UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1274-6
Program	Prior Authorization/Notification
Medication	Xospata®(gilteritinib)
P&T Approval Date	2/2019, 2/2020, 2/2021, 2/2022, 2/2023, 2/2024
Effective Date	5/1/2024

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) recommends the use of Xospata for the treatment of myeloid/lymphoid neoplasms with eosinophilia and FMS-like tyrosine kinase 3 (FLT3) rearrangement. NCCN also recommends Xospata for treatment of AML in combination with azacitidine in patients with FLT3 mutation for low-intensity treatment induction when not a candidate for intensive induction therapy, follow-up treatment after induction therapy following response to previous lower intensity therapy with the same regimen, or for maintenance therapy as a single agent in patients who are post-allogeneic hematopoietic cell transplantation, in remission, and have a history of FLT3 mutation.

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. Patients less than 19 years of age

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

   a. Member is less than 19 years of age

   Authorization will be issued for 12 months.

B. 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) **One** of the following:

(a) Used in combination with azacitidine as low-intensity treatment induction when not a candidate for intensive induction therapy

(b) Follow-up after induction therapy with response to previous lower intensity therapy with the same regimen

(c) Post-allogeneic hematopoietic cell transplantation and in remission

(d) 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.

C. 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 an FMS-like tyrosine kinase 3 (FLT3) rearrangement in chronic phase
(b) Patient has an 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.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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; January 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed December 22, 2023.

Program	Prior Authorization/Notification - Xospata (gilteritinib)
Change Control	
2/2019	New program.
2/2020	Annual review. Added general NCCN recommendations for use criteria. Updated references.
2/2021	Annual review. Added NCCN recommendation for Myeloid/Lymphoid Neoplasms to background and updated treatment criteria. References updated.
2/2022	Annual review. Updated references.
2/2023	Annual review. Updated treatment criteria for myeloid/lymphoid neoplasms per NCCN recommendations. Added state mandate and updated references.
2/2024	Annual review. Updated treatment criteria for AML to include additional NCCN recommendations.