

Specialty Guideline Management

Ensacove

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
Ensacove	ensartinib

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

Ensacove is indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive, locally advanced or metastatic non-small cell lung cancer (NSCLC) who have not previously received an ALK-inhibitor.

Compendial Uses²

Recurrent or advanced NSCLC, ALK rearrangement-positive

Documentation

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

Coverage Criteria

Non-small Cell Lung Cancer^{1,2}

Authorization of 12 months may be granted for treatment of recurrent, advanced or metastatic ALK-positive NSCLC as a single agent when either of the following criteria is met:

- The member has not previously received an ALK-inhibitor
- The member has experienced intolerance or disease progression with crizotinib (Xalkori)

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 while on the current regimen.

References

1. Ensacove [package insert]. Miami, FL: Xcovery Holdings, Inc.; December 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed January 8, 2025.