UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Xospata

Program	Prior Authorization
Medication	Xospata®(gilteritinib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York CHIP, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	2/2019
Pharmacy and Therapeutics Approval Date	2/2021
Effective Date	4/2021

1. Background:

Xospata® (gilteritinib) is a kinase inhibitor indicated for the 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.[1]

The National Cancer Comprehensive Network (NCCN) also recommends the use of Xospata the treatment of myeloid/lymphoid neoplasms with eosinophilia and FMS-like tyrosine kinase 3 (FLT3) rearrangement.

2. Coverage Criteria:

A. Acute Myeloid Leukemia (AML)

1. Initial Authorization

a. Xospata will be approved based on **all** of the following criteria:

(1) Diagnosis of acute myeloid leukemia (AML)

-AND-

(2) AML is FMS-like tyrosine kinase 3 (FLT3) mutation-positive

-AND-

(3) Disease is relapsed or refractory

Authorization will be issued for 12 months.

2. Reauthorization

a. Xospata will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Xospata therapy

Authorization will be issued for 12 months.

B. Myeloid/Lymphoid Neoplasms

1. Initial Authorization

a. Xospata will be approved based on **all** of the following criteria:

(1) Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

-AND-

(2) **One** of the following:

(a) Patient has a FMS-like tyrosine kinase 3 (FLT3) rearrangement in chronic phase
(b) Treatment in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible) and FMS-like tyrosine kinase 3 (FLT3) rearrangement in blast phase

Authorization will be issued for 12 months.

2. Reauthorization

a. Xospata will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Xospata therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

1. Initial Authorization

a. **Xospata** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Xospata** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Xospata therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Xospata [package insert]. Northbrook, IL: Astellas Pharma US; May 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed December 14, 2020.

Program	Prior Authorization
Change Control	
Date	Change
2/2019	New program
2/2020	Annual review. Updated references.
2/2021	Annual review. Added NCCN recommendation for Myeloid/Lymphoid Neoplasms to background and updated treatment criteria. Reference updated.