UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Iclusig

Program	Prior Authorization
Medication	Iclusig® (ponatinib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New York, New York EPP, Rhode Island, Pennsylvania- CHIP, New Jersey, South Carolina
Issue Date	3/2014
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

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) or 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 use as a component of Hyper-CVAD regimen for Ph+ ALL and the treatment of myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FGFR1 or ABL1 rearrangements.

2. Coverage Criteria:

A. <u>Chronic Myelogenous / Myeloid Leukemia (CML)</u>

1. **<u>Initial Authorization</u>**

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

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

      -AND-

      (2) **<u>One</u>** of the following:

         (a) 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-

         (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. Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ALL)

1. **Initial Authorization**

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

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

-AND-

b. **One** of the following:

(1) 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-

(2) Confirmed documentation of T315I mutation

-OR-

(3) Used as a component of Hyper-CVAD regimen induction or consolidation.

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.

C. Myeloid/Lymphoid Neoplasms

1. **Initial Authorization**

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

(1) Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

-AND-

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

(a) Patient has a FGFR1 rearrangement
(b) Patient has an ABL1 rearrangement

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.

D. NCCN Recommended Regimens

1. Initial Authorization

a. **Iclusig** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Iclusig therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Iclusig [package insert]. Cambridge, MA: ARIAD Pharmaceuticals, Inc.; July 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed October 2, 2020.

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.
11/2018	Added use with HyperCVAD (hyper-fractionated cyclophosphamide, vincristine, doxorubicin, and dexamethasone,

	alternating with high-dose methotrexate and cytarabine) induction or consolidation and as maintenance therapy in combination with vincristine and prednisone with or without methotrexate and mercaptopurine and post-hematopoietic stem cell transplant. Added NCCN Recommended Regimen review criteria. Updated background and criteria.
11/2019	Annual review. Updated references.
11/2020	Annual review. Updated background to reflect package insert. Updated clinical criteria for Ph+ ALL removing specific drug regimens. Updated NCCN guidelines for Myeloid/Lymphoid Neoplasms in background and criteria. Updated references. Added Additional Clinical Rules section.