BlueCross BlueShield Federal Employee Program

XOSPATA (gilteritinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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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 2025. National Comprehensive Cancer Network, Inc. Accessed on January 9, 2025.