



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 2/21/2019
LAST REVIEW DATE: 2/17/2022
LAST CRITERIA REVISION DATE: 2/17/2022
ARCHIVE DATE:

XOSPATA™ (gilteritinib) oral tablets

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**



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Criteria:

- **Criteria for initial therapy:** Xospata (gilteritinib) is considered *medically necessary* and will be approved when **ALL** of 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. A confirmed diagnosis of **ONE** of the following:
 - a. As single-agent therapy for relapsed/refractory acute myeloid leukemia (AML) with an FMS-like tyrosine kinase 3 (FLT3) mutation in the blood or bone marrow
 - 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. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring 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. Individual does not have severe renal impairment (CrCl < 30 mL/min)
 6. Individual does not have severe hepatic impairment (Child-Pugh Class C)
 7. There are no significant interacting drugs

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Xospata (gilteritinib) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
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
 - a. Response is defined as:
 - i. Documented evidence of efficacy, disease stability and/or improvement
 - ii. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use



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3. Individual has been adherent with the medication
4. Individual has not developed any significant adverse drug effects that may exclude continued use
 - a. Significant adverse effect such as:
 - i. Posterior reversible encephalopathy syndrome (PRES)
5. Individual does not have severe renal impairment (CrCl < 30 mL/min)
6. Individual does not have severe hepatic impairment (Child-Pugh Class C)
7. There are no significant interacting drugs

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**

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.

Resources:

Xospata (gilteritinib) product information, revised by Astellas Pharma US, Inc. 05-2019. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed December 07, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Acute Myeloid Leukemia Version 1.2022 – Updated December 02, 2021. Available at <https://www.nccn.org>. Accessed December 07, 2021.



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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.