T315I-positive.

III. Minimum age requirement: 18 years old.

IV. Treatment must be prescribed by or in consultation with an oncologist or a hematologist.

V. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VI. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Iclusig is not indicated and is not recommended for the treatment of patients with newly diagnosed CP-CML.

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Doses are limited to 45mg per day. The quantity is limited to a maximum of a 30 day supply per fill.

Approval Length

- **Authorization:** 1 year
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

Appendix

N/A

References

1. Iclusig. Prescribing information. Takeda Pharmaceuticals America Inc; 2022. Accessed July 31, 2023. https://www.iclusig.com/sites/default/files/2023-02/iclusig-prescribing-information.pdf.
2. NCCN Clinical Practice Guidelines in Oncology. Acute Lymphoblastic Leukemia V.2.2023. Updated July 28, 2023. Accessed July 31,2023. https://www.nccn.org/professionals/physician_gls/pdf/all.pdf.
3. NCCN Clinical Practice Guidelines in Oncology. Chronic Myeloid Leukemia V.1.2024. Updated August 1, 2023. Accessed August 6,2023. https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf.