Reference number(s)
6256-A

Specialty Guideline Management
Augtyro

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
Augtyro	repotrectinib

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 Indications[1]

- Treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC)
- Treatment of adult and pediatric patients 12 years of age and older with solid tumors that:
  - Have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion
  - Are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity, and
  - Have progressed following treatment or have no satisfactory alternative therapy

Compendial Uses[2]

- NSCLC, recurrent, advanced or metastatic NTRK1/2/3 gene fusion-positive or ROS1 rearrangement-positive tumors
- Histiocytic neoplasms with NTRK gene fusion:

- Erdheim-Chester Disease (ECD)
- Langerhans Cell Histiocytosis (LCH)
- Rosai-Dorfman Disease

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: NTRK gene fusion status or ROS1 status (where applicable).

Coverage Criteria

Non-Small Cell Lung Cancer[1,2]

Authorization of 12 months may be granted for treatment of recurrent, advanced, or metastatic ROS1-positive or NTRK gene fusion-positive non-small cell lung cancer as a single agent.

Solid tumors with NTRK gene fusion[1,2]

Authorization of 12 months may be granted for treatment of members 12 years of age and older with solid tumors that have an NTRK gene fusion, as demonstrated by laboratory testing (e.g., next-generation sequencing [NGS] or fluorescence in situ hybridization [FISH]).

Histiocytic Neoplasms with NTRK gene fusion [2]

Authorization of 12 months may be granted for the treatment of any of the following NTRK gene fusion-positive histiocytic neoplasm subtypes as a single agent:

- Symptomatic or relapsed/refractory Erdheim-Chester Disease (ECD)
- Langerhans Cell Histiocytosis (LCH)
- Symptomatic or relapsed/refractory Rosai-Dorfman Disease

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Continuation of Therapy

ROS1-positive non-small cell lung cancer (NSCLC) and NTRK gene-fusion positive gastrointestinal stromal tumor [1,2]

Authorization of 12 months may be granted for continued treatment of ROS1-positive non-small cell lung cancer (NSCLC) in members requesting reauthorization when there is no evidence of unacceptable toxicity while on the current regimen.

All Other Indications

Authorization of 12 months may be granted for continued treatment of solid tumors that have an NTRK gene fusion when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Augtyro [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; June 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed July 14, 2025.