

Applicable Drugs: Iclusig (ponatinib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/13/2013

Date Last Reviewed/Revised: 6/10/2026

PRIOR AUTHORIZATION CRITERIA

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

- I. Documentation of one of the following FDA approved diagnoses A and B AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

- A. Chronic myeloid leukemia (CML) and one of the following i, ii, or iii is met:
 - i. Chronic phase (CP)
 - a) Documented trial and failure, intolerance, or contraindication to at least 2 prior tyrosine kinase inhibitors (TKI).
 - ii. Accelerated or blast phase
 - a) Documentation that no other tyrosine kinase inhibitors (TKI) are indicated.
 - iii. T315I-positive in chronic, accelerated, or blast phase.
- B. Acute lymphoblastic leukemia (ALL)
 - i. Documentation of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) and one of the following is met (a or b):
 - a) Member is newly diagnosed, and Iclusig (ponatinib) will be used in combination with chemotherapy.
 - b) Documentation of T315I-positive disease.
 - (1) Documentation no other tyrosine kinase inhibitors are indicated.
 - (2) Iclusig (ponatinib) will be used as monotherapy.

Other Uses With Supportive Evidence

- C. Acute lymphoblastic leukemia (adult and pediatric)
- D. Chronic myeloid leukemia (CML)
- E. Gastrointestinal stromal tumors (GIST)
- F. Myeloid/lymphoid neoplasms with eosinophilia

- II. Minimum age requirement: 18 years old.
- III. Treatment must be prescribed by or in consultation with an oncologist or a hematologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.
- V. 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 (ponatinib) 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

- Newly diagnosed Ph+ ALL:
 - 10mg, 15mg, 30mg tablets: 30 per 30-day supply
- All other diagnoses listed above:
 - 10mg, 15mg, 30mg, 45mg tablets: 30 per 30-day supply

APPROVAL LENGTH

- **Authorization:** 1 year
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

1. Iclusig. Prescribing information. Takeda Pharmaceuticals America Inc; 2025. Accessed May 1, 2026. <https://www.iclusig.com/sites/default/files/2023-02/iclusig-prescribing-information.pdf>

2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Acute Lymphoblastic Leukemia. Version 1.2026. Updated April 8, 2026. Accessed May 1, 2026. https://www.nccn.org/professionals/physician_gls/pdf/all.pdf
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Chronic Myeloid Leukemia Version 1.2026. Updated July 16, 2025. Accessed May 1, 2026. https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Gastrointestinal Stromal Tumors Version 1.2026. Updated January 13, 2026. Accessed May 1, 2026. https://www.nccn.org/professionals/physician_gls/pdf/gist.pdf
5. George S, von Mehren M, Fletcher JA, et al. Phase II study of ponatinib in advanced gastrointestinal stromal tumors: efficacy, safety, and impact of liquid biopsy and other biomarkers. *Clin Cancer Res*. 2022;28(7):1268-1276. doi:10.1158/1078-0432.CCR-21-2037
6. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Version 1.2026. Updated October 3, 2025. Accessed May 1, 2026. https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf
7. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Pediatric Acute Lymphoblastic Leukemia Version 1.2026. Updated August 11, 2025. Accessed May 1, 2026. https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.