

# Specialty Guideline Management

## Hernexeos

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Hernexeos	zongertinib

### Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-Approved Indication<sup>1</sup>

Hernexeos is indicated for the treatment of adult patients with unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received prior systemic therapy.

#### Compendial Use<sup>2</sup>

Non-small cell lung cancer

All other indications are considered experimental/investigational and not medically necessary.

## Documentation

Submission of the following information is necessary to initiate the prior authorization review: human epidermal growth factor receptor 2 (HER2) status (e.g., immunohistochemistry (IHC) score, in situ hybridization (ISH) test).

## Coverage Criteria

### Non-Small Cell Lung Cancer (NSCLC)<sup>1,2</sup>

Authorization of 12 months may be granted for subsequent treatment of recurrent, advanced, unresectable, or metastatic non-small cell lung cancer (NSCLC) with HER2 (ERBB2) mutation, as a single agent.

## Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

## References

1. Hernexeos [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; August 2025.
2. The NCCN Drugs & Biologics Compendium™ © 2025 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed August 18, 2025.