Reference number(s)
2807-A

Specialty Guideline Management
Xospata

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
Xospata	gilteritinib

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]

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.

Compendial Uses[2]

- Myeloid/lymphoid neoplasms with eosinophilia and FLT3 rearrangement in chronic phase or blast phase
- Myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FLT3 rearrangement in blast phase
- AML

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

Documentation

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Submission of the following information is necessary to initiate the prior authorization review: medical record documentation of FLT3 and isocitrate dehydrogenase 1 (IDH1) mutation status, where applicable

Coverage Criteria

Acute Myeloid Leukemia (AML)[1,2]

Authorization of 12 months may be granted for the treatment of FLT3 mutation-positive AML without IDH1 mutation as a single agent or in combination with azacitidine in any of the following clinical settings:

- Induction therapy if not a candidate for or declines intensive induction therapy
- Post-induction therapy when the member has experienced response to Xospata therapy

Authoriation of 12 months may be granted for the treatment of FLT3 mutation-positive AML as a single agent in any of the following clinical settings:

- Maintenance therapy post-allogeneic hematopoietic cell transplantation
- Relapsed or refractory disease

Myeloid/Lymphoid Neoplasms with eosinophilia[2]

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.

Continuation of Therapy

Authorization of 12 months 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. Xospata [package insert]. Northbrook, IL: Astellas Pharma US, Inc.; January 2022.
2. The NCCN Drugs & Biologics Compendium® 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed January 21, 2025.