MEDICAL MUTUAL®

Drug Policy

Policy:	Xospata (gilteritinib)	Annual Review Date: 1/21/2021 Last Revised Date: 1/21/2021

OVERVIEW

Xospata, an inhibitor of tyrosine kinases including FMS-like tyrosine-kinase 3 (FLT3), 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. The recommended initial dose is 120 orally once daily (QD). Response may be delayed. In the absence of disease progression or unacceptable toxicity, treatment for a minimum of 6 months is recommended to allow time for a clinical response. Dosage modifications are recommended for patients who experience toxicities related to Xospata.

POLICY STATEMENT

This policy involves the use of Xospata. Prior authorization is recommended for pharmacy benefit coverage of Xospata. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Xospata as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Xospata be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, Xospata must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Xospata is recommended in those who meet the following criteria:

1. **Acute Myeloid Leukemia (AML)**
   Criteria. *Patient must meet the following criteria.*
   - **A.** Patient has AML with FLT3 mutation (ITD or TKD), as detected by an FDA-approved test; AND
   - **B.** Patient has relapsed or refractory disease; AND
   - **C.** Patient is 18 years of age or older; AND
   - **D.** Xospata is used as a single-agent therapy.

2. **Myeloid/Lymphoid Neoplasms with Eosinophilia**
   Criteria. *Patient must meet the following criteria.*

A. Patient has FLT3 rearrangement in chronic phase; OR
B. Patient has FLT3 rearrangement in blast phase AND Xospata will be used in combination with ALL- or AML-type induction chemotherapy followed by allogenic HCT (if eligible)

3. **Another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
Criteria. *Prescriber will provide specific diagnosis for documentation. Approve.*

4. **Patient has been started on Xospata**
Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Xospata® tablets [prescribing information]. Northbrook, IL: Astellas Pharma; May 2019.
2. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (Version 2.2018 – August 1, 2018). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on 21 January 2020.
3. Gilteritinib. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 7 December 2020. Accessed on 5 January 2021.
4. The NCCN Drugs and Biologics Compendium. © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed 5 January 2021.