Clinical Policy: Gilteritinib (Xospata)

Reference Number: PA.CP.PHAR.412
Effective Date: 4.17.19
Last Review Date: 04.19 Revision Log

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.

It is the policy of health plans affiliated with PA Health & Wellness® 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 AML;
2. Documentation of the presence of an FLT3 mutation;
3. Prescribed by or in consultation with an oncologist or hematologist;
4. Age ≥ 18 years;
5. Failure of a Rydapt® (midostaurin)-containing regimen (*see Appendix B*), unless contraindicated or clinically significant adverse effects are experienced;
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*).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Acute Myeloid Leukemia (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, 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*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

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 – PA.CP.PMN.53 for Medicaid 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

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Rydapt (midostaurin) + cytarabine + daunorubicin	Rydapt 50 mg PO Q12 hours on days 8-21 + cytarabine 200 mg/m^2 IV x 7 days + daunorubicin 60 mg/m^2 IV x 3 days	Rydapt 100 mg/day; cytarabine 200 mg/m^2/day; daunorubicin 60 mg/m^2/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity to Xospata or any of the excipients
- Boxed warning(s): none reported

V. Dosage and Administration

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

VI. Product Availability

Tablets: 40 mg

VII. References

1. Xospata Prescribing Information. Northbrook, IL: Astella Pharma US, Inc.; November 2018. Available at www.xospata.com. Accessed December 21, 2018.
2. Ravandi F, Alattar ML, et al. Phase 2 study of azacytidine plus sorafenib in patients with acute myeloid leukemia and FLT-3 internal tandem duplication mutation. Blood 2013;121(23):4655-62.
3. National Comprehensive Cancer Network. Acute Myeloid Leukemia Version 3.2018. Available at: http://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed December 21, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.17.19	