VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 08/02/2023; selected revision 08/09/2023

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 4.2023 – July 11, 2023) do not address Vanflyta.[2] The guidelines recommend Rydapt® (midostaurin capsules) in several settings in adults with *FLT3*-mutated AML. Rydapt + chemotherapy is recommended for induction for newly diagnosed *FLT3-ITD/TKD* mutation-positive AML and for consolidation therapy (category 2A). Other consolidation therapies include hematopoietic cell transplantation (HCT), high dose cytarabine, or other chemotherapy. For maintenance therapy in patients with *FLT3-ITD* mutation who are in remission, sorafenib (category 2A), Rydapt (category 2B), and Xospata® (gilteritinib tablets) [category 2B] are recommended. For relapsed or refractory AML, Xospata is recommended for patients with *FLT3-ITD/TKD* mutations.

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 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, 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 4.2023 – July 11, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 28, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New policy	--	08/02/2023
Selected Revision	**Acute Myeloid Leukemia (AML)**: The requirement that the medication is being used for induction, consolidation, or maintenance treatment was added.	08/09/2023