

Specialty Guideline Management

Komzifti

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Komzifti	ziftomenib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

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

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- NPM1 mutation status

Coverage Criteria

Acute Myeloid Leukemia (AML)¹

Authorization of 12 months may be granted for treatment of relapsed or refractory acute myeloid leukemia when all of the following criteria are met:

- Disease is positive for NPM1 mutation
- No other satisfactory alternative treatment options are available

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the Coverage Criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Komzifti [package insert]. San Diego, CA: Kura Oncology, Inc.; November, 2025.