

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2025 P 1467-1
Program	Prior Authorization/Notification
Medication	Danziten™ (nilotinib)
P&T Approval Date	1/2025
Effective Date	4/1/2025

**1. Background:**

Danziten™ (nilotinib) is a kinase inhibitor indicated for the treatment of adult patients 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.<sup>1</sup> The National Cancer Comprehensive Network (NCCN) recommends the use of Danziten for primary or follow-up CML therapy in all stages. NCCN also recommends Danziten for the treatment of Philadelphia chromosome-positive B-cell acute lymphoblastic leukemia (B-ALL) as well as for the treatment of soft tissue sarcoma of pigmented villonodular synovitis/tenosynovial giant cell tumor.<sup>2</sup>

**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<sup>a</sup>:**

<p><b>A. <u>Patients less than 19 years of age</u></b></p> <p>1. <b>Danziten</b> will be approved based on the following criterion:</p> <p style="padding-left: 40px;">a. Patient is less than 19 years of age</p> <p style="text-align: center;"><b>Authorization will be issued for 12 months.</b></p> <p><b>B. <u>Chronic Myeloid Leukemia</u></b></p> <p>1. <b><u>Initial Authorization</u></b></p> <p style="padding-left: 40px;">a. <b>Danziten</b> will be approved based on the following criterion:</p> <p style="padding-left: 80px;">(1) Diagnosis of chronic myeloid leukemia</p> <p style="text-align: center;"><b>Authorization will be issued for 12 months.</b></p> <p>2. <b><u>Reauthorization</u></b></p>
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a. **Danziten** will be approved based on the following criterion:

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

**Authorization will be issued for 12 months.**

**C. Acute Lymphoblastic Leukemia (Ph+B-ALL)**

**1. Initial Authorization**

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

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

**Authorization will be issued for 12 months.**

**D. Soft Tissue Sarcoma**

**1. Initial Authorization**

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

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

**Authorization will be issued for 12 months.**

**E. 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.**

<sup>a</sup> 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.

**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. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at [http://www.nccn.org/professionals/drug\\_compendium/content/contents.asp](http://www.nccn.org/professionals/drug_compendium/content/contents.asp). Accessed December 3, 2024.

Program	Prior Authorization/Notification - Danziten (nilotinib)
<b>Change Control</b>	
1/2025	New program.