Clinical Policy: Nilotinib (Tasigna)

Reference Number: ERX.SPA.80
Effective Date: 03.01.14
Last Review Date: 05.20
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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.

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

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Tasigna is **medically necessary** when 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 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*).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 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 (Gleevec®), Sutent®, or Stivarga®, unless clinically significant adverse effects are experienced or all are contraindicated;*
   **Prior authorization may be required for imatinib, Sutent, and Stivarga*
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*).*
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

D. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Tasigna for a covered indication and has received this medication for at least 30 days;
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*).
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. 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 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
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

V. 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

VI. Product Availability

Capsules: 50 mg, 150 mg, 200 mg

VII. References

1. Tasigna Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2019. Available at: http://www.us.tasigna.com/patient/about-ph-cml-treatment.jsp. Accessed February 7, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 7, 2020.
3. National Comprehensive Cancer Network Guidelines. Chronic Myeloid Leukemia Version 3.2020. Available at www.nccn.org. Accessed February 7, 2020.
4. National Comprehensive Cancer Network Guidelines. Acute Lymphoblastic Leukemia Version 1.2020. Available at www.nccn.org. Accessed February 7, 2020.
5. National Comprehensive Cancer Network Guidelines. Soft Tissue Sarcoma Version 5.2019. Available at www.nccn.org. Accessed February 7, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy converted to new template. Added NCCN recommended and compendial uses. Changed approval durations to 3 months for initial and 6 months for re-auth. Removed requirements regarding: administration counseling, all safety criteria (including monitoring), cytogenic response criteria, requests for documentation, test to detect Philadelphia chromosome, and negative T3151 mutation. Replaced specific questions related to cytogenetic/molecular response with generalized efficacy statement.	08/16	09/16
Converted to new template. Age added. CML NCCN: 1) “myeloid” is inserted to describe blast phase in “As a single agent for accelerated or myeloid blast phase CML”; 2) “In combination with steroids as primary treatment for CML in lymphoid blast phase” is added; 3)	07/17	08/17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
"for relapse" is deleted from "post stem cell transplant therapy" to incorporate history of responsive CML; 4) CML positive for a F317L/V/I/C, T315A, or V299L mutation is added. Maximum dose added. Dosing guidance added for off-label use. All off-label uses are referred to the off-label use policy. Approval periods are lengthened from 3/6 to 6/12 months. References updated.		
2Q 2018 annual review: no significant changes; age added (not ALL); NCCN and FDA approved uses summarized for improved clarity; specialist involvement in care added; continuity of care statement added; approval durations increased to length of benefit; references reviewed and updated.	02.13.18	05.18
No significant changes: new 50 mg capsule formulation added; pediatric labeled indications added for CML; CML age limit removed; package insert updated.	06.29.18	
2Q 2019 annual review: no significant changes; hematologist added to CML/ALL; references reviewed and updated.	02.19.19	05.19
2Q 2020 annual review: no significant changes; added Medicaid line of business with 6/12 month approval durations; references reviewed and updated.	02.11.20	05.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.