Reference number(s)
6096-A

Specialty Guideline Management
Vanflyta

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Vanflyta	quizartinib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

Acute Myeloid Leukemia

Vanflyta 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.

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.

All other indications are considered experimental/investigational and not medically necessary.

Compendial Use[2]

AML – as maintenance therapy post-allogeneic HSCT, in remission with history of FLT3-ITD

Documentation

Submission of the following information is necessary to initiate the prior authorization review: medical record documentation of FLT3 internal tandem duplication (ITD) mutation.

Coverage Criteria

Acute Myeloid Leukemia (AML)[1]

Authorization of 12 months may be granted for treatment of AML that is FLT3 internal tandem duplication (ITD)-positive in any of the following clinical settings:

- Induction therapy or re-induction in combination with cytarabine and daunorubicin or idarubicin
- Consolidation therapy in combination with cytarabine
- Maintenance therapy as a single agent

Continuation of Therapy

Authorization of 12 months (for up to 36 months maintenance therapy) may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Vanflyta [package insert]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; June 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 24, 2025.