nilotinib (Tasigna®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO136

Description

Nilotinib (Tasigna) is a Bcr-Abl kinase inhibitor that binds to, and stabilizes, the inactive conformation of the kinase domain of the Abl protein.

Length of Authorization

- Initial: Three months
- Renewal: 12 months

Quantity Limits

Product Name	Dosage Form	Indication	Quantity Limit
nilotinib (Tasigna)	50 mg capsules	Newly diagnosed OR resistant/intolerant Ph+ CML in chronic phase	112 capsules/28 days
	150 mg capsules	Newly diagnosed Ph+ CML in chronic phase	112 capsules/28 days
	200 mg capsules	Resistant or intolerant Ph+ CML Gastrointestinal Stromal Tumors (GIST)	112 capsules/28 days

Initial Evaluation

I. Nilotinib (Tasigna) may be considered medically necessary when the following criteria are met:
   A. Medication is prescribed by, or in consultation with, an oncologist; **AND**
   B. Medication will not be used in combination with other oncologic medications (i.e., will be used as monotherapy); **AND**
   C. A diagnosis of one of the following:
      1. **Chronic myelogenous leukemia (CML)**; **AND**
         i. Member is newly diagnosed with Philadelphia chromosome-positive (Ph+) or BCR-ABL1 mutation positive CML in chronic phase; **OR**
         ii. Member is diagnosed with chronic OR accelerated phase Ph+ or BCR-ABL1 mutation positive CML; **AND**
            a. Member is 18 years of age or older; **AND**
            b. Treatment with a tyrosine kinase inhibitor [e.g. imatinib (Gleevec)] has been ineffective, contraindicated, or not tolerated; **OR**
         iii. Member is diagnosed with chronic phase Ph+ or BCR-ABL1 mutation positive CML; **AND**
            a. Member is one year of age or older; **AND**

b. Treatment with a tyrosine kinase inhibitor [e.g. imatinib (Gleevec)] has been ineffective, contraindicated, or not tolerated; **OR**

2. **Gastrointestinal Stromal Tumors (GIST)**; **AND**
   i. Treatment with ALL the following have been ineffective, contraindicated, or not tolerated:
      a. imatinib (Gleevec)
      b. sunitinib (Sutent)
      c. regorafenib (Stivarga)

II. Nilotinib (Tasigna) is considered investigational when used for all other conditions, including but not limited to:
   A. CML without Philadelphia chromosome
   B. CML in the blast phase

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through use of samples, manufacturer coupons, or otherwise. Initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Nilotinib (Tasigna) is prescribed by, or in consultation with, an oncologist; **AND**
IV. Medication will not be used in combination with other oncologic medications (i.e., will be used as monotherapy); **AND**
V. Clinical documentation of response to treatment, such as stabilization of disease or decrease in tumor size or spread is provided.

Supporting Evidence

I. Nilotinib (Tasigna) is FDA-approved for treatment of adult and pediatric patients greater than one year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase and is a NCCN Category 1.
II. Nilotinib (Tasigna) for the treatment Ph+ CML resistant to prior therapy is only FDA-approved for use in the pediatric population in patients with chronic phase Ph+CML.
III. Nilotinib (Tasigna) is FDA-approved for use in adult patients with chronic phase and accelerated phase Ph+ CML resistant to, or intolerant of, prior therapy that included imatinib.

IV. Payment considerations for nilotinib for the treatment of Gastrointestinal Stromal tumors is reserved for members who have tried and failed imatinib (Gleevec) and sunitinib (Sutent) for the treatment of GIST. This recommendation is reflective of NCCN guidelines. Much of the data comes from phase II studies and retrospective analyses involving a small number of patients. In a randomized phase 3 study of nilotinib as 3rd line therapy and best supportive care (with or without a TKI) in patients with GIST resistant to imatinib and sunitinib (n=248) the PFS on nilotinib (Tasigna) was not found to be superior to best supportive care (109 days vs 111 days; P=0.56). Additionally, regorafenib has FDA approval and NCCN category 1 designation for GIST in patients previously treated with imatinib and sunitinib.

Investigational or Not Medically Necessary Uses

I. Nilotinib (Tasigna) has not been sufficiently evaluated in the following settings. Limited evidence may be available; however, safety and efficacy have not been established for:
   A. CML without Philadelphia chromosome
   B. CML in the blast phase.

References

1. Tasigna [Prescribing Information]. East Hanover, NJ: Novartis; September 2019.
2. National Comprehensive Cancer Network (NCCN); Clinical Practice Guidelines in Oncology: Chronic Myelogenous Leukemia – v.2.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf.
3. National Comprehensive Cancer Network (NCCN); Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma – v.3.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf.

Policy Implementation/Update:

Date Created	February 2012
Date Effective	August 2010
Last Updated	December 2019
Last Reviewed	03/2012, 07/2012, 08/2012, 01/2013, 05/2018, 12/2019

Action and Summary of Changes	Date
Prior authorization criteria transitioned to policy format. **Expanded renewal duration from 6 months to 12 months for all indications.** Required agent be used as monotherapy and not in combination with other oncologic medications.	12/2019
Added new indication in pediatric patients one year of age or older with Philadelphia chromosome-positive chronic myeloid leukemia in the chronic phase (Ph+ CML-CP). Allowed for approval in the second line CML	05/2018

setting after being treated with a TKI (other than imatinib). For GIST off-label use, added a requirement to try/fail regorafenib as well as the existing agents (imatinib and sunitinib).	