PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 08/02/2023; selected revision 08/09/2023 and 02/07/2024

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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

The National Comprehensive Cancer Network (NCCN) guidelines for AML (version 6.2023 – October 24, 2023) 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). 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.

- **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 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 COVERED

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

is(are) considered experimental, investigational, or unproven for ANY other use(s).

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 6.2023 – October 24, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 1, 2024.

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