MEDICAL MUTUAL®

Drug Policy

Policy:	Augtyro (repotrectinib)	Annual Review Date: 09/18/2025 Last Revised Date: 09/18/2025

OVERVIEW

Augtyro is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) and in adult and pediatric patients 12 years of age and older with solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion and 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. The indication for solid tumors with NTRK gene fusion is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

POLICY STATEMENT

This policy involves the use of Augtyro. Prior authorization is recommended for pharmacy benefit coverage of Augtyro. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Augtyro as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Augtyro be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Augtyro is recommended in those who meet the following criteria:

1. **Non-Small Cell Lung Cancer**
   Criteria. *Approve if the patient is 18 years of age or older and has locally advanced or metastatic ROS1-positive disease.*

2. **Solid Tumors**
   Criteria. *Patient must meet the following criteria*

   A. The patient is 12 years of age or older; AND

B. Tumors have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion *
C. The patient meets one of the following:
  a. Tumors are locally advanced or metastatic; OR
  b. Surgical resection is likely to result in severe morbidity; AND
D. The patient meets one of the following:
  a. The patient has progressed following treatment; OR
  b. The patient has no satisfactory alternative therapies; AND
E. Augtyro is prescribed by or in consultation with a hematologist or oncologist.

3. **Patient has started on Augtyro**
Criteria. *Approve for an indication or condition addressed as an approval in this document if the patient has not experienced intolerable side effects and has had a beneficial response to therapy, per the prescribing physician.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Augtyro has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

*** Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES