ConnectiCare

Commercial/Healthcare Exchange PA Criteria

Effective: March 8th, 2019

Prior Authorization: Xospata

Products Affected: Xospata (gilteritinib) oral tablet

Medication Description: Xospata is a small molecule that inhibits multiple receptor tyrosine kinases, including FMS-like tyrosine kinase 3 (FLT3). Xospata demonstrated the ability to inhibit 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 induced apoptosis in leukemic cells expressing FLT3-ITD.

Covered Uses: 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.

Exclusion Criteria:

1. Hypersensitivity to gilteritinib or any of the excipients.

Required Medical Information:

1. Diagnosis
2. Patients must have the FLT3-mutation, as detected by an FDA approved test

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, an oncologist.

Coverage Duration:

Initial: 12 months
Continuation: 3 years

Other Criteria:

A. The patient has a diagnosis of relapsed or refractory acute myeloid leukemia (AML); AND
B. The patient has FLT3-mutation positive AML as detected by an FDA-approved test.

References:

1. Product Information: XOSPATA(R) oral tablets, gilteritinib oral tablets. Astellas Pharma US Inc (per FDA), Northbrook, IL, 2018.

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Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date	
1	New Policy	New Policy	All	03/06/2019	
2	Update	Added continuation coverage duration of 3 years	Coverage Duration	7/1/2019	