

Generic Name: Nilotinib

Preferred: N/A

Therapeutic Class or Brand Name: Tasigna®

Non-preferred: N/A

Applicable Drugs (if Therapeutic Class): N/A

Date of Origin: 2/1/2013

GPI Code: 2153406020

Date Last Reviewed / Revised: 2/6/2019

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through II are met)

- I. Documented diagnosis of Philadelphia chromosome-positive (Ph+) Chronic Myelogenous Leukemia (CML) AND fulfills ONE of following patient criteria A through C:
 - A. Adult or pediatric patient 1 year of age or older who is newly diagnosed and in chronic phase.
 - B. Adult patient with both chronic phase (CP) and accelerated phase (AP) Ph+ CML with documented resistance or intolerance to imatinib.
 - C. Pediatric patient 1 year of age or older with chronic phase (CP) Ph+ CML and documented resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy.
- II. The prescribing physician is an oncologist or a hematologist.

EXCLUSION CRITERIA

- Patients with hypokalemia, hypomagnesemia, or long QT syndrome.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantities of up to 112 capsules per 28 days.

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

N/A

REFERENCES

1. https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf .
2. Medi-Span®.
3. <http://www.pharma.us.novartis.com/product/pi/pdf/tasigna.pdf> .

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
2/6/2019	<p>1. Changed under Prior Authorization Criteria for addition of new pediatric indications from:</p> <ul style="list-style-type: none"> I. Documented diagnosis of chronic or accelerated phase Chronic Myelogenous Leukemia (CML). II. Documentation that the patient's CML is Philadelphia chromosome-positive (Ph+). III. Minimum age requirement: 18 years old. IV. The prescribing physician is an oncologist or a hematologist. <p>To:</p> <ul style="list-style-type: none"> I. Documented diagnosis of Philadelphia chromosome-positive (Ph+) Chronic Myelogenous Leukemia (CML) AND fulfills ONE of following patient criteria A through C: <ul style="list-style-type: none"> A. Adult or pediatric patient 1 year of age or older who is newly diagnosed and in chronic phase. B. Adult patient with both chronic phase (CP) and accelerated phase (AP) Ph+ CML with documented resistance or intolerance to imatinib. C. Pediatric patient 1 year of age or older with chronic phase (CP) Ph+ CML and documented resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy. II. The prescribing physician is an oncologist or a hematologist. <p>2. Added link to NCCN guidelines for CML under References https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf .</p> <p>3. Deleted obsolete URL under References item #1 http://blue.regence.com/trgmedpol/drugs/dru151.pdf .</p>
12/7/2017	<p>1. Changed "2153406000" to "2153406020" following GPI Code.</p>
9/29/2016	<p>1. Policy reviewed: no changes made.</p>
3/28/2015	<p>1. Changed "Quantities of up to 120 capsules per 30 days" to "Quantities of up to 112 capsules per 28 days" under Quantity/Days Supply Restrictions.</p>

11/22/2013	<ol style="list-style-type: none">1. Adapted policy to new format.2. Added GPI Code.3. Changed "Prescriber is an oncologist" to "The prescribing physician is an oncologist or a hematologist" under Prior Authorization Criteria.4. Added "Patients with hypokalemia, hypomagnesemia, or long QT syndrome" to Exclusion Criteria.5. Changed Quantity/Days Supply Restrictions from "120 capsules per 30 days" to "Quantities of up to 120 capsules per 30 days".6. Updated references to include Medi-Span.
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DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.