gilteritinib (Xospata®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO032

Description

Gilteritinib (Xospata) is an orally administered FLT3 Tyrosine Kinase Inhibitor.

Length of Authorization

- Initial: 6 months
- Renewal: Twelve months

Quantity limits

gilteritinib (Xospata)	Indication	Quantity Limit	DDID
40 mg tablets	Relapse/Refractory FLT3 AML	90 tablets/30 days	204950

Initial Evaluation

I. Gilteritinib (Xospata) may be considered medically necessary when the following criteria are met:
   A. Member is 18 years of age or older; **AND**
   B. Prescribed by, or in consultation with, an oncologist or hematologist; **AND**
   C. A diagnosis of **relapsed/refractory FLT3-mutated acute myeloid leukemia** and all of the following are met:
      1. Relapsed/refractory defined as those that fail to attain a complete remission (CR) with intensive induction chemotherapy; **AND**
      2. Xospata (gilteritinib) will be used as monotherapy; **AND**
      3. FLT3 mutation status has been detected by an FDA-approved test (LeukoStrat CDx FLT3 mutation Assay by Invivoscribe Technologies,Inc.)

II. Gilteritinib (Xospata) is considered investigational when used for all other conditions, including but not limited to:
   A. Newly diagnosed AML
   B. AML in the absence of FLT3 mutation
   C. AML in combination with other therapies in the relapsed/refractory setting

Renewal Evaluation

I. Relapsed/refractory FLT3-mutated AML
   A. Clinical documentation of response to treatment, such as stabilization or improvement in disease; **AND**

B. Absence of disease progression after six months; **AND**
C. Absence of unacceptable toxicity from the medication; **AND**
D. Gilteritinib (Xospata) continues to be used as monotherapy

Supporting Evidence

I. Gilteritinib (Xospata) was studied in a phase III, randomized controlled trial against salvage chemotherapy in those that had relapsed or were refractory (i.e., had not reached CR following treatment).
II. Subjects included were adults with confirmed FLT3-mutated AML as detected by an FDA-approved test. Use of gilteritinib (Xospata) in assigned subjects was as monotherapy only. Currently, there are no literature available on safety and efficacy outside of this setting.

Investigational or Not Medically Necessary Uses

I. Newly diagnosed AML
    A. There is lack of evidence for the use of gilteritinib (Xospata)) in this setting.
II. AML in the absence of FLT3 mutation
    A. Clinical trials have only evaluated gilteritinib (Xospata) in patients that have a confirmed FLT3 mutation by an FDA-approved test.
III. AML in combination with other therapies in the relapsed/refractory setting
    A. There is a lack of evidence for the safety and efficacy of gilteritinib (Xospata) outside of the monotherapy setting. Clinical trials evaluated monotherapy only.

References

1. Xospata [Prescribing Information]. Northbrook, Illinois: Astellas Pharma; November 2018.
2. NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia. Version 3.2018. National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 10, 2019.
3. Rydapt [Prescribing Information]. East Hanover, New Jersey: Novartis pharmaceuticals; June 2018.
4. ClinicalTrials.gov

Policy Implementation/Update:

Date Created	January 2019
Date Effective	February 2019
Last Updated	
Last Reviewed	

Action and Summary of Changes	Date