Generic Name: zongertinib

Therapeutic Class or Brand Name: Hernexeos

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: N/A

Date Last Reviewed / Revised: 2/9/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met.)

I. Documentation of one of the following diagnoses AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Non-Small Cell Lung Cancer

i. Documentation of unresectable or metastatic disease

ii. Documentation of non-squamous disease

iii. Documentation of HER2 (ERBB2) tyrosine kinase domain (TKD) activating mutation as detected by an FDA-approved test.

iv. Documentation of progression on or intolerance to at least one prior systemic therapy

v. If request is for 180 mg dose, patient must have an intolerance to or a contraindication to Hyrnuo (sevabertinib).

vi. Hernexeos will be used as monotherapy

II. Minimum age requirement: 18 years old

III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Documentation of progression on Hyrnuo (sevabertinib).

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantity limits: 30 day supply
- Maximum dose:
  - <90 kg: 120 mg
  - ≥90 kg: 180 mg

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 6 months. An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

1. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer. Version 2.2026. Updated December 2, 2025. Accessed December 4, 2025. www.nccn.org/professionals/physician_gls?pdf/NSLCL.pdf
2. Hernexeos. Prescribing Information. Boehringer Ingelheim International. 2025. Accessed October 2, 2025. www.pro.boehringer-ingelheim.com/us/products/hernexeos/bipdf/hernexeos-prescribing-information