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

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 prior 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.

- **Ensacove® (ensartinib capsules - Xcovery)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 COVERED

- **Ensacove® (ensartinib capsules - Xcovery)**

is(are) considered not medically necessary for ANY other use(s); 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.