PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Augtyro Prior Authorization Policy
- Augtyro™ (repotrectinib capsules – Bristol-Myers Squibb Company)

REVIEW DATE: 07/03/2024

OVERVIEW

Augtyro, a kinase inhibitor, is indicated for the following uses[1]:

- **Non-small cell lung cancer (NSCLC),** for the treatment of locally advanced or metastatic *ROS1*-positive, disease in adults.
- **Solid tumors,** in adults and pediatric patients ≥ 12 years of age:
  - Have neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion-positive tumor; AND
  - For the treatment of locally advanced or metastatic disease or where surgical resection is likely to result in severe morbidity; AND
  - For disease that have progressed following treatment or have no satisfactory alternative therapy.

The NTRK gene fusion-positive solid tumor indication 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 a confirmatory trial.

Guidelines

The National Comprehensive Cancer Network (NCCN) NSCLC guidelines (version 1.2024 – December 21, 2023) recommend Augtyro, Rozlytrek® (entrectinib capsules and oral pellets), and Xalkori® (crizotinib capsules) as "Preferred" first-line treatment options (all category 2A) for patients with *ROS1* rearrangement-positive NSCLC.[2] Zykadia® (ceritinib capsules and tablets) is also an option under "Other Recommended" therapy (category 2A) in the first-line setting.

The NTRK gene fusion-positive solid tumor indication is not yet addressed in the NCCN guidelines/compendium.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Augtyro. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has locally advanced or metastatic disease; AND
   - **C)** Patient has *ROS1*-positive non-small cell lung cancer; AND
   - **D)** The mutation was detected by an approved test.

2. **Solid Tumors.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   Note: Examples of solid tumors include breast cancer, cholangiocarcinoma, colorectal cancer, esophageal cancer, glioblastoma, head/neck cancer, non-small cell lung cancer (*NTRK* gene fusion-positive), peripheral nerve sheath tumor, salivary gland tumor, soft tissue sarcoma, thyroid cancer.
   - **A)** Patient is ≥ 12 years of age; AND
   - **B)** The tumor is positive for neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion; AND
   - **C)** Patient meets ONE of the following (i or ii):
     - **i.** The tumor is locally advanced or metastatic; OR
     - **ii.** Surgical resection of tumor will likely result in severe morbidity; AND
   - **D)** Patient meets ONE of the following (i or ii):
     - **i.** The disease has progressed following treatment; OR
     - **ii.** There are no satisfactory alternative therapies.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Augtyro is not recommended in the following situations:

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

REFERENCES

1. Augtyro™ capsules [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; November 2023.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 5, 2024.