UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1468-1
Program	Prior Authorization/Notification
Medication	Ensacove (ensartinib)
P&T Approval Date	2/2025
Effective Date	5/1/2025

1. Background:

Ensacove (ensartinib) is a kinase inhibitor 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. The National Cancer Comprehensive Network (NCCN) also recommends the use of Ensacove as a preferred first-line, single agent therapy for ALK-positive recurrent, advanced, or metastatic disease in patients who are intolerant to or disease has progressed on Xalkori (crizotinib).

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Ensacove** will be approved based on the following criterion

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months

B. <u>Non-Small Cell Lung Cancer (NSCLC)</u>

1. **<u>Initial Authorization</u>**

   a. **Ensacove** will be approved based on **all** the following criteria:

   (1) Diagnosis of non-small cell lung cancer (NSCLC)

   -AND-

   (2) Tumor is anaplastic lymphoma kinase (ALK)-positive

   -AND-

(3) Disease is **one** of the following:

(a) Advanced
(b) Metastatic
(c) Recurrent

-AND-

(4) **One** of the following:

(a) Patient has not previously received an ALK-inhibitor [e.g. Alecensa (alectinib), Alunbrig (brigatinib), Lorbrena (lorlatinib), Xalkori (crizotinib), Zykadia (ceritinib)]

-OR-

(b) Patient is intolerant to or experiences disease progression on Xalkori (crizotinib)

Authorization will be issued for 12 months

2. **Reauthorization**

a. **Ensacove** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Ensacove therapy

Authorization will be issued for 12 months

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Ensacove [package insert]. Miami, FL: Xcovery Holdings, Inc; December, 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed January 7, 2025.

Program	Prior Authorization/Notification – Ensacove (ensartinib)
Change Control	
2/2025	New program.