# Commercial/Healthcare Exchange PA Criteria

***Effective: November 2, 2016***

***Prior Authorization:*** Tasigna

***Products Affected:*** Tasigna (nilotinib) oral capsules

***Medication Description:***
Nilotinib 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 Ph+ CML. In vivo, nilotinib reduced the tumor size in a murine BCR-ABL xenograft model. Nilotinib inhibited the autophosphorylation of the following kinases, BCR-ABL, PDGFR, c-KIT, CSF-1R, and DDR1.

Tasigna has a Boxed Warning regarding QT prolongation and sudden deaths. Tasigna prolongs the QT interval. Prior to Tasigna administration, and periodically, providers are encouraged to monitor for hypokalemia or hypomagnesemia and correct deficiencies. Sudden deaths have been reported in patients receiving Tasigna and should not be administered to patients with hypokalemia, hypomagnesemia, or long QT syndrome. Tasigna shouldn't be administered with drugs known to prolong the QT interval or strong CYP3A4 inhibitors. Food should be avoided 2 hours before and 1 hour after taking Tasigna.

***Covered Uses:***
1. Adult and Pediatric Patients with Newly Diagnosed Philadelphia chromosome positive (Ph+) Chronic Myeloid Leukemia (CML) in chronic phase
2. Adult Patients with Resistant or Intolerant Ph+ CML-Chronic Phase and CML-Accelerated Phase
3. Pediatric Patients with Resistant or Intolerant Ph+ CML-Chronic Phase

***Exclusion Criteria:***
1. Patients with uncorrected electrolyte disorders (hypokalemia, hypomagnesemia)
2. Long QT syndrome

***Required Medical Information:***
1. Diagnosis
2. Philadelphia chromosome (Ph) status
3. Stage of disease (chronic, accelerated)
4. Previous therapies tried

***Age Restrictions:*** N/A

***Prescriber Restrictions:*** Prescribed by, or in consultation with, an oncologist.

***Coverage Duration:*** 12 months

***Other Criteria:***

**Newly Diagnosed CML**

A. Patient (adult/pediatric) has a diagnosis of newly diagnosed CML; AND
B. Patient has Philadelphia chromosome-positive CML in chronic phase.

**Resistant or intolerant CML - Adult**

A. Patient (adult) has a diagnosis of resistant or intolerant CML; AND
B. Patient has Philadelphia chromosome positive CML in chronic or accelerated phase; AND
C. Patient has resistance or intolerance to prior therapy that included imatinib.

**Resistant or intolerant CML - Pediatric**

A. Patient (pediatric) has a diagnosis of resistant or intolerant CML; AND
B. Patient has Philadelphia chromosome positive CML in chronic phase; AND
C. Patient has resistance or intolerance to prior tyrosine-kinase inhibitor therapy.

***References:***

1. Tasigna [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2016.
2. The NCCN Chronic Myelogenous Leukemia Clinical Practice Guidelines in Oncology (Version 1.2016). © 2015 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 17, 2016.

***Policy Revision history***

| Rev # | Type of Change | Summary of Change | Sections Affected | Date |
|---|---|---|---|---|
| 1 | New Policy | New Policy | All | 8/17/16 |
| 2 | Update | Updated to match indication<br><br>Tasigna removed from CCI "Oncology" Policy<br><br>CCI adopted EH criteria | All | 3/7/19 |

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| 3 | Update | Addition of FDA approved indication | Covered Uses<br>Other Criteria | 12/5/2019 |