UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3082-9
Program	Step Therapy
Medication	Tasigna® (nilotinib)
P&T Approval Date	10/2016, 10/2017, 10/2018, 10/2019, 10/2020, 10/2021, 4/2022, 4/2023, 4/2024
Effective Date	7/1/2024

1. Background:

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a patient trial or physician consideration of imatinib before providing coverage for Tasigna in the setting of Philadelphia chromosome-positive chronic myelogenous/myeloid leukemia.

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.
Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a,b]:

A. Patients less than 19 years of age

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

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. Philadelphia Chromosome-Positive Chronic Myelogenous / Myeloid Leukemia (Ph+ CML)

1. **Tasigna** will be approved based on **both** of the following criterion:

   a. Diagnosis of Philadelphia chromosome-positive chronic myelogenous / myeloid leukemia (Ph+ CML)

   -AND-

   b. **One** of the following:

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

      -OR-

      (2) **Both** of the following:

(a) Patient is currently on Tasigna therapy

-AND-

(b) Patient has not received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from a Novartis sponsored financial assistance program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Tasigna

Authorization will be issued for 12 months

C. Other Indications

1. **Tasigna** will be approved

Authorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

[b] Coverage of oncology medications may be approved based on state mandates.

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 and/or Notification may be in place.
- Coverage of oncology medications may be approved based on state mandates.

4. References:

1. Tasigna [package insert]. East Hanover, NJ: Novartis; February 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed February 20, 2024.

Program	Step Therapy - Tasigna® (nilotinib)
Change Control	
10/2016	New program.
10/2017	Annual review. Updated state mandate verbiage. Updated references.
10/2018	Annual review with no changes to coverage criteria. Updated references.
10/2019	Annual review with no changes to coverage criteria. Updated references.
10/2020	Annual review with no changes to coverage criteria. Updated references.

10/2021	Annual review. Updated criteria for patients previously established on therapy with Tasigna. Updated references.
4/2022	Added oncology medications state mandate note.
4/2023	Annual review. Updated references.
4/2024	Annual review with no changes to coverage criteria. Updated references.