PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Vanflyta Prior Authorization Policy
- Vanflyta® (quizartinib tablets – Daiichi Sankyo)

REVIEW DATE: 06/19/2024

OVERVIEW

Vanflyta, a kinase inhibitor, is indicated in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of **newly diagnosed acute myeloid leukemia (AML)** that is FMS-like tyrosine kinase 3 internal tandem duplication (**FLT3-ITD)-positive** as detected by an FDA-approved test in adults.[1]

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

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for AML (version 3.2024 – May 17, 2024) recommend Vanflyta in combination with standard 7+3 (cytarabine + daunorubicin or idarubicin) for patients with AML with *FLT3-ITD* mutation as induction therapy for those that are induction eligible (category 1).[2] Vanflyta in combination with chemotherapy is also recommended as re-induction after standard-dose induction and as consolidation therapy for patients with *FLT3-ITD* mutation (category 2A). Vanflyta is recommended as maintenance therapy for patients with *FLT3-ITD* mutation who have previously received Vanflyta and no allogeneic hematopoietic stem cell transplantation (HSCT) is planned (category 2A) or post allogeneic HSCT in remission (category 2B). Single-agent Vanflyta is recommended for relapsed/refractory disease for patients with *FLT3-ITD* mutation (category 2B).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Vanflyta. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vanflyta is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Acute Myeloid Leukemia.** Approve for 1 year if the patient meets ALL of the following (A, B and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has *FLT3-ITD* mutation-positive disease as detected by an approved test; AND
   - **C)** This medication is being used for induction, re-induction, consolidation, or maintenance treatment.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Vanflyta is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Vanflyta® tablets [prescribing information]. Basking Ridge, NJ: Daiichi Sankyo, July 2023.
2. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 3.2024 – May 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 13, 2024.