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: treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC)

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 if:

A. Patient has locally advanced or metastatic disease; **AND**

B. Patient has *ROS1*-positive non-small cell lung cancer; **AND**

C. The mutation was detected by an approved test.

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