

**Generic Name:** repotrectinib

**Therapeutic Class or Brand Name:** Augtyro™

**Applicable Drugs:** N/A

**Preferred:** N/A

**Non-preferred:** N/A

**Date of Origin:** 9/30/2024

**Date Last Reviewed / Revised:** N/A

## PRIOR AUTHORIZATION CRITERIA

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

- I. Documented diagnosis of A or B and following criteria under perspective diagnosis:
  - A. Non-small cell lung cancer (NSCLC).
    - i. Age:  $\geq$  18 years old.
    - ii. Locally advanced or metastatic disease.
    - iii. Documented ROS-1 mutation detected by an approved test.
  - B. Neurotrophic tyrosine receptor kinase (NTRK) positive solid tumor cancer (examples of solid tumors, include breast cancer, cholangiocarcinoma, colorectal cancer, esophageal cancer, glioblastoma, head/neck cancer, NSCLC, peripheral nerve sheath tumor, salivary gland tumor, soft tissue sarcoma, and thyroid cancer).
    - i. Age:  $\geq$  12 years old.
    - ii. Locally advanced or metastatic disease or surgical resection of tumor will result in severe morbidity.
    - iii. Documented NTRK gene fusion detected by an approved test.
    - iv. Documented progression following treatment or lack of satisfactory alternative therapies.
- II. Treatment must be prescribed by or in consultation with a hematologist or oncologist.
- III. Prescribed according to FDA labeling, or its use is supported by current clinical practice guidelines.

## 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 documentation of absence of disease progression while on therapy.

## APPENDIX

N/A

## REFERENCES

1. Augtyro. Prescribing information. Bristol Myers Squibb; June 2024. Accessed August 4, 2024. [https://packageinserts.bms.com/pi/pi\\_augtyro.pdf](https://packageinserts.bms.com/pi/pi_augtyro.pdf)
2. Drlon A, Camidge DR, Lin JJ, et al; TRIDENT-1 Investigators. Repotrectinib in ROS1 Fusion-Positive Non-Small-Cell Lung Cancer. *N Engl J Med*. 2024;390(2):118-131. doi: 10.1056/NEJMoa2302299
3. Solomon BJ, Drillon 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
4. Non-Small Cell Lung Cancer. 7.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed August 11, 2024.
5. Soft Tissue Sarcoma. 2.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed August 11, 2024.
6. Breast Cancer. 4.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed August 11, 2024.
7. Esophageal and Esophagogastric Junction Cancers. 4.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed August 11, 2024
8. Central Nervous System Cancers. 2.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed August 11, 2024.
9. Biliary Tract Cancers. 3.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed August 11, 2024.
10. Colon Cancer. 4.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed August 11, 2024.
11. Rectal Cancer. 3.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed August 11, 2024.
12. Neuroendocrine and Adrenal Tumors. 2.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed August 11, 2024.

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13. Pancreatic Adenocarcinoma. 3.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed August 11, 2024.

**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.