Xospata (gilteritinib)

Override(s)	Approval Duration
Prior Authorization	1 year
Quantity Limit	-

Medications	Quantity Limit
Xospata (gilteritinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Xospata (gilteritinib) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has a diagnosis for relapsed or refractory acute myeloid leukemia (AML); AND
- III. Individual has an FMS-like tyrosine kinase 3 (FLT3) mutation;

OR

- IV. Individual has a diagnosis for myeloid/lymphoid neoplasm with eosinophilia (NCCN 2A);AND
- V. Individual has an FMS-like tyrosine kinase 3 (FLT3) mutation.

Key References:

- Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
- 2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
- 3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- 4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
- 5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information, visit the NCCN website: http://www.nccn.org/index.asp. Accessed on September 13, 2023.
 - a. Acute Myeloid Leukemia. V4.2023. Revised July 11, 2023.
 - Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes. V2.2023. Revised July 14, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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