UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1493-1
Program	Prior Authorization/Notification
Medication	Hernexeos© (zongertinib)
P&T Approval Date	10/2025
Effective Date	1/1/2026

1. Background:

Hernexeos© (zongertinib) is a kinase inhibitor 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

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Hernexeos** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Non-Small Cell Lung Cancer</u>

1. **<u>Initial Authorization</u>**

   a. **Hernexeos** will be approved based on **<u>all</u>** the following criteria:

      (1) Diagnosis of non-small cell lung cancer

      -AND-

      (2) Disease is <u>one</u> of the following:
         (a) Recurrent
         (b) Advanced
         (c) Metastatic
         (d) Unresectable

-AND-

(3) Presence of ERBB2 (HER2) mutation

-AND-

(4) Patient has received prior systemic therapy

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Hernexeos** will be approved based on the following criterion:

(1) Patient does not show evidence of disease progression while on Hernexeos.

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Hernexeos [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; August 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed August 22, 2025.

Program	Prior Authorization/Notification – Hernexeos (zongertinib)
Change Control	
10/2025	New program