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Ensacove

Description

Ensacove (ensartinib)

Background
Ensacove (ensartinib) is a kinase inhibitor of anaplastic lymphoma kinase (ALK) and inhibits other kinases including MET and ROS1. In vitro, Ensacove inhibited phosphorylation of ALK and its downstream signaling proteins AKT, ERK, and S6, thereby blocking ALK-mediated signaling pathways and inhibiting proliferation in cell lines harboring ALK fusions and mutations. In vivo, Ensacove showed anti-tumor activity in a mouse xenograft model of human NSCLC harboring an ALK fusion (1).

Regulatory Status
FDA-approved indication: Ensacove 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 (1).

Treatment with Ensacove has been associated with interstitial lung disease (ILD)/pneumonitis, hepatotoxicity, dermatologic adverse reactions, bradycardia, hyperglycemia, visual disturbances, increased creatinine phosphokinase (CPK), and hyperuricemia. Withhold, reduce the dose, or permanently discontinue Ensacove based on severity (1).

Ensacove can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception during treatment with Ensacove and for at least 1 week after the last dose. Males with female partners of reproductive

potential should be advised to use effective contraception during treatment with Ensacove and for 1 week after the last dose (1).

The safety and effectiveness of Ensacove in pediatric patients less than 18 years of age have not been established (1).

Related policies
Alecensa, Alunbrig, Lorbrena, Xalkori, Zykadia

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Ensacove may be considered **medically necessary** if the conditions indicated below are met.

Ensacove may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Locally advanced or metastatic non-small cell lung cancer (NSCLC)
    a. Anaplastic lymphoma kinase (ALK)-positive
    b. Patient has not been previously treated with an ALK-inhibitor
    c. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Ensacove and for 1 week after the last dose
    d. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Ensacove and for 1 week after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Locally advanced or metastatic non-small cell lung cancer (NSCLC)
    a. **NO** disease progression or unacceptable toxicity
    b. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Ensacove and for 1 week after the last dose
    c. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Ensacove and for 1 week after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 225 mg per day

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Ensacove (ensartinib) is a kinase inhibitor indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive who have not previously received an ALK-inhibitor. Treatment with Ensacove has been associated with interstitial lung disease (ILD)/pneumonitis, hepatotoxicity, dermatologic adverse reactions, bradycardia, hyperglycemia, visual disturbances, increased creatinine phosphokinase (CPK), hyperuricemia, and embryo-fetal toxicity. The safety and effectiveness of Ensacove in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Ensacove while maintaining optimal therapeutic outcomes.

References

1. Ensacove [package insert]. Miami, FL: Xcovery Holdings, Inc.; January 2026.
2. NCCN Drugs & Biologics Compendium® Ensartinib 2026. National Comprehensive Cancer Network, Inc. Accessed on January 13, 2026.

Policy History

Date	Action
January 2025	Addition to PA
September 2025	Annual review and reference update
March 2026	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.