CareFirst Family of health care plans

CVS caremark™

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]
1. Treatment of 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. Treatment of chronic phase and accelerated phase Ph+ CML in adult patients resistant or intolerant to prior therapy that included imatinib
3. Treatment of pediatric patients greater than or equal to 1 year of age with chronic phase Ph+ CML with resistance or intolerance to prior tyrosine-kinase inhibitor (TKI) therapy.

B. Compendial Uses[2-5]
1. Treatment of patients with advanced phase CML (accelerated phase or blast phase)
2. Follow-up therapy for CML patients after hematopoietic stem cell transplant (HSCT)
3. Follow-up therapy for CML patients resistant or intolerant to primary treatment with alternative tyrosine kinase inhibitors (TKIs)
4. Ph+ acute lymphoblastic leukemia (ALL)
5. Gastrointestinal stromal tumor (GIST) in patients with disease progression on imatinib, sunitinib or regorafenib

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Chronic Myelogenous Leukemia, Chronic Phase (CP-CML)[1-3]
Authorization of 12 months may be granted for members initiating Tasigna for the treatment of CP-CML when ALL of the following criteria are met:
1. Diagnosis of CML was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing
2. Member meets ANY of the following criteria:
   a. Member has a high or intermediate risk score according to the Sokal or Hasford scoring methodology
   b. Member has a low risk score according to the Sokal or Hasford scoring methodology AND meets EITHER of the following:
      i. Member is less than or equal to 18 years of age.
      ii. Member has experienced resistance to prior therapy with imatinib or an alternate TKI AND results of mutational testing are negative for T315I mutation
      iii. Member has experienced toxicity or intolerance to prior therapy with imatinib or an alternate TKI

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B. Chronic Myelogenous Leukemia, Accelerated Phase (AP-CML) or Blast Phase (BP-CML)[1-3]
Authorization of 12 months may be granted for members initiating Tasigna for the treatment of AP-CML or BP-CML when diagnosis was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing.

C. CML, Post-Hematopoietic Stem Cell Transplant (HSCT)[2-3]
Authorization of 12 months may be granted for members who are initiating treatment with Tasigna and have received a HSCT for CML when diagnosis was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing.

D. Ph+ Acute Lymphoblastic Leukemia (ALL)[1,2,4]
Authorization of 12 months may be granted for members who are prescribed Tasigna for the treatment of ALL when the diagnosis was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing

E. Gastrointestinal stromal tumor (GIST)[2,5]
Authorization of 12 months may be granted for members who are prescribed Tasigna for the treatment of GIST and have experienced disease progression on imatinib, sunitinib, or regorafenib.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL diagnosis-specific authorization criteria below:

A. Chronic Myelogenous Leukemia (CML)[1-3]
Authorization of up to 12 months may be granted for members continuing treatment with Tasigna for CML when ALL of the following criteria are met:
1. Diagnosis of CML was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing
2. Member meets ANY of the following criteria:
    a. Authorization of up to 12 months for members with chronic phase CML if receiving benefit from Tasigna therapy (i.e., achieved or maintained a cytogenic or molecular response to therapy)
    b. Authorization of 12 months for members with accelerated or blast phase CML
    c. Authorization of 12 months for members who have received a HSCT for CML (any phase)

B. Ph+ Acute Lymphoblastic Leukemia (ALL)[1,2,4]
All members (including new members) requesting authorization for continuation of Tasigna therapy for Ph+ ALL must meet ALL initial authorization criteria

C. GIST[2,5]
All members (including new members) requesting authorization for continuation of Tasigna therapy for GIST must meet ALL initial authorization criteria

IV. REFERENCES

1. Tasigna [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2018.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 23, 2018.

3. The NCCN Clinical Practice Guidelines in Oncology® Chronic Myelogenous Leukemia (Version 4.2018). © 2018 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 23, 2018.
4. The NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 1.2018). © 2018 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 23, 2018.
5. The NCCN Clinical Practice Guidelines in Oncology® Soft Tissue Sarcoma (Version 1.2018). © 2018 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 23, 2018.