

PHARMACY COVERAGE GUIDELINE

XOSPATA™ (gilteritinib) oral tablets Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

Scope

- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance

- To determine whether a member is eligible for the Service, read the entire PCG.
 - This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
 - Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
 - The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
 - The “Description” section describes the Service.
 - The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
 - The “Resources” section lists the information and materials we considered in developing this PCG
 - **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
 - Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.
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Criteria:

- **Criteria for initial therapy:** Xospata (gilteritinib) and/or generic equivalent (if available) are considered **medically necessary** and will be approved when **ALL** the following criteria are met:
 1. Prescriber is a physician specializing in the patient’s diagnosis or is in consultation with an Oncologist
 2. Individual is 18 years of age or older
 3. Individual has a confirmed diagnosis of **ONE** of the following:
 - a. Treatment of relapsed/refractory acute myeloid leukemia (AML) with an FMS-like tyrosine kinase 3 (FLT3) mutation in the blood or bone marrow

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- b. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A
4. Individual has received and completed **ALL** the following **baseline tests** before initiation of treatment and with continued monitoring of the individual as clinically appropriate:
 - a. Presence of FLT3 mutation in the blood or bone marrow
 - b. Creatine phosphokinase
 - c. Correction of hypokalemia and hypomagnesemia, if present
 - d. Electrocardiogram
 - e. Negative pregnancy test in a woman of childbearing potential
 - f. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-2
5. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] ([see Definitions section](#))
6. Individual does not have severe renal impairment (creatinine clearance (CrCl) less than 30 mL/min)
7. Individual does not have severe hepatic impairment (Child-Pugh Class C)

Initial approval duration: 6 months

➤ **Criteria for continuation of coverage (renewal request):** Xospata (gilteritinib) and/or generic equivalent (if available) are considered **medically necessary** and will be approved when **ALL** the following criteria are met (**samples are not considered for continuation of therapy**):

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist
2. Individual's condition has responded while on therapy with response defined as the following:
 - a. Documented evidence of efficacy, disease stability and/or improvement
 - b. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use
3. Individual has been adherent with the medication
4. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] ([see Definitions section](#))
5. Individual has not developed significant adverse drug effects that may exclude continued use such as posterior reversible encephalopathy syndrome (PRES)
6. Individual does not have severe renal impairment (creatinine clearance (CrCl) less than 30 mL/min)
7. Individual does not have severe hepatic impairment (Child-Pugh Class C)

ORIGINAL EFFECTIVE DATE: 02/21/2019 | ARCHIVE DATE: | LAST REVIEW DATE: 02/20/2025 | LAST CRITERIA REVISION DATE: 02/15/2024

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Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:
1. **Off-Label Use of Non-Cancer Medications**
 2. **Off-Label Use of Cancer Medications**
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Description:

Xospata (gilteritinib) is indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with FLT3 mutation. Gilteritinib is a small molecule that inhibits multiple receptor tyrosine kinases, including FMS-like tyrosine kinase 3 (FLT3). Gilteritinib demonstrated the ability to inhibit FLT3 receptor signaling and proliferation in cells exogenously expressing FLT3 including internal tandem duplications (FLT3-ITD), tyrosine kinase domain mutations (TKD) FLT3-D835Y and FLT3-ITD-D835Y, and it induced apoptosis in leukemic cells expressing FLT3-ITD.

AML is a rapidly progressing cancer that crowds out normal cells in the bone marrow and bloodstream, resulting in low numbers of normal blood cells and a continuous need for transfusions. Approximately 25-30% of patients with AML have a mutation in the FLT3 gene.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
[MedWatch Forms for FDA Safety Reporting | FDA](#)

Resources:

Xospata (gilteritinib) tab product information, revised by Astellas Pharma US, Inc. 01-2022. Available at DailyMed
<http://dailymed.nlm.nih.gov>. Accessed December 09, 2024.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Acute Myeloid Leukemia Version 2.2025 – Updated January 27, 2025. Available at <https://www.nccn.org>. Accessed January 30, 2025.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.