# 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 Indications

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

## B. Compendial Uses

- 1. Myeloid/lymphoid neoplasms with eosinophilia and FLT3 rearrangement in chronic 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 (new starts only): 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 Inc.; May 2019.

Xospata 2807-A SGM P2021.docx

© 2021 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.



Reference	number(s)
2807-A	

2. The NCCN Drugs & Biologics Compendium® @2021 National Comprehensive Cancer Network, Inc. <a href="http://www.nccn.org">http://www.nccn.org</a>. Accessed January 14, 2021.

Xospata 2807-A SGM P2021.docx

© 2021 CVS Caremark. All rights reserved.

