

Specialty Guideline Management

Hyrnuo

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
Hyrnuo	sevabertinib

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 Indication¹

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 Uses²

Non-Small Cell Lung Cancer (NSCLC)

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:

Reference number(s)
7295-A

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

Coverage Criteria

Non-Small Cell Lung Cancer (NSCLC)¹⁻³

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:

- The tumor is positive for a HER2 (ERBB2) TKD activating mutation (e.g., Y772_A775dupYVMA, other HER2 ex20ins, or HER2 point mutations).
- The member has received prior systemic therapy and has not experienced progression on a HER2 (ERBB2) directed regimen.
- The requested medication will be used 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 disease progression or unacceptable toxicity while on the current regimen.

References

1. Hyrnuo [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; November 2025.
2. The NCCN Drugs & Biologics Compendium® ©2025 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed December 2, 2025.
3. 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.