Reference number
1793-A

SPECIALTY GUIDELINE MANAGEMENT

TASIGNA (nilotinib)

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 and pediatric patients greater than or equal to 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase
2. Adult patients with chronic phase and accelerated phase Ph+ CML resistant or intolerant to prior therapy that included imatinib
3. Pediatric patients greater than or equal to 1 year of age with chronic phase and accelerated phase Ph+ CML with resistance or intolerance to prior tyrosine-kinase inhibitor (TKI) therapy.

B. Compendial Uses
1. Primary treatment of advanced phase CML (accelerated phase or blast phase)
2. Follow-up therapy for CML patients after hematopoietic stem cell transplant (HSCT)
3. CML patients resistant or intolerant to primary treatment with alternative tyrosine kinase inhibitors (TKIs)
4. Ph+ acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LL)
5. Unresectable, recurrent, or metastatic gastrointestinal stromal tumor (GIST) after failure on approved therapies
6. Myeloid/lymphoid neoplasms with eosinophilia and ABL1 rearrangement in chronic phase
7. Lymphoid, myeloid or mixed lineage neoplasms with eosinophilia and ABL1 rearrangement in blast phase

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

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:
A. 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 CML or ALL/LL after experiencing resistance to prior tyrosine kinase inhibitor (TKI) therapy: results of BCR-ABL1 mutation testing for T315I, Y253H, E255K/V, F359V/C/I, and G250E mutations, where applicable
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 ABL1 rearrangement

III. CRITERIA FOR INITIAL APPROVAL

A. Chronic Myeloid Leukemia (CML)

Authorization of 7 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 not received prior therapy with a TKI (e.g., bosutinib, dasatinib, imatinib, ponatinib)
2. Member experienced toxicity or intolerance to prior therapy with a TKI
3. Member experienced resistance to prior therapy with a TKI and results of BCR-ABL1 mutational testing are negative for all of the following mutations: T315I, Y253H, E255K/V, F359V/C/I
4. Member has received HSCT for CML and results of BCR-ABL1 mutational testing are negative for all of the following mutations: T315I, Y253H, E255K/V, F359V/C/I

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

Authorization of 12 months may be granted for treatment of Ph+ ALL or 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 not received prior therapy with a TKI (e.g., bosutinib, dasatinib, imatinib, ponatinib)
2. Member experienced toxicity or intolerance to prior therapy with a TKI
3. Member experienced resistance to prior therapy with a TKI and results of BCR-ABL1 mutational testing are negative for all of the following mutations: T315I, Y253H, E255K/V, F359V/C/I, and G250E

C. Gastrointestinal Stromal Tumor (GIST)

Authorization of 12 months may be granted for treatment of unresectable, recurrent, or metastatic GIST for members who have failed at least four FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib) when the requested medication is used as a single agent.

D. Myeloid/Lymphoid Neoplasms with Eosinophilia

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

IV. CONTINUATION OF THERAPY

A. CML

Authorization may be granted for continued treatment of CML that has been confirmed by detection of Ph chromosome or BCR-ABL gene by cytogenetic and/ or molecular testing when either of the following criteria is met:

1. Authorization of 12 months may be granted when any of the following criteria is met:
   a. BCR-ABL1 is less than or equal to 10% and there is no evidence of disease progression or unacceptable toxicity while on the current regimen for members who have been receiving treatment with the requested medication for 6 months or greater
   b. Member has received HSCT when there is no evidence of unacceptable toxicity or disease progression while on the current regimen
2. Authorization of up to 7 months may be granted when the member has completed less than 6 months of therapy with the requested medication.

B. Ph+ ALL/LL

Authorization of 12 months may be granted for continued treatment of Ph+ ALL or LL that has been confirmed by detection of Ph chromosome or BCR-ABL gene by cytogenetic and/ or molecular testing when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

C. GIST and Myeloid/Lymphoid Neoplasms with Eosinophilia

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

V. REFERENCES

1. Tasigna [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2021.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed September 27, 2021.
3. NCCN Clinical Practice Guidelines in Oncology® Chronic Myeloid Leukemia (Version 1.2022). © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed September 27, 2021.
4. NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 2.2021). © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed September 7, 2021.