VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Oral – Anaplastic Lymphoma Kinase [ALK]-Positive Agent) – Ensacove Prior Authorization Policy
- Ensacove® (ensartinib capsules – Xcovery)

REVIEW DATE: 01/02/2025

OVERVIEW

Ensacove, a kinase inhibitor, is indicated for the treatment of anaplastic lymphoma kinase **(ALK)-positive**, locally advanced or metastatic **Non-Small Cell Lung Cancer (NSCLC)** in adults who have not previously received an ALK inhibitor.[1]

An FDA-approved test to detect ALK rearrangements for selecting patients for treatment with Ensacove is not currently available.[1] However, other approved tests are available to detect *ALK* rearrangements.[3]

GUIDELINES

The National Comprehensive Cancer Network (NCCN) NSCLC guidelines (version 3.2025 – January 14, 2025) have several recommendations regarding the ALK inhibitors.[2] For the first-line options in the metastatic setting, if *ALK* rearrangement was discovered <u>prior</u> to first-line systemic therapy, Alecensa® (alectinib capsules), Alunbrig® (brigatinib tablets), Ensacove, and Lorbrena® (lorlatinib tablets) are all "Preferred" therapies (all category 1); Zykadia® (ceritinib capsules and tablets) and Xalkori are both listed under "Useful in Certain Circumstances" as first-line therapies (both category 1). For patients who progress on Alecensa, Alunbrig, Ensacove, Lorbrena, or Zykadia, the recommendations for subsequent therapy are to continue the ALK inhibitor the patient is currently receiving, use Lorbrena for resistant mutations, and consider definitive local therapy for limited lesions or systemic therapy for multiple lesions. Lorbrena is recommended for multiple lesions in the subsequent therapy setting if not previously given (category 2A).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Ensacove. All approvals are provided for the duration noted below.

<u>**Automation:**</u> None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Ensacove is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has locally advanced or metastatic disease; AND
   C) Patient has anaplastic lymphoma kinase (*ALK*)-positive disease; AND
   D) The mutation was detected by an approved test; AND
   E) Patient has not previously received an ALK inhibitor.
   Note: Examples of ALK inhibitors are Alecensa® (alectinib capsules), Alunbrig® (brigatinib tablets), Lorbrena® (lorlatinib tablets), Zykadia® (ceritinib capsules and tablets), and Xalkori® (crizotinib capsules and oral pellets).

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Coverage of Ensacove is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES
1. Ensacove® capsules [prescribing information]. Miami, FL: Xcovery; December 2024.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – January 14, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 23, 2025.
3. List of cleared or approved companion diagnostic devices (in vitro and imaging tools) [website]. U.S. Food & Drug Administration. Current as of November 15, 2024. Available at: https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools. Accessed on December 31, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	01/02/2025
DEU Update	01/23/2025: Updated guidelines section in Overview to address Ensacove.	--
Update	04/21/2025: The policy name was changed from "Oncology – Ensacove PA Policy" to "Oncology (Oral – Anaplastic Lymphoma Kinase [ALK]-Positive Agent) – Ensacove PA Policy".	N/A

N/A – Not applicable.