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.

FDA-Approved Indications

A. 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)
B. 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

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

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

A. For all members: Results of cytogenetic and/or molecular testing for detection of the Ph chromosome or the BCR-ABL gene obtained prior to initiation of therapy
B. For members requesting authorization of Iclusig for the treatment T315I-positive CML or T315I-positive Ph+ ALL: Results of T315I mutation testing

III. CRITERIA FOR INITIAL APPROVAL

A. Chronic Myelogenous Leukemia (CML)

Authorization of 12 months may be granted for members initiating Iclusig for the treatment of 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 is 18 years of age or older
3. Member has T315I-positive CML OR treatment with any other TKI is not indicated for the member (e.g., imatinib, nilotinib, dasatinib, bosutinib)

B. Ph+ Acute Lymphoblastic Leukemia (ALL)

Authorization of 12 months may be granted for members initiating Iclusig for the treatment of Ph+ ALL when ALL of the following criteria are met:

1. Diagnosis of Ph+ ALL was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing
2. Member is 18 years of age or older
3. Member has T315I-positive Ph+ ALL OR treatment with any other TKI is not indicated for the member (e.g., imatinib, nilotinib, dasatinib, bosutinib)

CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL diagnosis-specific authorization criteria below:

A. Chronic Myelogenous Leukemia (CML)
Authorization of up to 12 months may be granted for members continuing treatment with Iclusig for 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 is 18 years of age or older
3. Member has T315I-positive CML OR treatment with any other TKI is not indicated for the member (e.g., imatinib, nilotinib, dasatinib, bosutinib)
4. Member meets ANY of the following criteria:
    a. Authorization of up to 12 months for members with chronic phase CML who have been receiving Iclusig for < 12 months
    b. Authorization of 12 months for members with chronic phase CML who have been receiving Iclusig for ≥ 12 months and do not show evidence of disease progression or unacceptable toxicity
    c. Authorization of 12 months for members with accelerated or blast phase CML
    d. Authorization of 12 months for members who have received a HSCT for CML (any phase)

B. Ph+ Acute Lymphoblastic Leukemia (ALL)
All members (including new members) requesting authorization for continuation of Iclusig therapy for Ph+ ALL must meet ALL initial authorization criteria.

IV. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The following dosing limits apply: 45mg per day.

V. REFERENCES

1. Iclusig [package insert]. Cambridge, MA: Ariad Pharmaceuticals, Inc.; December 2015.
2. The NCCN Drugs & Biologics Compendium® © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 3, 2016.
3. The NCCN Clinical Practice Guidelines in Oncology® Chronic Myelogenous Leukemia (Version 1.2016). © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 3, 2016.
4. The NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 2.2015). © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 3, 2016.