

Danziten (nilotinib) tablet
Effective 05/01/2025

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange		Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit			<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.			
Contact Information	Medical Benefit Pharmacy Benefit		Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A			

Overview

Danziten (nilotinib) tablet 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
- Chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted for members when all of the following criteria are met:

1. Member is 18 years of age or older
2. Diagnosis of Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML)
3. Member meets ONE of the following:
 - a. Disease is in accelerated phase
 - b. Member meets BOTH of the following:
 - i. Disease is in chronic phase
 - ii. Member meets ONE of the following:
 1. Disease is intermediate or high risk
 2. Disease is low-risk and member has had a trial and failure, contraindication, or intolerance to imatinib
4. Member has had a trial and failure, intolerance or contraindication to nilotinib capsule or a clinical rationale why the member cannot administer nilotinib capsule is provided

Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. Member has had a positive response to therapy and does not show evidence of disease progression or toxicity

Limitations

1. Initial and reauthorization requests will be approved for 12 months.
2. The following quantity limitations apply:

Drug Name	Quantity Limit
Danziten tablet	4 tablets/day

References

1. Danziten (nilotinib) tablet [prescribing information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; November 2024.
2. National Comprehensive Cancer Network (2025). *NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Chronic myeloid leukemia* [v.3.2025].

Review History

02/12/2025 – Created and reviewed at February P&T. Effective 05/01/2025.

