ConnectiCare

Commercial PA Criteria

Effective: November 2, 2016

Prior Authorization: Nilotinib Oral Products

Products Affected: Tasigna (nilotinib) oral capsules, Danziten (nilotinib) oral tablet

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 should not 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. **Chronic myeloid leukemia (CML),** Philadelphia chromosome positive (Ph+), that is newly diagnosed, in chronic phase: Tasigna is approved for use in adults and pediatric patients ≥ 1 year of age. Danziten is approved for use in adults.
2. **CML**, Ph+, chronic phase and accelerated phase: Tasigna and Danziten are approved for use **in adults** with resistance or intolerance to prior therapy that included imatinib.
3. **CML,** Ph+, chronic phase and accelerated phase: Tasigna is approved for use in **pediatric patients** ≥ 1 year of age with resistance or intolerance to prior TKI therapy.

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:

1. Tasigna: adults and pediatric patients ≥ 1 year
2. Danziten: ≥ 18 years of age and older

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

Coverage Duration: 12 months

Other Criteria:

1. **Newly Diagnosed CML –** Approve for the duration noted if the patient meets the following criteria (A **AND** B)
   A. Patient (adult/pediatric) has a diagnosis of newly diagnosed CML; **AND**
   B. Patient has Philadelphia chromosome-positive CML in chronic phase.

2. **Resistant or intolerant CML – Adult -**Approve for the duration noted if the patient meets the following criteria (A, B **AND** C)
   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.

3. **Resistant or intolerant CML – Pediatric -** Approve for the duration noted if the patient meets the following criteria (A, B **AND** C)
   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® capsules [prescribing information]. East Hanover, NJ: Novartis; February 2024.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 4.2023 – February 5, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org.

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 Tasigna removed from CCI "Oncology" Policy CCI adopted EH criteria	All	3/7/19
3	Update	Addition of FDA approved indication	Covered Uses Other Criteria	12/5/2019
4	Update	Addition of Danziten oral tablets Addition of Age clarification: Tasigna: adults and pediatric patients ≥ 1 year Danziten: ≥ 18 years of age and older Policy name change from Tasigna to Nilotinib Oral Products	Products Affected Age restriction	12/20/2024