Clinical Policy: Nilotinib (Tasigna)

Reference Number: PA.CP.PHAR.76
Effective Date: 01/18
Last Review Date: 04/19

Revision Log

Description
Nilotinib (Tasigna®) is a kinase inhibitor.

FDA Approved Indication(s)
Tasigna is indicated for:

- Treatment of adult and pediatric patients greater than or equal to 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP).*
- Treatment of Ph+ CML-CP and accelerated phase (Ph+ CML-AP) in adult patients resistant or intolerant to prior therapy that included imatinib.*
- Treatment of pediatric patients greater than or equal to 1 year of age with Ph+ CML-CP resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy.

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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

A. Chronic Myeloid Leukemia (must meet all):
1. Diagnosis of Ph+ (BCR-ABL1-positive) CML;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Request meets one of the following (a or b):
   a. Dose does not exceed 800 mg per 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

B. Acute Lymphoblastic Leukemia (off-label) (must meet all)**:**
1. Diagnosis of Ph+ (BCR-ABL1-positive) acute lymphoblastic leukemia (ALL);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Dose is within FDA maximum limit for any FDA-approved indication or 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. Dose is within FDA maximum limit for any FDA-approved indication or 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.PMN.53

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.
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 800 mg per day;
   b. New 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

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.PMN.53

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALL: acute lymphoblastic leukemia
CML: chronic myeloid leukemia
FDA: Food and Drug Administration
GIST: gastrointestinal stromal tumor
Ph+: positive Philadelphia chromosome

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
imatinib (Gleevec)	GIST: 400 mg PO QD to 800 PO BID	800 mg/day
Sutent (sunitinib)	GIST: 50 mg PO QD	50 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Stivarga (regorafenib)	GIST: 160 mg PO QD for the first 21 days of each 28-day cycle	160 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypokalemia, hypomagnesemia, long QT syndrome
- Boxed warning(s): QT prolongation, sudden death

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Newly diagnosed Ph+ CML-CP	Adults: 300 mg PO BID	Adults: 600 mg/day
Resistant/intolerant Ph+ CML-CP or Ph+ CML-AP	Adults: 400 mg PO BID	Adults: 800 mg/day
Newly diagnosed Ph+ CML-CP or resistant/intolerant Ph+ CML-CP	Pediatrics: 230 mg/m2 PO BID, rounded to the nearest 50 mg dose (to a maximum single dose of 400 mg)	Pediatrics: 400 mg/day

V. Product Availability

Capsules: 50 mg, 150 mg, 200 mg

VI. References

1. Tasigna Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2018. Available at: http://www.us.tasigna.com/patient/about-ph-cml-treatment.jsp. Accessed February 5, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 5, 2019.
3. National Comprehensive Cancer Network Guidelines. Chronic Myeloid Leukemia Version 1.2019. Available at www.nccn.org. Accessed February 5, 2019.
4. National Comprehensive Cancer Network Guidelines. Acute Lymphoblastic Leukemia Version 1.2018. Available at www.nccn.org. Accessed February 5, 2019.
5. National Comprehensive Cancer Network Guidelines. Soft Tissue Sarcoma Version 2.2019. Available at www.nccn.org. Accessed February 5, 2019.

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	
2Q 2019 annual review: hematologist added to CML/ALL; references reviewed and updated.	04/19	