

Applicable Drugs: Hyrnuo (sevabertinib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: N/A

Date Last Reviewed / Revised: 2/9/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met.)

- I. Documentation of one of the following diagnoses AND must meet all criteria listed under the applicable diagnosis:
FDA-Approved Indication(s)
 - A. Non-Squamous Non-Small Cell Lung Cancer
 - i. Documentation of locally advanced or metastatic disease
 - ii. Documentation of non-squamous disease
 - iii. Documentation of HER2 (ERBB2) tyrosine kinase domain (TKD) activating mutation as detected by an FDA-approved test
 - iv. Documentation of progression on or intolerance to at least one prior systemic therapy
 - v. Hyrnuo will be used as monotherapy
- II. Minimum age requirement: 18 years old
- III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.
- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Documentation of progression on Hernexeos (zongertinib).

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantity limits: 30-day supply
 - Maximum dose: 20 mg orally twice daily

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 6 months. An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

1. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer. Version 2.2026. Updated December 2, 2025. Accessed December 4, 2025. www.nccn.org/professionals/physician_gls/pdf/NSLCL.pdf
2. Hyrnuo. Prescribing Information. Bayer HealthCare Pharmaceuticals, Inc. 2025. Accessed December 4, 2025. labeling.bayerhealthcare.com/html/products/pi/HYRNUO_PI.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.