PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Oral – FMS-Like Tyrosine Kinase 3 Inhibitor) – Vanflyta Prior Authorization Policy
- Vanflyta® (quizartinib tablets – Daiichi Sankyo)

REVIEW DATE: 05/07/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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

Vanflyta is discussed in the National Comprehensive Cancer Network (NCCN) guidelines:

- **AML:** NCCN guidelines (version 2.2025 – January 27, 2025) recommend Vanflyta in combination with standard 7+3 (cytarabine + daunorubicin or idarubicin) regimen for patients with AML with *FLT3-ITD* mutation as induction therapy for those who are candidates for intensive induction therapy (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 as a single agent for patients with *FLT3-ITD* mutation who have previously received a FLT3 inhibitor and no allogeneic hematopoietic stem cell transplantation (HSCT) is planned or post allogeneic HSCT in remission (category 2A). Single-agent Vanflyta is recommended for relapsed/refractory disease for patients with *FLT3-ITD* mutation (category 2B).
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusion:** NCCN guidelines (version 2.2025 – April 4, 2025) recommend Vanflyta for patients with eosinophilia and FLT3 rearrangement in chronic or blast phase (category 2A).[4] Vanflyta is also recommended for treatment in combination with acute lymphoblastic leukemia (ALL)- or AML-type induction chemotherapy followed by allogeneic hematopoietic cell transplantation (if eligible) for lymphoid, myeloid or mixed lineage neoplasms with eosinophilia and *FLT3* rearrangements in blast phase (category 2A).

POLICY STATEMENT

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

- **Vanflyta® (quizartinib tablets - Daiichi Sankyo)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Acute Myeloid Leukemia.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has *FLT3-ITD* mutation-positive disease as detected by an approved test.

Other Uses with Supportive Evidence

2. **Myeloid or Lymphoid Neoplasms.** 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 eosinophilia; AND
   C) The tumor has an *FLT3* rearrangement.

CONDITIONS NOT COVERED

- **Vanflyta® (quizartinib tablets - Daiichi Sankyo)**

is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Vanflyta® tablets [prescribing information]. Basking Ridge, NJ: Daiichi Sankyo, June 2024.
2. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 2.2025 – January 27, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.ncc.org. Accessed on May 5, 2025.
3. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Clinical Practice Guidelines in Oncology (version 2.2025 – April 4, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.ncc.org. Accessed on May 5, 2025.

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
Selected Revision	**Acute Myeloid Leukemia (AML**): "Re-induction" was added to the criterion which states that this medication is being used for induction, consolidation, or maintenance treatment.	02/07/2024
Annual Revision	No criteria changes.	06/19/2024
Update	04/08/2025: The policy name was changed from "Oncology – Vanflyta PA Policy" to "Oncology (Oral - FMS-Like Tyrosine Kinase 3 Inhibitor) – Vanflyta PA Policy".	--
Annual Revision	**Acute Myeloid Leukemia:** The requirement that the medication is being used for induction, re-induction, consolidation, or maintenance treatment was removed. **Myeloid or Lymphoid Neoplasms:** This condition and criteria for approval were added to Other Uses with Supportive Evidence.	05/07/2025