

DRUG POLICY

Danziten® (nilotinib)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Danziten is indicated for adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase

Danziten is indicated for adult patients with chronic phase and accelerated phase Ph+ CML resistant or intolerant to prior therapy that included imatinib

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. For treatment of CML: results of cytogenetic and/or molecular testing for detection of the Ph chromosome or the BCR::ABL gene
2. For members requesting initiation of therapy with the requested medication for treatment of CML after experiencing resistance to prior tyrosine kinase inhibitor (TKI) therapy: results of BCR::ABL1 mutation testing for T315I, Y253H, E255K/V, and F359V/C/I, where applicable

Criteria for Initial Approval

Chronic Myeloid Leukemia (CML)

Authorization may be granted for treatment of CML that has been confirmed by detection of the Ph chromosome or BCR::ABL gene by cytogenetic and/or molecular testing when **ANY** of the following criteria are met:

1. Member has not received prior therapy with a TKI (e.g., bosutinib, dasatinib, imatinib, ponatinib)
2. Member experienced toxicity or intolerance to prior therapy with a TKI
3. Member experienced resistance to prior therapy with a TKI and results of BCR::ABL1 mutational testing are negative for all of the following: T315I, Y253H, E255K/V, F359V/C/I

Approval will be for 7 months

Continuation of Therapy

Chronic Myeloid Leukemia (CML)

Authorization may be granted for continued treatment of CML when BCR::ABL1 is less than or equal to 10% and there is no evidence of disease progression or unacceptable toxicity while on the current regimen

Approval will be for 12 months

Other

Danziten (nilotinib) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer’s patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider’s ability to access medication samples.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Danziten (nilotinib) 71 mg tablets	112 capsules per 28 days	<ul style="list-style-type: none"> • Newly diagnosed Ph+ CML-CP: 142 mg orally twice daily • Resistant or intolerant Ph+ CML-CP and CML-AP: 190 mg orally twice daily <p><i>Dose adjustments may be necessary for adverse reactions, hepatic impairment, or use with strong CYP3A4 inhibitors</i></p>
Danziten (nilotinib) 95 mg tablets	112 capsules per 28 days	

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

- Danziten [package insert]. Woburn, MA: Azurity Pharmaceuticals, Inc.; November 2024.
- The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed March 26, 2024.
- NCCN Clinical Practice Guidelines in Oncology® Chronic Myeloid Leukemia (Version 2.2024). © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed March 26, 2024.
- NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 4.2023). © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed March 26, 2024.
- Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics, Inc. Updated periodically. Available at: <https://www.micromedexsolutions.com> [available with subscription]. Accessed March 26, 2024.
- NCCN Clinical Practice Guidelines in Oncology® Gastrointestinal Stromal Tumors (Version 1.2024). © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed March 26, 2024.

POLICY HISTORY

Policy #: 05.05.74

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Current Effective Date: February 28, 2025