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).

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 in patients 18 years of age or older with relapsed or refractory acute myeloid leukemia (AML) and if the conditions indicated below are met.

Xospata is considered investigational in patients under 18 years of age and 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. Prescriber agrees to advise female patients of reproductive potential to use effective contraception during therapy and for at least 6 months after the final dose.

4. Prescriber agrees to advise male patients with female partners of reproductive potential to use effective contraception during therapy and for at least 4 months after the final 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. Prescriber agrees to advise female patients of reproductive potential to use effective contraception during therapy and for at least 6 months after the final dose.
4. Prescriber agrees to advise male patients with female partners of reproductive potential to use effective contraception during therapy and for at least 4 months after the final 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


### Policy History

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<td>Addition to PA</td>
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<td>Annual review</td>
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### Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.