PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Xospata Prior Authorization Policy
- Xospata® (gilteritinib tablets – Astellas)

REVIEW DATE: 01/17/2024

OVERVIEW

Xospata, an inhibitor of tyrosine kinases including FMS-like tyrosine kinase 3 (*FLT3*), is indicated for the treatment of relapsed or refractory **acute myeloid leukemia** in adults with an *FLT3* mutation as detected by an FDA-approved test.[1]

Guidelines

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

- **Acute Myeloid Leukemia:** Guidelines (version 6.2023 – October 24, 2023) recommend Xospata in patients with relapsed or refractory disease and *FLT3*-internal tandem duplication (*FLT3-ITD*) or *FLT3*-tyrosine kinase domain (*FLT3-TKD*) mutation (category 1 for both).[2] Xospata is also recommended as treatment induction for patients with a *FLT3* mutation who are not candidates for intensive induction therapy (category 2B); it is also recommended for follow-up after treatment induction and consolidation therapy in specific situations (category 2B) and as maintenance therapy for patients who are post-allogeneic hematopoietic stem cell transplantation in remission with a *FLT3* mutation (category 2B).
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes:** Guidelines (version 1.2024 – December 21, 2023) recommend Xospata for the treatment of myeloid/lymphoid neoplasms with eosinophilia and *FLT3* rearrangement in chronic phase or blast phase (category 2A). Xospata is also recommended in combination with acute lymphocytic leukemia- or acute myeloid leukemia-type induction chemotherapy followed by allogeneic hematopoietic stem cell transplantation (if eligible) for lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia and *FLT3* rearrangement in blast phase (category 2A).[3]

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Xospata is recommended in those who meet one of 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 relapsed or refractory disease; AND
   - **C)** Disease is *FLT3*-mutation positive as detected by an approved test.

Other Uses with Supportive Evidence

2. Myeloid/Lymphoid Neoplasms. 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 eosinophilia; AND
- **C)** Disease is *FLT3*-mutation positive as detected by an approved test.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Xospata 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 Condition.

REFERENCES

1. Xospata® tablets [prescribing information]. Northbrook, IL: Astellas Pharma; January 2022.
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 January 12, 2024.
3. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 12, 2024.