KURA RxKONNECT

komzifti™ (ziftomenib) 200 mg capsules

How to order KOMZIFTI for your patients

3 steps to Rx fulfillment

1 Send the prescription

KOMZIFTI is filled through a tailored oncology distribution network. Please send the prescription to one of the fulfilling pharmacies to the right or to your Medically Integrated Dispensing pharmacy.

2 Confirmation

- The fulfilling pharmacy will confirm insurance coverage and out-of-pocket costs
- Prior authorization (PA) will need to be submitted
- The fulfilling pharmacy will coordinate with your office for completion of the PA

3 Shipping

The fulfilling pharmacy will call the patient to schedule shipment. **Please remind your patient to accept the call from the fulfilling pharmacy.** Let your patient know that they may not recognize the phone number.

Refills

The fulfilling pharmacy will contact the patient regarding refills.

Flexibility that supports patient access to medicine

Fulfilling Pharmacies

	Phone	Fax
Biologics	1-800-850-4306	1-800-823-4506
Onco360	1-877-662-6633	1-877-662-6355

Specialty Distributors

	Phone	Fax
ASD Healthcare	1-800-746-6273	1-800-547-9413
Cardinal Health	1-855-855-0708	1-614-553-6301
McKesson Plasma and Biologics	1-877-625-2566	1-888-752-7626
McKesson Specialty Health	1-800-482-6700	1-855-824-9489
Oncology Supply	1-800-633-7555	1-800-248-8205

For support, contact

Kura RxKonnect™

SCAN
to enroll online

Go to KuraRxKonnect.com

OR

Call 1-844-587-2777
Monday – Friday, 8 AM to 8 PM ET

Helping patients, caregivers, and prescribers navigate fulfillment obstacles.

Please see Indication and Important Safety Information on pages 2-4 and full Prescribing Information, including Boxed WARNING.

Helpful information to include with a prior authorization

Prior Authorization Checklist

- Submit via pharmacy benefit
- ICD-10 CM code(s)
- NDC
- Prescriber NPI
- Prior treatments
- Biomarker test(s)
- NPM1 mutation and date of test

Commonly accepted biomarker laboratory tests

Testing for NPM1 mutations

- PCR
- NGS

An FDA-approved test for the detection of NPM1 mutations is not currently available.

National Drug Code (NDC) 10-digit

NDC 10-digit[1]	Tradename	Description	Strength	Units	UOM
84696-200-90	KOMZIFTI™ (ziftomenib)	200-mg capsule	200 mg	1	Each

UOM=unit of measure.

International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes

The ICD-10 codes below are supplied for informational purposes only and represent no statement or guarantee by Kura Oncology that these codes are appropriate to specific circumstances, products, or services provided to an individual patient or that the product will be covered. It is the healthcare provider's responsibility to accurately report the patient's diagnosis, consistent with the payer's guidelines. If providers have questions about coverage or coding, providers should consult the specific payers. Reimbursement is dynamic — new codes are added and existing codes may be revised. Coverage policies also change. The information contained in this document is current as of the date of publication.

ICD-10-CM[2]	Description
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.02	Acute myeloblastic leukemia, in relapse
C92.50	Acute myelomonocytic leukemia, not having achieved remission
C92.52	Acute myelomonocytic leukemia, in relapse
C92.A0	Acute myeloid leukemia with multilineage dysplasia, not having achieved remission
C92.A2	Acute myeloid leukemia with multilineage dysplasia, in relapse
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse

The information contained in this document is publicly available from third-party sources and Kura Oncology is providing it for general informational purposes only. This information is not intended to constitute guaranteed coverage guidance and you should always use your independent clinical judgment in completing required documents for coverage.

INDICATION

KOMZIFTI is indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (R/R AML) with a susceptible nucleophosmin 1 (*NPM1*) mutation who have no satisfactory alternative treatment options.

SELECT IMPORTANT SAFETY INFORMATION

WARNING: DIFFERENTIATION SYNDROME

Differentiation syndrome, which can be fatal, has occurred with KOMZIFTI. Signs and symptoms may include fever, joint pain, hypotension, hypoxia, dyspnea, rapid weight gain or peripheral edema, pleural or pericardial effusions, pulmonary infiltrates, acute kidney injury, and rashes. If differentiation syndrome is suspected, interrupt KOMZIFTI, and initiate oral or intravenous corticosteroids with hemodynamic and laboratory monitoring until symptom resolution; resume KOMZIFTI upon symptom improvement.

Please see additional Important Safety Information on pages 3-4 and full Prescribing Information, including Boxed WARNING.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Differentiation Syndrome

KOMZIFTI can cause fatal or life-threatening differentiation syndrome (DS). DS is associated with rapid proliferation and differentiation of myeloid cells. Symptoms of DS, including those seen in patients treated with KOMZIFTI, may include fever, hypoxia, joint pain, hypotension, dyspnea, rapid weight gain or peripheral edema, pleural or pericardial effusions, acute kidney injury, and rashes.

In the clinical trial, DS occurred in 29 (26%) of 112 patients with R/R AML with an *NPM1* mutation who were treated with KOMZIFTI at the recommended dosage. DS was Grade 3 in 13% and fatal in two patients. In broader evaluation of all patients with any genetic form of AML treated with KOMZIFTI monotherapy in clinical trials, DS occurred in 25% of patients. Four fatal cases of DS occurred out of 39 patients with *KMT2A*-rearranged AML treated with KOMZIFTI. KOMZIFTI is not approved for use in patients with *KMT2A*-rearranged AML.

In the 112 patients with an *NPM1* mutation, DS was observed with and without concomitant hyperleukocytosis, in as early as 3 days and up to 46 days after KOMZIFTI initiation. The median time to onset was 15 days. Two patients experienced more than one DS event. Treatment was interrupted and resumed in 15 (13%) patients, while it was permanently discontinued in 2 (2%) patients.

Prior to starting treatment with KOMZIFTI, reduce the WBC counts to less than 25 x 10^9/L. If DS is suspected, interrupt KOMZIFTI, initiate oral or intravenous corticosteroids (e.g., dexamethasone 10 mg every 12 hours) for a minimum of 3 days with hemodynamic and laboratory monitoring. Resume treatment with KOMZIFTI at the same dose level when signs and symptoms improve and are Grade 2 or lower. Taper corticosteroids over a minimum of 3 days after adequate control or resolution of symptoms. Symptoms of DS may recur with premature discontinuation of corticosteroid treatment.

QTc Interval Prolongation

KOMZIFTI can cause QTc interval prolongation. In the clinical trial, QTc interval prolongation was reported as an adverse reaction in 12% of 112 patients treated with KOMZIFTI at the recommended dosage for R/R AML with an *NPM1* mutation. QTc interval prolongation was Grade 3 in 8% of patients. The heart-rate corrected QT interval (using Fridericia's method) (QTcF) was greater than 500 msec in 9% of patients, and the increase from baseline QTcF was greater than 60 msec in 12% of patients. KOMZIFTI dose reduction was required for 1% of patients due to QTc interval prolongation. QTc prolongation occurred in 14% of the 42 patients less than 65 years of age and in 10% of the 70 patients 65 years of age or older.

Correct electrolyte abnormalities, including hypokalemia and hypomagnesemia, prior to treatment with KOMZIFTI. Perform an ECG prior to initiation of treatment with KOMZIFTI, and do not initiate KOMZIFTI in patients with QTcF >480 msec. Perform an ECG at least once weekly for the first four weeks on treatment, and at least monthly thereafter. Interrupt KOMZIFTI if the QTc interval is >500 ms or the change from baseline is >60 ms (Grade 3). In patients with congenital long QTc syndrome, congestive heart failure, electrolyte abnormalities, or those who are taking medications known to prolong the QTc interval, more frequent ECG monitoring may be necessary. Concomitant use of KOMZIFTI with drugs known to prolong the QTc interval may increase the risk of QTc interval prolongation, result in a greater increase in the QTc interval and adverse reactions associated with QTc interval prolongation, including Torsades de pointes, other serious arrhythmias, and sudden death.

Embryo-Fetal Toxicity

Based on findings in animals and its mechanism of action, KOMZIFTI can cause embryo-fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with KOMZIFTI and for 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with KOMZIFTI and for 3 months after the last dose.

ADVERSE REACTIONS

Fatal adverse reactions occurred in 4 (4%) patients who received KOMZIFTI, including 2 with differentiation syndrome, 1 with infection, and 1 with sudden death. Serious adverse reactions were reported in 79% of patients who received KOMZIFTI. Serious adverse reactions occurring in ≥5% of patients included infection without an identified pathogen (29%), febrile neutropenia (18%), bacterial infection (16%), differentiation syndrome (16%), and dyspnea (6%).

Dosage interruption of KOMZIFTI due to an adverse reaction occurred in 54% of patients. Adverse reactions that required dose interruption in ≥2% of patients included infection without an identified pathogen (15%), differentiation syndrome (13%), febrile neutropenia (5%), pyrexia (4%), electrocardiogram QT prolonged (4%), leukocytosis (4%), bacterial infection (3%), cardiac failure (2%), cholecystitis (2%), diarrhea (2%), pruritus (2%), and thrombosis (2%). Dose reduction of KOMZIFTI due to an adverse reaction occurred in 4% of patients. Permanent discontinuation of KOMZIFTI due to an adverse reaction occurred in 21% of patients. Adverse reactions that required permanent discontinuation of KOMZIFTI in ≥2% of patients were infection without an identified pathogen (8%), bacterial infection (4%), cardiac arrest (2%), and differentiation syndrome (2%).

Please see additional Important Safety Information on page 4 and full Prescribing Information, including Boxed WARNING.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

Most common (≥20%) adverse reactions, including laboratory abnormalities, were aspartate aminotransferase increased (53%), infection without an identified pathogen (52%), potassium decreased (52%), albumin decreased (51%), alanine aminotransferase increased (50%), sodium decreased (49%), creatinine increased (45%), alkaline phosphatase increased (41%), hemorrhage (38%), diarrhea (36%), nausea (35%), fatigue (34%), edema (30%), bacterial infection (28%), musculoskeletal pain (28%), bilirubin increased (27%), potassium increased (26%), differentiation syndrome (26%), pruritus (23%), febrile neutropenia (22%), and transaminases increased (21%).

DRUG INTERACTIONS

Drug interactions may occur when KOMZIFTI is concomitantly used with:

- Strong or Moderate CYP3A4 Inhibitors: Monitor patients more frequently for KOMZIFTI-associated adverse reactions.
- Strong or Moderate CYP3A4 Inducers: Avoid concomitant use of KOMZIFTI.
- Gastric Acid Reducing Agents: Avoid concomitant use of KOMZIFTI with proton pump inhibitors (PPIs), H2 receptor antagonists (H2RAs), or locally acting antacids. If concomitant use with H2RAs or locally acting antacids cannot be avoided, modify KOMZIFTI administration time:
  - Take KOMZIFTI 2 hours before or 10 hours after administration of an H2 receptor antagonist
  - Take KOMZIFTI 2 hours before or 2 hours after administration of a locally acting antacid.
- Drugs that Prolong the QT Interval: Avoid concomitant use of KOMZIFTI. If concomitant use cannot be avoided, obtain ECGs when initiating, during concomitant use, and as clinically indicated. Interrupt KOMZIFTI if the QTc interval is >500 ms or the change from baseline is >60 ms.

USE IN SPECIFIC POPULATIONS

Pregnancy: Based on findings in animals and its mechanism of action, KOMZIFTI can cause embryo-fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Verify pregnancy status in females of reproductive potential prior to starting KOMZIFTI.

Lactation: Because of the potential for adverse reactions in the breastfed child, advise women not to breastfeed during treatment with KOMZIFTI and for 2 weeks after the last dose.

Infertility: Based on findings in animals, KOMZIFTI may impair fertility in females and males of reproductive potential.

Please see full Prescribing Information, including Boxed WARNING for additional information.

REFERENCES: 1. KOMZIFTI™ [Prescribing Information]. San Diego, CA; Kura Oncology, Inc. **2.** CMS. ICD-10-CM/PCS MS-DRG v37.2 Definitions Manual. MDC 17 myeloproliferative diseases & disorders, poorly differentiated neoplasms acute leukemia without major procedure. https://www.cms.gov/icd10m/version372-fullcode-cms/fullcode_cms/P0314.html. Accessed August 24, 2025.