

Quizartinib (VANFLYTA) in Acute Myeloid Leukemia

Criteria for Use

April 2026

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If ANY of the following are selected, the patient will NOT meet criteria for quizartinib.

- Uncorrected severe hypokalemia (< 3 mmol/L) or severe hypomagnesemia (< 0.4 mmol/L)
- History of ventricular arrhythmias or torsade de pointes
- Prolonged QTc interval (at baseline or during monitoring as recommended in prescribing information) including history of long QT syndrome
- Use of quizartinib for maintenance monotherapy following allogeneic hematopoietic stem cell transplantation
- Unmanageable drug-drug interactions¹
- Pregnancy
- Lactating

¹. When used concomitantly with strong CYP3A inhibitors: Dose of quizartinib is reduced as per prescribing information.

Inclusion Criteria

All of the following must be selected to meet criteria.

- Care is provided by a VA / VA Community Care hematology/ oncology provider
- Goals of care and role of Palliative Care consult have been discussed and documented
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2
- Newly diagnosed acute myeloid leukemia (AML) positive for FLT3 internal tandem duplication (ITD) mutation
- Use in combination with standard cytarabine and anthracycline induction and cytarabine consolidation regimens or as maintenance monotherapy following consolidation chemotherapy
- Provider and pharmacy are certified in the VANFLYTA Risk Evaluation and Mitigation Strategy (REMS) restricted access program

Additional Inclusion Criteria – Select if Applicable

- For females who can become pregnant: Pregnancy should be excluded prior to receiving quizartinib. Counselor on potential risks vs benefits of treatment and the use of effective contraception during treatment and for up to 7 months after the last dose.
- For females who can become pregnant and males with partners who can become pregnant: Counselor provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 4 months after stopping treatment.
- For females who are lactating/providing breastmilk to an infant or planning to do so: Advise not to breastfeed during treatment and for 1 month after the last dose.

Other Justification

Prepared: December 2023 by Francine Goodman, PharmD, BCPS, National PBM Clinical Pharmacy Program Manager, Formulary Management, VA Pharmacy Benefits Management Services (12PBM); Revised Apr 2026

Contact person: B. Heron, PharmD, BCOP, National National PBM Clinical Pharmacy Program Manager, Formulary Management, VA Pharmacy Benefits Management Services (12PBM)
