

DRUG POLICY

HernexeosTM (zongertinib)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

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

FDA-Approved Indications

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 Uses

Non-small cell lung cancer

POLICY

Required 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].

Criteria for Initial Approval

Non-Small Cell Lung Cancer (NSCLC)

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

Non-Small Cell Lung Cancer (NSCLC)

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.

Other

Hernexeos (zongertinib) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	Exception Limit	FDA Recommended Dosing
Hernexeos (zongertinib) 60 mg tablet	120 tablets per 30 days	180 tablets per 30 days	Based on body weight: <90 kg: 120 mg once daily ≥90 kg: 180 mg once daily Dose modification for concomitant use with strong CYP3A inducer: <90 kg: 240 mg once daily ≥90 kg: 360 mg once daily <i>Dose modification may be required for adverse reactions.</i>

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

Hernexeos [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; August 2025.

The NCCN Drugs & Biologics Compendium™ © 2025 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed August 18, 2025.

POLICY HISTORY

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Revised:

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