PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Oral – Epidermal Growth Factor Receptor Exon 20 Mutation Agent) – Zegfrovy Prior Authorization Policy
- Zegfrovy™ (sunvozertinib tablets – Dizal (Jiangsu) Pharmaceutical)

REVIEW DATE: 10/29/2025

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

Zegfrovy, a kinase inhibitor, is indicated for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (*EGFR*) exon 20 insertion mutations, as detected by an FDA-approved test, in adults whose disease has progressed on or after platinum-based chemotherapy.[1]

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Guidelines

The National Comprehensive Cancer Network (NCCN) non-small cell lung cancer guidelines (version 8.2025 – August 15, 2025) for *EGFR* exon 20 insertion mutation

recommend Zegfrovy as a subsequent therapy option (category 2A) after progression on first-line regimen with Rybrevant® (amivantamab-vmjw intravenous infusion) + carboplatin/pemetrexed. Rybrevant or Zegfrovy are recommended as subsequent therapy options (if not received previously), for patients progressed on systemic therapy regimens containing chemotherapy and/or immunotherapy first-line. Both Rybrevant and Zegfrovy are category 2A recommended therapies.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Zegfrovy. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Zegfrovy as well as the monitoring required for adverse events and long-term efficacy, approval requires Zegfrovy to be prescribed by or in consultation with a physician who specializes in the condition being treated.

- **Zegfrovy™ (sunvozertinib tablets – Dizal [Jiangsu] Pharmaceutical) 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) The tumor is positive for epidermal growth factor receptor (*EGFR*) exon 20 insertion mutations; AND
   D) The patient has tried platinum-based chemotherapy; AND
   Note: Examples include cisplatin or carboplatin-containing chemotherapy regimens.
   E) The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT COVERED

- **Zegfrovy™ (sunvozertinib tablets – Dizal [Jiangsu] Pharmaceutical) is(are) considered not medically necessary for ANY other use(s) including the following; criteria will be updated as new published data are available.**

REFERENCES

1. Zegfrovy™ tablets [prescribing information]. Shanghai, China: Dizal (Jiangsu) Pharmaceuticals; July 2025.

2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 8.2025 – August 15, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed October 26, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	New policy	10/29/2025