

Applicable Drugs: Vanflyta (quizartinib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 8/26/2024

Date Last Reviewed / Revised: 2/20/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

- I. Documentation of the following FDA-approved diagnosis (A) AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Acute Myeloid Leukemia (AML)

- i. Documentation of AML that is FLT3 internal tandem duplication (ITD) positive by an FDA-approved test.
- ii. Documented use in combination with standard cytarabine and anthracycline induction and cytarabine consolidation regimens or as maintenance monotherapy following consolidation chemotherapy.

Other Uses With Supportive Evidence

B. Myeloid/lymphoid neoplasms with eosinophilia and FLT3 rearrangement

- II. Minimum age requirement: 18 years old.
- III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.
- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Maintenance monotherapy following allogeneic hematopoietic stem cell transplantation.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 17.7mg or 26.5mg tablet: 28/28 days

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 12 months with an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

1. Vanflyta. Prescribing information. Daiichi Sankyo, Inc. 2024. Accessed February 20, 2026. <https://daiichisankyo.us/prescribing-information-portlet/getPIContent?productName=Vanflyta&inline=true>
2. Erba HP, Montesinos P, Kim HJ, et al; QuANTUM-First Study Group. Quizartinib plus chemotherapy in newly diagnosed patients with FLT3-internal-tandem-duplication-positive acute myeloid leukaemia (QuANTUM-First): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2023;401(10388):1571-1583. doi: 10.1016/S0140-6736(23)00464-6
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia. Version 3.2026. Updated November 24, 2025. Accessed February 20, 2026. www.nccn.org/professionals/physician_gls/pdf/aml/pdf.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.