MEDICATION POLICY

Generic Name: Ponatinib

Therapeutic Class or Brand Name: Iclusig®

Applicable Drugs (if Therapeutic Class)**:** N/A

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 12/6/17

GPI Code: 2153407510

Prior Authorization Criteria (may be considered medically necessary when criteria I through III are met):

I. Documented diagnosis of one of the following conditions A or B AND must meet criteria listed under applicable diagnosis:
   A. Chronic, accelerated, or blast phase Chronic Myelogenous Leukemia (CML) and ONE of criteria 1 or 2 is met:
      1. Documentation of a T315I mutation.
      2. Documentation that no other tyrosine kinase inhibitor (TKI) therapy is indicated.
   B. Philadelphia chromosome positive Acute Lymphoblastic Leukemia (Ph+ ALL) and ONE of criteria 1 or 2 is met:
      1. Documentation of a T315I mutation.
      2. Documentation that no other tyrosine kinase inhibitor (TKI) therapy is indicated.

II. Minimum age requirement: 18 years old.

III. The prescribing physician is an oncologist or a hematologist.

Exclusion Criteria:

- N/A

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- Doses are limited to 45mg per day. The quantity is limited to a maximum of a 30 day supply per fill.

Approval Length:

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

Appendix:

N/A

References:

1. http://blue.regence.com/trgmedpol/drugs/dru292.pdf.
2. https://www.rmhp.org/-/media/RMHPdotOrg/Files/PDF/Learning-Center/Prior-Auth-Services/Prior-Auth-Forms-MD/Iclusig-ponatinib.ashx.
3. Medi-Span.
4. http://iclusig.com/pi.

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Historical Tracking Of Changes Made To Policy	
12/6/2017	1. **Changed** "I. A. 2. Documented trial and failure of, intolerance to, or contraindication to, ALL of the following other tyrosine kinase inhibitor (TKI) therapies: dasatinib (Sprycel®), imatinib (Gleevec®), nilotinib (Tasigna®), and bosutinib (Bosulif®)" **to** "I. A. 2. Documentation that no other tyrosine kinase inhibitor (TKI) therapy is indicated" **and** "I. B. 2. Documented trial and failure of, intolerance to, or contraindication to, ALL of the following other tyrosine kinase inhibitor (TKI) therapies: dasatinib (Sprycel®) and imatinib (Gleevec®)" **to** "I. B. 2. Documentation that no other tyrosine kinase inhibitor (TKI) therapy is indicated" **under Prior Authorization Criteria**. 2. **Updated** "http://www.ariad.com/pdf/Iclusig-Prescribing-Information_Oct2014.pdf" **to** "http://iclusig.com/pi" **and** "http://www.rmhp.org/docs/provider/iclusig_(ponatinib).pdf?sfvrsn=2" **to** "https://www.rmhp.org/-/media/RMHPdotOrg/Files/PDF/Learning-Center/Prior-Auth-Services/Prior-Auth-Forms-MD/Iclusig-ponatinib.ashx" **under References**.
9/29/2016	1. Policy reviewed: no changes made.
3/27/2015	1. **Changed** "I. Documented diagnosis of one of the following conditions A or B: A. Chronic, accelerated, or blast phase Chronic Myelogenous Leukemia (CML); B. Philadelphia chromosome positive Acute Lymphoblastic Leukemia (Ph+ ALL); II. Documented trial and failure of, intolerance to, or contraindication to, one of the following other tyrosine kinase inhibitor (TKI) therapies: dasatinib (Sprycel®), imatinib (Gleevec®), nilotinib (Tasigna®), or bosutinib (Bosulif®)" **to** "I. Documented diagnosis of one of the following conditions A or B AND must meet criteria listed under applicable diagnosis: A. Chronic, accelerated, or blast phase Chronic Myelogenous Leukemia (CML) and ONE of criteria 1 or 2 is met: 1. Documentation of a T315I mutation; 2. Documented trial and failure of, intolerance to, or contraindication to, ALL of the following other tyrosine kinase inhibitor (TKI) therapies: dasatinib (Sprycel®), imatinib (Gleevec®), nilotinib (Tasigna®), and bosutinib (Bosulif®); B. Philadelphia chromosome positive Acute Lymphoblastic Leukemia (Ph+ ALL) and ONE of criteria 1 or 2 is met: 1. Documentation of a T315I mutation; 2. Documented trial and failure of, intolerance to, or contraindication to, ALL of the following other tyrosine kinase inhibitor (TKI) therapies: dasatinib (Sprycel®) and imatinib (Gleevec®)" **under Prior Authorization Criteria**. 2. **Removed** "http://www.fdhc.state.fl.us/medicaid/Prescribed_Drug/drug_creteria_pdf/Iclusig_Criteria.pdf" **from References** (link no longer valid). 3. **Updated** "http://s368855769.onlinehome.us/iclusig.com/wp-content/uploads/2013/10/Iclusig-Prescribing-Information.pdf" **to** "http://www.ariad.com/pdf/Iclusig-Prescribing-Information_Oct2014.pdf" **under References**.
11/21/2013	1. **Adapted policy to new format.** 2. **Added GPI Code**. 3. **Changed Prior Authorization Criteria from:** "Documented diagnosis of one of the Covered Uses listed below: Chronic phase, accelerated phase, or blast phase chronic myelogenous leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL); Must have resistance and/or intolerance to prior TKI therapy [i.e. Gleevec® (imatinib), Sprycel® (dasatinib), Tasigna® (nilotinib), Bosulif® (bosutinib)]; Minimum age requirement: 18 years old; Prescriber is an oncologist." **to:** . "Documented diagnosis of one of the following conditions A or B: A. Chronic, accelerated, or blast phase Chronic Myelogenous Leukemia (CML), B. Philadelphia chromosome positive Acute Lymphoblastic Leukemia (Ph+ ALL); Documented trial and failure of, intolerance to, or contraindication to, one of the following other tyrosine kinase inhibitor (TKI) therapies: dasatinib (Sprycel®), imatinib (Gleevec®), nilotinib (Tasigna®), or bosutinib (Bosulif®); Minimum age requirement: 18 years old; The prescribing physician is an oncologist or a hematologist".

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Historical Tracking Of Changes Made To Policy	
	4. **Updated references** to include Regence policy, Medi-Span, and updated website for Iclusig package insert.