

Applicable Drugs: Augtyro (repotrectinib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 9/30/2024

Date Last Reviewed / Revised: 2/27/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I-IV are met)

- I. Documentation of the following FDA-approved diagnoses A or B AND must meet all criteria listed under the applicable diagnosis:

FDA Approved Indication(s)

A. Non-small cell lung cancer (NSCLC).

- i. Locally advanced or metastatic disease.
- ii. Documented ROS-1 mutation detected by an approved test.
- iii. Minimum age requirement: 18 years old.

B. Solid tumor (examples include: appendix cancer, cervical cancer, breast cancer, cholangiocarcinoma, colorectal cancer, endometrial cancer, esophageal cancer, gallbladder cancer, gastric cancer, glioblastoma, liver cancer, neuroendocrine tumors, ovarian cancer, pancreatic cancer, rectal cancer, salivary gland tumor, soft tissue sarcoma, thyroid cancer, uterine cancer, vaginal cancer, and vulvar cancer).

- i. Locally advanced or metastatic disease or surgical resection of tumor will result in severe morbidity.
- ii. Documented neurotrophic tyrosine receptor kinase (NTRK) gene fusion detected by an approved test.
- iii. Documented progression following treatment or lack of satisfactory alternative therapies.
- iv. Minimum age requirement: 12 years old.

Other Uses With Supportive Evidence

C. Histiocytic neoplasms (Langerhans cell histiocytosis, Erdheim-Chester disease, Rosai-Dorfman disease)

- II. Treatment must be prescribed by or in consultation with a hematologist or oncologist.
- III. 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.

- IV. 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

- None

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Two-hundred forty 40mg capsules/30 days or sixty 160mg capsules/30 days.

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 6 months with 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

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3. Solomon BJ, Drilon A, Lin JJ, et al. 1372P Repotrectinib in patients (pts) with NTRK fusion-positive (NTRK+) advanced solid tumors, including NSCLC: update from the phase I/II TRIDENT-1 trial. *Ann Oncolog*. 2023;34(Suppl 2):S787-S788. doi:10.1016/j.annonc.2023.09.2405
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11. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Rectal Cancer. Version 4.2025. Updated October 31, 2025. Accessed February 27, 2026. www.nccn.org/professionals/physician_gls/pdf/rectal.pdf
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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.