

DRUG POLICY

Hyrnuo™ (sevabertinib)

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

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

Compendial Uses

Non-Small Cell Lung Cancer (NSCLC)

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Testing or analysis confirming the tumor is positive for a human epidermal growth factor receptor 2 (HER2) tyrosine kinase domain (TKD) activating mutation.

Criteria for Initial Approval

Non-Small Cell Lung Cancer (NSCLC)

Authorization of 12 months may be granted for treatment of recurrent, advanced or metastatic non-small cell lung cancer (NSCLC) when all of the following criteria are met:

1. The tumor is positive for a HER2 (ERBB2) TKD activating mutation (e.g., Y772_A775dupYVMA, other HER2 ex20ins, or HER2 point mutations).

2. The member has received prior systemic therapy and has not experienced progression on a HER2 (ERBB2) directed regimen.
3. The requested medication will be used 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 disease progression or unacceptable toxicity while on the current regimen.

Other

Hyrnuo (sevabertinib) 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	FDA Recommended Dosing
Hyrnuo (sevabertinib) 10 mg tablet	120 tablets per 30 days	20 mg orally twice daily with food. <i>Dose modification may be required for adverse reactions or concomitant use with strong CYP3A4 inhibitors.</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

Hyrnuo [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; November 2025.

The NCCN Drugs & Biologics Compendium® ©2025 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed December 2, 2025.

National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer Version 2.2026. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed December 2, 2025.

POLICY HISTORY

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