Quizartinib (VANFLYTA) in Acute Myeloid Leukemia
Criteria for Use
December 2023

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

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
- ☐ Concomitant strong or moderate CYP3A inducers and unmanageable drug-drug interactions
- ☐ Inability to swallow the tablets whole
- ☐ Lactating

Inclusion Criteria

ALL of the following must be selected in order to meet criteria:

- ☐ Newly diagnosed acute myeloid leukemia (AML) positive for FLT3 internal tandem duplication (ITD) mutation
- ☐ Has an absolute contraindication or unmanageable intolerance to midostaurin
- ☐ 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. See VANFLYTAREMS.com.
- ☐ Prescribed and monitored by a VA / VA Community Care hematologist / oncologist
- ☐ 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

Additional Inclusion Criteria

Select if appropriate.

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

☐ For pregnant patients: Advised of the potential risk to a fetus.
☐ For patients who can become pregnant: Pregnancy status verified within 7 days pre-treatment. Counseled 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 males with female partners who can become pregnant: Counseled on potential risks vs benefits of treatment and the use of effective contraception during treatment and for up to 4 months after the last dose.
☐ For patients who are lactating: Advised not to share breastmilk with infant during treatment and for 1 month after the last dose.

Other Justification

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