Iclusig (ponatinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Iclusig (ponatinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Iclusig (ponatinib) may be approved if the following criteria are met:

I. Individual has a diagnosis of one of the following:

A. Chronic, accelerated, or blast phase Chronic Myeloid Leukemia (CML) or Philadelphia chromosome positive Acute Lymphoblastic Leukemia (ALL) where no other tyrosine kinase inhibitor therapy is indicated (e.g. is contraindicated, intolerant, or failed other prior TKI therapies) (Label); **OR**
B. Chronic Myeloid Leukemia (CML) in chronic, accelerated or blast phase where CML is T315I-positive; **OR**
C. Chronic phase CML in individuals with resistance or intolerance to at least two prior kinase inhibitors; **OR**
D. Acute Lymphoblastic Leukemia (ALL), Philadelphia chromosome positive (Label, NCCN 2A); **OR**
E. Pediatric Acute Lymphoblastic Leukemia (ALL) with ABL-class translocation (NCCN 2A); **OR**
F. Unresectable, recurrent, or metastatic gastrointestinal stromal tumors (GIST) after progression on imatinib, sunitinib, regorafenib, and standard dose ripretinib (NCCN 2A).

Note:
Iclusig (ponatinib) has black box warnings for vascular occlusion, heart failure, and hepatotoxicity. Arterial and venous thrombosis and occlusions have occurred in at least 27% of Iclusig-treated individuals, including fatal myocardial infarction, stroke, stenosis of large arterial vessels of the brain, severe peripheral vascular disease, and the need for urgent revascularization procedures. Individuals with and without cardiovascular risk factors, including age 50 years or younger, experienced these events. Hepatotoxicity, liver failure, and death have occurred with Iclusig. Hepatic function should be monitored and interruption of therapy may be necessary if hepatotoxicity is suspected.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2025. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. 2025. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025. Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on December 12, 2024.
    a. Acute Lymphoblastic Leukemia. V3.2024. Revised December 20, 2024.
    b. Chronic Myeloid Leukemia. V3.2025. Revised November 27, 2024.
    c. Gastrointestinal Stromal Tumors V2.2024. Revised July 31, 2024.
    d. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions V2.2024. Revised June 19, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.