Commercial/Healthcare Exchange PA Criteria

Effective: October 3, 2023

Prior Authorization: Vanflyta (quizartinib)

Products Affected: Vanflyta (quizartinib) oral tablets

Medication Description: VANFLYTA is indicated in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive as detected by an FDA-approved test. Quizartinib is a small molecule inhibitor of the receptor tyrosine kinase FLT3. Quizartinib and its major active metabolite AC886 bind to the adenosine triphosphate (ATP) binding domain of FLT3 with comparable affinity, and both had 10-fold lower affinity towards FLT3-ITD mutation compared to FLT3 in a binding assay. Quizartinib and AC886 inhibited FLT3 kinase activity, preventing autophosphorylation of the receptor, thereby inhibiting downstream FLT3 receptor signaling and blocking FLT3-ITD-dependent cell proliferation. Quizartinib showed antitumor activity in a mouse model of FLT3-ITD-dependent leukemia.

Covered Uses:

1. Newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive

Exclusion Criteria:

1. Severe hypokalemia
2. Severe hypomagnesemia
3. Long QT syndrome
4. History of ventricular arrhythmias or torsades de pointes

Required Medical Information:

1. Diagnosis
2. Medical History
3. Current laboratory values and EKG

Prescriber Restriction: Medication must be prescribed by, or in consultation with, and oncologist

Age Restriction: 18 years and older

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

1. Acute Myeloid Leukemia.

A. Patient has *FLT3-ITD* mutation-positive disease as detected by an approved test; **AND**

B. This medication is being used for induction, consolidation, or maintenance treatment.

References:

1. Product Information: VANFLYTA® oral tablets, quizartinib oral tablets. Daiichi Sankyo (per FDA), Basking Ridge, NJ, 2023.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	10/3/2023