Reference number(s)
2173-A

SPECIALTY GUIDELINE MANAGEMENT

ICLUSIG (ponatinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
   1. Adult patients with chronic phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to at least two prior kinase inhibitors
   2. Adult patients with accelerated phase (AP) or blast phase (BP) chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) for whom no other kinase inhibitors are indicated
   3. Adult patients with T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Ph+ ALL

   Limitation of use: Iclusig is not indicated and is not recommended for the treatment of patients with newly diagnosed CP-CML.

B. Compendial Uses
   1. Follow-up therapy for CML patients after hematopoietic stem cell transplant (HSCT)
   2. Ph+ B-cell acute lymphoblastic leukemia or lymphoblastic lymphoma (Ph+ B-ALL/LL)
   3. Maintenance therapy for Ph+ B-ALL/LL patients after hematopoietic stem cell transplant (HSCT)
   4. Myeloid/lymphoid neoplasms with eosinophilia and FGFR1 or ABL1 rearrangements in chronic phase or blast phase
   5. Gastrointestinal Stromal Tumors (GIST)

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

The following information is necessary to initiate the prior authorization review:
A. Prior to initiation of therapy for treatment of CML or Ph+ ALL/LL: results of cytogenetic and/or molecular testing for detection of the Ph chromosome or the BCR::ABL gene
B. For members requesting initiation of therapy with the requested medication for treatment of T315I-positive CML or Ph+ ALL/LL: results of BCR::ABL1 mutation testing for T315I mutation
C. For members requesting initiation of therapy with the requested medication for treatment of myeloid and/or lymphoid neoplasms with eosinophilia: results of testing or analysis confirming FGFR1 or ABL1 rearrangement

III. CRITERIA FOR INITIAL APPROVAL

A. Chronic Myeloid Leukemia (CML)

Authorization of 12 months may be granted for treatment of CML that has been confirmed by detection of the Ph chromosome or BCR::ABL gene by cytogenetic and/or molecular testing when any of the following criteria are met:

1. Member has T315I-positive CML
2. Member has chronic phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to at least two prior kinase inhibitors (e.g., bosutinib, dasatinib, imatinib, nilotinib)
3. Member has accelerated phase (AP) or blast phase (BP) CML and treatment with any other kinase inhibitors (e.g., bosutinib, dasatinib, imatinib, nilotinib) is not indicated

B. Ph+ Acute Lymphoblastic Leukemia (ALL)/Lymphoblastic Lymphoma (LL)

Authorization of 12 months may be granted for treatment of Ph+ ALL/LL that has been confirmed by detection of the Ph chromosome or BCR::ABL gene by cytogenetic and/or molecular testing when any of the following criteria are met:

1. Member has T315I-positive mutation
2. Treatment with any other kinase inhibitors (e.g., bosutinib, dasatinib, imatinib, nilotinib) is not indicated

C. Myeloid/Lymphoid Neoplasms with Eosinophilia

Authorization of 12 months may be granted for treatment of myeloid and/or lymphoid neoplasms with eosinophilia and FGFR1 or ABL1 rearrangement in the chronic phase or blast phase.

D. Gastrointestinal Stromal Tumors (GIST)

Authorization of 12 months may be granted for treatment of GIST as a single agent for residual, unresectable, recurrent or metastatic/tumor rupture disease after progression on at least four FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, and ripretinib)

IV. CONTINUATION OF THERAPY

A. CML

Authorization of 12 months may be granted for continued treatment of CML when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and either of the following is met:

1. Member has CML that has been confirmed by detection of Ph chromosome or BCR::ABL gene by cytogenetic and/ or molecular testing
2. Member has received HSCT for CML

B. Ph+ ALL/LL

Authorization of 12 months may be granted for continued treatment of ALL/LL when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and either of the following criteria is met:

1. Member has Ph+ ALL/LL that has been confirmed by detection of Ph chromosome or BCR::ABL gene by cytogenetic and/ or molecular testing
2. Member has received HSCT for ALL/LL

C. Myeloid/Lymphoid Neoplasms with Eosinophilia, GIST

Authorization of 12 months may be granted for continued treatment of myeloid/lymphoid neoplasms with eosinophilia or GIST when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

Reference number(s)
2173-A

1. Iclusig [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; February 2022.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 6, 2023.
3. NCCN Clinical Practice Guidelines in Oncology® Chronic Myeloid Leukemia (Version 2.2023). © 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 6, 2023.
4. NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 1.2022). © 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 6, 2023.