Commercial/Healthcare Exchange PA Criteria

Effective: May 4, 2016

Prior Authorization: Iclusig

Products Affected: Iclusig (ponatinib) oral tablet

Medication Description/Class Description:

Iclusig is a kinase inhibitor indicated for the treatment of adult patients with T315I-positive chronic myeloid leukemia (CML) [chronic phase {CP}, accelerated phase {AP}, or blast phase {BP}] and T135I-positive Philadelphia chromosome positive (Ph+) acute lymphocytic leukemia (ALL). Iclusig is also indicated for the treatment of adult patients with CP, AP, or BP CML or Ph+ ALL for whom no other tyrosine kinase inhibitor (TKI) therapy is indicated.

According to the National Comprehensive Cancer Network (NCCN) guidelines for CML (version 1.2015), Iclusig is recommended for patients with a T315I mutation or for patients who have not responded to two or more TKI therapies.

Iclusig has a Black Box Warning regarding vascular occlusion, heart failure, and hepatotoxicity.

On December 12, 2013, the U.S. Food and Drug Administration (FDA) announced the requirement of several safety meausres for Iclusig to address the risk of life-threatening blood clots and severe narrowing of blood vessels. Iclusig is now part of a Risk Evaluation and Mitigation Strategy (REMS) program.

Covered Uses:

- Chronic myeloid leukemia,
  - Chronic, accelerated, or blast phase; for whom no other tyrosine kinase inhibitor therapy is indicated
  - T315I-positive, chronic, accelerated, or blast phase
- Acute lymphoblastic leukemia
  - Philadelphia chromosome-positive acute lymphoblastic leukemia, for whom no other tyrosine kinase inhibitor therapy is indicated
  - Philadelphia chromosome-positive acute lymphoblastic leukemia, T315I-positive

Exclusion Criteria: Iclusig is not indicated and is not recommended for the treatment of patients with newly diagnosed chronic phase CML

Required Medical Information:

1. Diagnosis
2. For indications of ALL and CML, the Philadelphia chromosome (Ph) status of the leukemia must be reported
3. For indications of ALL and CML, the T315I mutation status must be reported
4. Dose and frequency

Age Restrictions: Adults, 18 years of age and older

Prescriber Restrictions: None

Coverage Duration:
Initial: 12 months

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Continuation: 3 years

Other Criteria:

1. **Acute lymphoblastic leukemia (ALL) (chronic phase, accelerated phase, or blast phase).**
    a. The patient is Philadelphia chromosome positive and no other tyrosine kinase inhibitor therapy is indicated; **OR**
    b. The patient is T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL)
2. **Chronic myelogenous leukemia (CML) (chronic phase, accelerated phase, or blast phase).**
    a. No other tyrosine kinase inhibitor therapy is indicated; **OR**
    b. Patient is T315I-positive

References:

1. Iclusig [prescribing information]. Cambridge, MA: ARIAD Pharmaceuticals, Inc.; March 2016.
2. NCCN Clinical Practice Guidelines in Oncology, Acute Lymphoblastic Leukemia v.2.2015. Accessed on March 9, 2016.
3. NCCN Clinical Practice Guidelines in Oncology, Chronic Myelogenous Leukemia v.1.2016. Accessed on March 9, 2016.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	03/09/2016
2	Revision	Updated policy to match FDA Label Removed Iclusig from CCI "Oncology" Policy, adopted EH criteria	All	3/13/19

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3	Update	Added continuation coverage duration to 3 years	Coverage Duration	7/1/2019
4	Annual Review	Re-worded Covered Uses and Criteria, no change of content/criteria	Covered Uses Other Criteria	5/14/2020

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