Clinical Policy: Nilotinib (Tasigna)

Reference Number: PA.CP.PHAR.76
Effective Date: 01/18
Last Review Date: 04/18

Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for nilotinib (Tasigna®) capsules.

FDA Approved Indication(s)
Tasigna is indicated for:

- Treatment of adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase (Ph+ CML-CP).*
- Treatment of Ph+ CML-CP and accelerated phase Ph+ CML (Ph+ CML-AP) in adult patients resistant or intolerant to prior therapy that included imatinib.*

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**The effectiveness of Tasigna is based on hematologic and cytogenetic response rates.*

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness that Tasigna is **medically necessary** when one of the following criteria are met:

I. Initial Approval Criteria

Approval duration: 6 months

A. Chronic Myeloid Leukemia (must meet all):
1. Diagnosis of Ph+ (i.e., BCR-ABL1 positive) CML;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 1 years;
4. Dose does not exceed 800 mg/day.

Approval duration: 6 months

B. Acute Lymphoblastic Leukemia (off-label) (must meet all)**:**
1. Diagnosis of Ph+ (i.e., BCR-ABL1 positive) acute lymphoblastic leukemia (ALL);
2. Prescribed by or in consultation with an oncologist;
3. Request meets one of the following (a or b):
   a. Dose does not exceed 800 mg/day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

C. Gastrointestinal Stromal Tumor (off-label) (must meet all)**:**

1. Diagnosis of gastrointestinal stromal tumor (GIST) (a soft tissue sarcoma);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Failure of imatinib, sunitinib, or regorafenib unless contraindicated or clinically significant adverse effects are experienced;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 800 mg/day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

D. Other diagnoses/indications:

1. Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy.

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:
Nilotinib belongs to a pharmacologic class of drugs known as kinase inhibitors. It is an inhibitor of the BCR-ABL kinase. Nilotinib binds to and stabilizes the inactive conformation of the kinase domain of ABL protein. In vitro, nilotinib inhibited BCR-ABL mediated proliferation of murine leukemic cell lines and human cell lines derived from patients with Philadelphia chromosome positive CML.

Formulations:
Capsule, oral administration
Tasigna: 150 mg, 200 mg

Appendices

Appendix A: Abbreviation Key

ALL: acute lymphoblastic leukemia
CML: chronic myeloid leukemia
Ph+: positive Philadelphia chromosome
GIST: gastrointestinal stromal tumor

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: Added age (not ALL) ; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; added continuity of care statement; references reviewed and updated.	02.13.18	

References

1. Tasigna Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2017. Available at: http://www.us.tasigna.com/patient/about-ph-cml-treatment.jsp. Accessed February 2018.
2. Nilotinib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 2018.
3. Chronic myelogenous leukemia (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed June 19, 2017.
4. Acute lymphoblastic leukemia (Version 5.2017). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 2018.
5. Soft tissue sarcoma (Version 1.2018). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 2018.