UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1417-2
Program	Prior Authorization/Notification
Medication	Vanflyta® (quizartinib)
P&T Approval Date	9/2023, 9/2024
Effective Date	11/17/2024

1. Background:

Vanflyta (quizartinib) is a kinase inhibitor 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. NCCN also recommends Vanflyta for the treatment of relapsed/refractory disease as a component of repeating the initial successful induction regimen or as a single agent.

Limitations of Use:
Vanflyta is not indicated as maintenance monotherapy following allogeneic hematopoietic stem cell transplantation (HSCT); improvement in overall survival with Vanflyta in this setting has not been demonstrated.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Vanflyta** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Acute Myeloid Leukemia</u>

1. **<u>Initial Authorization</u>**

   a. **Vanflyta** will be approved based on **<u>all</u>** of the following criteria:

      (1) Diagnosis of acute myeloid leukemia (AML)

-AND-

(2) Disease is FLT3 internal tandem duplication (ITD) positive

-AND-

(3) One of the following:

i. Vanflyta will be used in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy

-OR-

ii. Vanflyta will be used for patients with relapsed/refractory disease as a component of repeating the initial successful induction regimen or as a single agent.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Vanflyta** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Vanflyta therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limit may be in place.

4. References:

1. Vanflyta [package insert]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; July 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org . Accessed August 8, 2024.

Program	Prior Authorization/Notification - Vanflyta (quizartinib)
Change Control	
9/2023	New program
9/2024	Annual review. Added coverage on relapsed/refractory disease per NCCN recommendations. Updated references.