UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Iclusig

Program	Prior Authorization
Medication	Iclusig® (ponatinib)
Issue Date	3/2014
Pharmacy and Therapeutics Approval Date	11/2017
Effective Date	1/2018

1. Background:

Iclusig® (ponatinib) is a kinase inhibitor FDA-labeled for the treatment of adult patients with T315I-positive chronic myeloid leukemia (CML) (chronic phase, accelerated phase, or blast phase) and T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL). It is also indicated for treatment of adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia or Ph+ ALL for whom no other tyrosine kinase inhibitor (TKI) therapy is indicated.[1] The National Comprehensive Cancer Network (NCCN) also recommends Iclusig for treatment of Ph+ALL patients when used in combination with an induction regimen not previously used.[2]

2. Coverage Criteria:

A. Chronic Myelogenous / Myeloid Leukemia (CML)

1. **Initial Authorization**

a. **Iclusig** will be approved based on **both** of the following criteria:

(1) Diagnosis of chronic myelogenous/ myeloid leukemia (CML)

-AND-

(2) **One** of the following:

(a) Patient is unable to take or has failed treatment with **two** or more tyrosine kinase inhibitor (TKI) therapies [e.g., imatinib mesylate, Sprycel (dasatinib), or Tasigna (nilotinib)]

-OR-

(b) Confirmed documentation of T315I mutation

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Iclusig** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Iclusig therapy

Authorization will be issued for 12 months.

B. <u>Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ALL)</u>

1. **Iclusig** will be approved based on **<u>both</u>** of the following criteria:

a. Diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL)

-AND-

b. **<u>One</u>** of the following:

(1) Patient is unable to take or has failed treatment with **<u>two</u>** or more tyrosine kinase inhibitor (TKI) therapies [e.g., imatinib mesylate, Sprycel (dasatinib), or Tasigna (nilotinib)]

-OR-

(2) Confirmed documentation of T315I mutation

-OR-

(3) Used in combination with an induction regimen not previously used

Authorization will be issued for 12 months.

2. **<u>Reauthorization</u>**

a. **Iclusig** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Iclusig therapy

Authorization will be issued for 12 months.

3. References:

1. Iclusig [package insert]. Cambridge, MA: ARIAD Pharmaceuticals, Inc.; November 2016.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed October 10, 2017.

Program	Prior Authorization –Iclusig (ponatinib)
Change Control	
Date	Change
3/2014	New drug policy –FDA approval
12/2015	Annual Review, no change
10/2016	Removed "chronic phase, accelerated phase, or blast phase" from CML diagnosis requirement Changed prerequisite therapy from "all" to "two" alternative tyrosine kinase inhibitors Added 'used in combination with an induction regimen not previously used' to Ph+ALL. Removed prescriber requirement Increased authorization from 10 months to 12 month.
12/2016	Changed Gleevec to imatinib mesylate. Updated formatting and references.
11/2017	Removed acute lymphoblastic lymphoma based on NCCN recommendations. Updated references.