UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Tasigna

Program	Prior Authorization
Medication	Tasigna® (nilotinib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New York, New York EPP, Rhode Island, Pennsylvania- CHIP, New Jersey, South Carolina
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

1. Background:

Tasigna® (nilotinib) is a kinase inhibitor indicated for the treatment of adult and pediatric patients greater than or equal to 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase, as well as treatment of adult patients with chronic phase (CP) and accelerated phase Ph+ CML resistant to or intolerant to prior therapy that included Gleevec® (imatinib).[1] Tasigna is also indicated for treatment of pediatric patients greater than 1 year of age with Ph+ CML-CP resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy. 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); for the treatment of Philadelphia chromosome-positive acute lymphoblastic leukemia (ALL); and for myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes [2].

2. Coverage Criteria:

A. <u>Chronic Myeloid Leukemia</u>

1. <u>Initial Authorization</u>

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

(1) Diagnosis of chronic myeloid leukemia

-AND-

(2) **<u>One</u>** of the following:

(a) Patient is not a candidate for imatinib as attested by physician

-OR-

(b) Patient is currently on Tasigna therapy

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)

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 **all** 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)

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

Authorization will be issued for 12 months.

D. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes

1. **Initial Authorization**

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

(1) Diagnosis of myeloid/lymphoid neoplasms with eosinophilia and ABL1 rearrangement

-AND-

(2) Neoplasm is in blast or chronic phase

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.

E. NCCN Recommended Regimens

1. Initial Authorization

a. **Tasigna** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Tasigna therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Tasigna [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed October 5, 2020.

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.

11/2018	Added step through generic imatinib for CML. Added NCCN Recommended Regimen review criteria. Updated background and references.
11/2019	Annual review. Updated coverage criteria for GIST. Updated references.
11/2020	Annual review. Addition of coverage criteria for myeloid/lymphoid neoplasms with eosinophilia and ABL1 rearrangement according to NCCN. Updated background and references. Added Additional Clinical Rules section.