Reference number(s)
2807-A

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.

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.

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 as detected by an FDA-approved test

III. CRITERIA FOR INITIAL APPROVAL

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.

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 who have not experienced disease progression or an unacceptable toxicity.

V. REFERENCES

1. Xospata [package insert]. Northbrook, IL: Astellas Pharma Inc.; May 2019.
2. The NCCN Drugs & Biologics Compendium 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed July 17, 2019.

© 2019 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.