

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Iclusig Prior Authorization Policy

- Iclusig® (ponatinib tablets – ARIAD/Takeda)

**REVIEW DATE:** 05/04/2022; selected revision 06/22/2022

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### OVERVIEW

Iclusig, a tyrosine kinase inhibitor (TKI), is indicated for the treatment of adults with:<sup>1</sup>

- **Chronic myeloid leukemia (CML)**, chronic phase, with resistance or intolerance to at least two prior TKIs.
- **CML**, accelerated phase or blast phase or Philadelphia chromosome-positive **acute lymphoblastic leukemia (ALL)** for whom no other TKIs are indicated.
- **CML, T315I-positive** (chronic phase, accelerated phase, or blast phase) or **ALL** that is **T315I-positive**, as well as Philadelphia chromosome-positive.

A limitation of use is that Iclusig is not indicated and is not recommended for the treatment of patients with newly diagnosed chronic phase CML.

### Guidelines

Iclusig is addressed in a few guidelines from National Comprehensive Cancer Network (NCCN):<sup>2-4</sup>

- **Acute Lymphoblastic Leukemia (ALL):** The NCCN guidelines for ALL (version 1.2022 – April 4, 2022) [adults] recommend Iclusig as a treatment option for patients with the T315I mutation and/or for patients in for whom no other TKI is indicated (category 2A).<sup>2</sup> Iclusig has also shown promising activity when included in various regimens.
- **CML:** NCCN guidelines for CML (version 3.2022 – January 27, 2022) state that for patients with chronic phase CML with a low-risk score, the primary treatment recommended includes a first-generation TKI (imatinib [brand or generic]), or a second-generation TKI (Bosulif® [bosutinib tablets], Sprycel® [dasatinib tablets], or Tasigna® [nilotinib capsules] {all category 1}).<sup>3</sup> For patients with chronic phase CML with an intermediate- or high-risk score, a second-generation TKI is preferred (Bosulif [category 1], Sprycel [category 1], or Tasigna [category 1]). A first-generation TKI (imatinib [brand or generic]) is an alternative (category 2A). Iclusig is an option for patients with a T315I mutation and/or chronic phase CML with resistance or intolerance to at least two prior TKIs or for patients with accelerated-phase CML or blast-phase CML for whom no other TKI is indicated (category 2A). Scemblix® (asciminib tablets) is a treatment option for chronic phase CML in patients with the T315I mutation and/or chronic phase CML with resistance or intolerance to at least two prior TKIs (category 2A).
- **Myeloid/Lymphoid Neoplasms with Eosinophilia:** The NCCN guidelines for myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes (version 1.2022 – April 14, 2022) note that Iclusig is a TKI with activity against *ABL1* and *FGFR1* rearrangements (category 2A).<sup>4</sup>

### Safety

Iclusig has a Boxed Warning regarding arterial occlusive events, venous thromboembolic events, heart failure and hepatotoxicity.<sup>1</sup>

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## **POLICY STATEMENT**

Prior Authorization is recommended for prescription benefit coverage of Iclusig. All approvals are provided for the duration noted below.

**Automation:** None.

## **RECOMMENDED AUTHORIZATION CRITERIA**

Coverage of Iclusig is recommended in those who meet one of the following criteria:

### **FDA-Approved Indications**

- 1. Acute Lymphoblastic Leukemia.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
  - A) Patient is  $\geq$  18 years of age; AND
  - B) Patient has Philadelphia chromosome-positive acute lymphoblastic leukemia; AND
  - C) Patient meets one of the following (i or ii)
    - i. The acute lymphoblastic leukemia is T315I-positive; OR
    - ii. Patient has tried at least two other tyrosine kinase inhibitors that are used for Philadelphia chromosome positive acute lymphoblastic leukemia.  
Note: Examples include imatinib tablets and Sprycel (dasatinib tablets).
  
- 2. Chronic Myeloid Leukemia.** Approve for 1 year if the patient meets the following (A, B, and C):
  - A) Patient is  $\geq$  18 years of age; AND
  - B) Patient has Philadelphia chromosome-positive chronic myeloid leukemia; AND
  - C) Patient meets one of the following (i or ii):
    - i. The chronic myeloid leukemia is T315I-positive, OR
    - ii. Patient has tried at least two other tyrosine kinase inhibitors indicated for use in Philadelphia chromosome-positive chronic myeloid leukemia.  
Note: Examples include imatinib tablets, Sprycel (dasatinib tablets), and Tassigna (nilotinib capsules).

### **Other Uses with Supportive Evidence**

- 3. Myeloid/Lymphoid Neoplasms with Eosinophilia.** Approve for 1 year if the patient meets the following (A and B):
  - A) Patient is  $\geq$  18 years of age; AND
  - B) Patient meets one of the following (i or ii):
    - i. The tumor has an *ABL1* rearrangement; OR
    - ii. The tumor has an *FGFR1* rearrangement.

## **CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Coverage of Iclusig is not recommended in the following situations:

- 1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

**REFERENCES**

1. Iclusig® tablets [prescribing information]. Lexington, MA: ARIAD/Takeda; February 2022.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2022 – April 4, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on April 27, 2022.
3. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 3.2022 – January 27, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on April 27, 2022.
4. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 1.2022 – April 14, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on April 27, 2022.