

SPECIALTY GUIDELINE MANAGEMENT

XOSPATA (gilteritinib)

POLICY

I. 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.

A. FDA-Approved Indication

Xospata is indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test.

B. Compendial Uses

1. Myeloid/lymphoid neoplasms with eosinophilia and FLT3 rearrangement in chronic phase or blast phase
2. Myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FLT3 rearrangement in blast phase

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

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: medical record documentation of FLT3 mutation

III. CRITERIA FOR INITIAL APPROVAL

A. **Acute Myeloid Leukemia (AML)**

Authorization of 12 months may be granted for the treatment of FLT3 mutation-positive relapsed or refractory AML when the requested medication is used as a single-agent.

B. **Myeloid/Lymphoid Neoplasms with eosinophilia**

Authorization of 12 months may be granted for the treatment of myeloid and/or lymphoid neoplasms with eosinophilia with a FLT3 rearrangement in the chronic phase or blast phase.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Xospata [package insert]. Northbrook, IL: Astellas Pharma US, Inc.; January 2022.

Reference number(s)
2807-A

2. The NCCN Drugs & Biologics Compendium® 2023 National Comprehensive Cancer Network, Inc.
<http://www.nccn.org>. Accessed January 09, 2023.