

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Augtyro Prior Authorization Policy

- Augtyro™ (repotrectinib capsules – Bristol-Myers Squibb Company)

REVIEW DATE: 11/29/2023

OVERVIEW

Augtyro, a kinase inhibitor, is indicated for the treatment of locally advanced or metastatic **ROS1-positive** non-small cell lung cancer (NSCLC) in adults.¹

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.

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 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.

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.

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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.