Commercial PA Criteria

Effective: December 18, 2023

Prior Authorization: Augtyro (repotrectinib)

Products Affected: Augtyro (repotrectinib) oral capsules

Medication Description: Repotrectinib is an inhibitor of proto-oncogene tyrosine-protein kinase ROS1 (ROS1) and of the tropomyosin receptor tyrosine kinases (TRKs) TRKA, TRKB, and TRKC. Fusion proteins that include ROS1 domains can drive tumorigenic potential through hyperactivation of downstream signaling pathways leading to unconstrained cell proliferation. Repotrectinib exhibited anti-tumor activity in cultured cells expressing ROS1 fusions and mutations including SDC4-ROS1, SDC4-ROS1(G2032R), CD74-ROS1, CD74-ROS1(G2032R), CD74ROS1(D2033N), and CD74-ROS1(L2026)

Covered Uses:

- **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.

Exclusion Criteria: None

Required Medical Information:

1. Diagnosis

Prescriber Restriction: Medication must be prescribed by, or in consultation with, an oncologist

Age Restriction: 18 years and older

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

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.

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2. **Solid Tumors.** Approve for 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.

References:

1. Product Information: AUGTYRO™ oral capsules, repotrectinib oral capsules. Bristol-Myers Squibb Company (per FDA), Princeton, NJ, 2023.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	12/18/2023
2	Update Policy	Solid Tumors: Added new FDA-approval condition and criteria	Covered uses Other criteria	12/26/2024

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