UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Tasigna

Program	Prior Authorization
Medication	Tasigna® (nilotinib)
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	11/2017
Effective Date	1/2018

1. Background:

Tasigna® (nilotinib) is a kinase inhibitor FDA-approved for the treatment of newly diagnosed adult patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase, as well as treatment of chronic phase and accelerated phase Ph+ CML in adult patients resistant to or intolerant to prior therapy that included Gleevec® (imatinib).[1] The National Cancer Comprehensive Network (NCCN) recommends the use of Tasigna for primary or follow-up CML therapy in all stages. NCCN also recommends Tasigna for the treatment of the following: progressive gastrointestinal stromal tumors (GIST) when patient is no longer receiving benefit from Gleevec® (imatinib), Stivarga® (regorafenib), or Sutent® (sunitinib); and for the treatment of Philadelphia chromosome-positive acute lymphoblastic leukemia (ALL).

2. Coverage Criteria:

A. Chronic Myelogenous / Myeloid Leukemia

1. Initial Authorization

a. Tasigna will be approved based on the following criterion:

(1) Diagnosis of chronic myelogenous / myeloid leukemia

Authorization will be issued for 12 months.

2. Reauthorization

a. Tasigna will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Tasigna therapy

Authorization will be issued for 12 months.

B. Gastrointestinal Stromal Tumor (GIST) (off-label)

1. **Initial Authorization**

   a. **Tasigna** will be approved based on **both** of the following criteria:

      (1) Diagnosis of progressive gastrointestinal stromal tumor (GIST)

      -AND-

      (2) History of failure, contraindication, or intolerance to **one** of the following:

         (a) Gleevec (imatinib)
         (b) Sutent (sunitinib)
         (c) Stivarga (regorafenib)

      Authorization will be issued for 12 months.

2. **Reauthorization**

   a. **Tasigna** will be approved based on the following criterion:

      (1) Patient does not show evidence of progressive disease while on Tasigna therapy

      Authorization will be issued for 12 months.

C. **Acute Lymphoblastic Leukemia (ALL) (off-label)**

1. **Initial Authorization**

   a. **Tasigna** will be approved based on the following criterion:

      (1) Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)

      Authorization will be issued for 12 months.

2. **Reauthorization**

   a. **Tasigna** will be approved based on the following criterion:

      (1) Patient does not show evidence of progressive disease while on Tasigna therapy

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Authorization will be issued for 12 months.

3. References:

1. Tasigna [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed October 6, 2017.

Program	Prior Authorization/Notification - Tasigna (nilotinib)
Change Control	
9/2013	New guideline; individual guideline created to replace the general Oral Chemotherapy guideline
12/2015	Annual review, no change
10/2016	Separated Tasigna and Sprycel into individual policies to align with Employer & Individual's notification policies and updated policy template
12/2016	Updated language for ALL with no changes to criteria intent. Updated background and references.
11/2017	Updated background information and coverage criteria to include NCCN recommended use for Ph+ ALL. Removed acute lymphoblastic lymphoma criteria as no longer recommended by NCCN. Updated references.