Clinical Policy: Gilteritinib (Xospata)

Reference Number: ERX.SPA.316
Effective Date: 03.01.19
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Gilteritinib (Xospata®) is a tyrosine kinase inhibitor.

FDA Approved Indication(s)
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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Xospata is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acute Myeloid Leukemia (must meet all)**:**
1. Diagnosis of relapsed or refractory AML;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. For Xospata requests, member must use gilteritinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. Documentation of a FLT3 mutation;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 120 mg (3 tablets) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

B. Myeloid/Lymphoid Neoplasm with Eosinophilia (off-label) (must meet all)**:**
1. Diagnosis of a myeloid/lymphoid neoplasm with eosinophilia (MLNE);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. For Xospata requests, member must use gilteritinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. Documentation of a FLT3 mutation;
6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit

Medicaid – 6 months

B. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Xospata for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. For Xospata requests, member must use gilteritinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 120 mg (3 tablets) per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration:
Commercial – Length of Benefit
Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AML: acute myeloid leukemia
FDA: Food and Drug Administration
FLT3: FMS-like tyrosine kinase 3
MLNE: myeloid/lymphoid neoplasm with eosinophilia
NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): hypersensitivity to Xospata or any of the excipients
- Boxed warning(s): differentiation syndrome

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
AML	120 mg PO QD	120 mg/day

VI. Product Availability
Tablet: 40 mg

VII. References

1. Xospata Prescribing Information. Northbrook, IL: Astella Pharma US, Inc.; May 2019. Available at www.xospata.com. Accessed November 9, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed November 9, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01.15.19	02.19
No significant changes: added that Rydapt may require PA.	04.25.19	
1Q 2020 annual review: Nexavar added as a prior therapy option given unique place in FLT3 therapy per NCCN; added Medicaid line of business with 6/12 month approval durations; references reviewed and updated.	11.19.19	02.20
1Q 2021 annual review: oral oncology generic redirection language added; TKI trials removed from AML given increased Xospata NCCN rating from 2A to 1; AML continuing therapy duration increased to 12 months; MLNE NCCN recommended use added; references reviewed and updated.	10.12.20	02.21
1Q 2022 annual review: no significant changes; clarified oral oncology generic redirection language to “must use”; references reviewed and updated.	11.09.21	02.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.