UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1105-15
Program	Prior Authorization/Notification
Medication	Danziten™ (nilotinib)*, nilotinib d-tartrate (nilotinib)*, Tasigna® (nilotinib)
P&T Approval Date	8/2008, 6/2009, 9/2010, 12/2010, 9/2011, 8/2012, 07/2013, 2/2014, 2/2015, 2/2016, 12/2016, 11/2017, 11/2018, 11/2019, 11/2020, 11/2021, 11/2022, 11/2023, 11/2024, 11/2025
Effective Date	2/1/2026

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 imatinib. Tasigna is also indicated for treatment of pediatric patients greater than or equal to 1 year of age with Ph+ CML-CP and CML-AP resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy. Danziten™ (nilotinib) is a kinase inhibitor indicated for the treatment of adult patients with newly diagnosed 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 imatinib. The FDA has also approved a 505(b)(2) capsule formulation of nilotinib D-tartrate manufactured by Cipla USA Inc. Nilotininb d-tartrate is a d-tartrate salt formulation.

The National Cancer Comprehensive Network (NCCN) recommends the use of nilotinib (e.g., Danziten, 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), Qinlock® (ripretinib), or Sutent® (sunitinib); for the treatment of Philadelphia chromosome-positive B-cell acute lymphoblastic leukemia (B-ALL); in cutaneous melanoma with activating mutations of KIT and/or projected risk of progression with BRAF-targeted therapy; for the treatment of soft tissue sarcoma of pigmented villonodular synovitis/tenosynovial giant cell tumor; and for myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes.
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]:

A. <u>Patients less than 19 years of age</u>

1. Danziten*, **nilotinib d-tartrate***, or **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. Chronic Myeloid Leukemia

1. **Initial Authorization**

a. **Danziten***, **nilotinib d-tartrate***, or **Tasigna** will be approved based on the following criterion:

(1) Diagnosis of chronic myeloid leukemia

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Danziten***, **nilotinib d-tartrate***, or **Tasigna** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Danziten***, **nilotinib d-tartrate***, or **Tasigna** therapy

Authorization will be issued for 12 months.

C. Gastrointestinal Stromal Tumor (GIST)

1. **Initial Authorization**

a. **Danziten***, **nilotinib d-tartrate***, or **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) imatinib
(b) sunitinib
(c) Stivarga (regorafenib)
(c) Qinlock (ripretinib)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Danziten***, **nilotinib d-tartrate***, or **Tasigna** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Danziten***, **nilotinib d-tartrate***, or **Tasigna** therapy

Authorization will be issued for 12 months.

D. Acute Lymphoblastic Leukemia (Ph+B-ALL)

1. **Initial Authorization**

a. **Danziten***, **nilotinib d-tartrate***, or **Tasigna** will be approved based on the following criterion:

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

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Danziten***, **nilotinib d-tartrate***, or **Tasigna** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Danziten***, **nilotinib d-tartrate***, or **Tasigna** therapy

Authorization will be issued for 12 months.

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

1. **Initial Authorization**

a. **Danziten***, **nilotinib d-tartrate***, or **Tasigna** will be approved based on the following criteria:

(1) Diagnosis of myeloid, lymphoid or mixed lineage 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. **Danziten***, **nilotinib d-tartrate***, or **Tasigna** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Danziten***,

nilotinib d-tartrate*, or **Tasigna** therapy

Authorization will be issued for 12 months.

F. Melanoma: Cutaneous

1. **Initial Authorization**

   a. **Danziten***, **nilotinib d-tartrate***, or **Tasigna** will be approved based on **both** of the following criteria:

      (1) Diagnosis of metastatic or unresectable melanoma cutaneous tumors with activating mutations of KIT

      -AND-

      (2) Used as second-line or subsequent therapy for disease progression, intolerance, and or projected risk of progression with BRAF-targeted therapy

      Authorization will be issued for 12 months.

2. **Reauthorization**

   a. **Danziten***, **nilotinib d-tartrate***, or **Tasigna** will be approved based on the following criterion:

      (1) Patient does not show evidence of progressive disease while on **Danziten***, **nilotinib d-tartrate***, or **Tasigna** therapy

      Authorization will be issued for 12 months.

G. Soft Tissue Sarcoma

1. **Initial Authorization**

   a. **Danziten***, **nilotinib d-tartrate***, or **Tasigna** will be approved based on the following criterion:

      (1) Diagnosis of pigmented villonodular synovitis/tenosynovial giant cell tumor

      Authorization will be issued for 12 months.

2. **Reauthorization**

   a. **Danziten***, **nilotinib d-tartrate***, or **Tasigna** will be approved based on the following criterion:

      (1) Patient does not show evidence of progressive disease while on **Danziten***, **nilotinib d-tartrate***, or **Tasigna** therapy

Authorization will be issued for 12 months.

H. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

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.

*Danziten and nilotinib d-tartrate are typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

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. Danziten [package insert]. Woburn, MA: Azurity Pharmaceuticals, Inc.; November 2024.
2. Nilotinib [package insert]. Warren, NJ: Cipla USA, Inc.; January 2025.
3. Tasigna [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2024.
4. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed October 13, 2025.

Program	Prior Authorization/Notification - Danziten™ (nilotinib)*, nilotinib d-tartrate (nilotinib)*, Tasigna (nilotinib)
Change Control	
2/2014	Updated references.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
2/2015	Annual review. Added Stivarga as t/f option for GIST. Expanded Ph+ALL criteria to include genetic mutations or transplant. Updated background and references.
2/2016	Annual review with clinical updates based on NCCN recommendations which expanded coverage for all CML diagnoses. Updated background and references.
12/2016	Annual review. No changes to criteria intent. Updated background and

	references.
11/2017	Annual review. 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	Annual review. Minor change to coverage rationale for CML with no change in clinical intent. Removed "off-label" from NCCN Compendium supported indications. Updated background and references.
11/2019	Annual review. Updated coverage criteria for GIST, added NCCN recommended regimens criteria. 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.
11/2021	Annual review. Clarified B-cell type ALL in coverage criteria. Updated background and references.
11/2022	Annual review. Added state mandate. Updated background per package insert and references.
11/2023	Annual review. Updated criteria for GIST. Updated criteria for Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions. Added Melanoma Cutaneous and Soft Tissue Sarcoma as indications for criteria per NCCN recommendations. Updated background and reference.
11/2024	Annual review with no changes to criteria. Updated references.
11/2025	Annual review. Added Danziten and nilotinib d-tartrate as typically excluded from coverage. Updated references.