Reference number(s)
2173-A

SPECIALTY GUIDELINE MANAGEMENT

ICLUSIG (ponatinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications[1]
1. Treatment of adult patients with T315I-positive chronic myeloid leukemia (CML) (chronic phase, accelerated phase, or blast phase) or T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
2. Treatment of adult patients with chronic phase, accelerated phase, or blast phase CML or Ph+ ALL for whom no other tyrosine kinase inhibitor (TKI) therapy is indicated

Limitation of use: Iclusig is not indicated and is not recommended for the treatment of patients with newly diagnosed chronic phase CML.

B. Compendial Uses[2-4]
1. Treatment of patients with advanced phase CML (accelerated phase or blast phase)
2. Follow-up therapy for after hematopoietic stem cell transplant (HSCT) for CML and ALL patients
3. Treatment of Ph+ ALL

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Chronic Myelogenous Leukemia (CML), Chronic Phase[1-3]
Authorization of 12 months may be granted for members initiating Iclusig for the treatment of chronic phase CML when ALL of the following criteria are met:
1. Diagnosis of CML was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing
2. Member has T315I-positive CML OR treatment with any other TKI is not indicated for the member (e.g., imatinib, nilotinib, dasatinib, bosutinib)

B. Chronic Myelogenous Leukemia, Accelerated Phase (AP-CML) or Blast Phase (BP-CML)[1-3]
Authorization of 12 months may be granted for members initiating Iclusig for the treatment of accelerated phase or blast phase CML when diagnosis was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing.

C. CML or ALL, Post-Hematopoietic Stem Cell Transplant (HSCT)[2,3]
Authorization of 12 months may be granted for members who are initiating treatment with Iclusig and have received a HSCT for CML or ALL when diagnosis was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing.

D. Ph+ Acute Lymphoblastic Leukemia (ALL)[1,2,4]
Authorization of 12 months may be granted for members initiating Iclusig for the treatment of Ph+ ALL when the diagnosis was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

IV. REFERENCES

1. Iclusig [package insert]. Cambridge, MA: Ariad Pharmaceuticals, Inc.; December 2017.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 28, 2018.
3. The NCCN Clinical Practice Guidelines in Oncology® Chronic Myelogenous Leukemia (Version 4.2018). © 2018 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 28, 2018.
4. The NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 1.2018). © 2018 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 28, 2018.