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Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	December 7, 2018
Subject:	Xospata	**Page:**	1 of 5

Last Review Date: December 8, 2023

Xospata

Description

Xospata (gilteritinib)

Background

Xospata (gilteritinib) is a small molecule that inhibits multiple receptor tyrosine kinases, including FMS-like tyrosine kinase 3 (FLT3). Xospata inhibits FLT3 receptor signaling and proliferation in cells exogenously expressing FLT3 including FLT3-ITD, tyrosine kinase domain mutations (TKD) FLT3-D835Y and FLT3-ITD-D835Y, and it also induces apoptosis in leukemic cells expressing FLT3-ITD (1).

Regulatory Status

FDA-approved indication: Xospata is a kinase inhibitor 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 (1).

Xospata has a boxed warning regarding differentiation syndrome. If differentiation syndrome is suspected, corticosteroid therapy and hemodynamic monitoring should be initiated until symptom resolution (1).

Prior to initiation of Xospata, blood counts and blood chemistries, including creatine phosphokinase, should be assessed at least once weekly for the first month, once every other week for the second month, and once monthly for the duration of therapy (1).

Posterior reversible encephalopathy syndrome (PRES) may occur in patients taking Xospata. Xospata should be discontinued in patients who develop PRES (1).

Xospata may cause prolonged cardiac ventricular repolarization (QT interval). An electrocardiogram (ECG) should be performed before initiating therapy, on days 8 and 15 of cycle 1, and prior to the start of the next two subsequent cycles. Xospata should be interrupted and reduced in patients who have a QTcF > 500 msec (1).

Xospata may cause fetal harm. Females of reproductive potential should be advised of the potential risk to the fetus and to use effective contraception during treatment and for at least 6 months after the final dose of Xospata. Males with female partners of reproductive potential should be advised to use effective contraception during treatment and for at least 4 months after the last dose of Xospata (1).

The safety and effectiveness of Xospata in pediatric patients have not been established (1).

Related policies
Rydapt

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Xospata may be considered **medically necessary** if the conditions indicated below are met.

Xospata may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Relapsed or refractory acute myeloid leukemia (AML)

AND ALL of the following:

1. Documented FLT3 mutation as detected by an FDA-approved test
2. Prescriber agrees to monitor electrocardiogram (ECG), complete blood

count (CBC), and creatine phosphokinase
3. Females of reproductive potential **only**: patient will be advised to use effective contraception during therapy and for at least 6 months after the last dose
4. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during therapy and for at least 4 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Relapsed or refractory acute myeloid leukemia (AML)

AND ALL of the following:
1. **NO** disease progression or unacceptable toxicity
2. Prescriber agrees to monitor electrocardiogram (ECG), complete blood count (CBC), and creatine phosphokinase
3. Females of reproductive potential **only**: patient will be advised to use effective contraception during therapy and for at least 6 months after the last dose
4. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during therapy and for at least 4 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 270 tablets per 90 days

Duration 6 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Xospata (gilteritinib) is a small molecule that inhibits multiple receptor tyrosine kinases, including FMS-like tyrosine kinase 3 (FLT3). Xospata inhibits FLT3 receptor signaling and proliferation in cells exogenously expressing FLT3 including FLT3-ITD, tyrosine kinase domain mutations (TKD) FLT3-D835Y and FLT3-ITD-D835Y, and it also induces apoptosis in leukemic cells expressing FLT3-ITD. The safety and effectiveness of Xospata in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Xospata while maintaining optimal therapeutic outcomes.

References

1. Xospata [package insert]. Northbrook, IL: Astellas Pharma US, Inc.; January 2022.
2. NCCN Drugs & Biologics Compendium® Gilteritinib 2023. National Comprehensive Cancer Network, Inc. Accessed on October 2, 2023.

Policy History

Date	Action
December 2018	Addition to PA
March 2019	Annual review
June 2020	Annual review and reference update
December 2021	Annual review and reference update
December 2022	Annual editorial review and reference update. Updated contraception requirements for consistency
March 2023	Annual review and reference update
December 2023	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.