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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	December 8, 2023
Subject:	Augtyro	**Page:**	1 of 5

Last Review Date: September 6, 2024

Augtyro

Description

Augtyro (repotrectinib)

Background

Augtyro (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. Augtyro exhibited anti-tumor activity in cultured cells expressing ROS1 fusions and mutations including SDC4-ROS1, SDC4-ROS1^{G2032R}, CD74-ROS1, CD74-ROS1^{G2032R}, CD74- ROS1D^{2033N}, and CD74-ROS1^{L2026M} (1).

Regulatory Status

FDA-approved indications: Augtyro is a kinase inhibitor indicated for the treatment of (1):

- adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC).
- 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
    - have progressed following treatment or have no satisfactory alternative therapy.

Augtyro has been associated with an increased risk of central nervous system effects, interstitial lung disease/pneumonitis, hepatotoxicity, myalgia with creatine phosphokinase elevations, and

hyperuricemia. If needed, Augtyro may be withheld and resumed at the same or reduced dose upon improvement, or permanently discontinued based on severity (1).

Augtyro can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective non-hormonal contraception during treatment with Augtyro and for at least 2 months after the final dose. Males with female partners of reproductive potential should be advised to use effective contraception during treatment with Augtyro and for 4 months after the final dose (1).

The safety and effectiveness of Augtyro in pediatric patients less than 18 years of age with ROS1-positive NSCLC have not been established. The safety and effectiveness of Augtyro in pediatric patients less than 12 years of age with solid tumors who have an NTRK gene fusion have not been established (1).

Related policies
Alunbrig, Cabometyx, Xalkori

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Augtyro may be considered **medically necessary** if the conditions indicated below are met.

Augtyro may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Locally advanced or metastatic non-small cell lung cancer (NSCLC)
    a. 18 years of age or older
    b. ROS1-positive
2. Solid tumors
    a. 12 years of age or older
    b. Neurotrophic tyrosine receptor kinase (NTRK) gene fusion
    c. Locally advanced **OR** metastatic **OR** surgical resection is likely to result in

severe morbidity

d. Disease has progressed following treatment **OR** patient has no satisfactory alternative therapy

AND ALL of the following for **ALL** indications:

a. Prescriber agrees to monitor uric acid level and liver function tests (LFTs) including bilirubin
b. Female patients of reproductive potential **only**: patient will be advised to use effective non-hormonal contraception during treatment with Augtyro and for 2 months after the last dose
c. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Augtyro and for 4 months after the last dose

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Locally advanced or metastatic non-small cell lung cancer (NSCLC)
    a. 18 years of age or older
2. Solid tumors
    a. 12 years of age or older

AND ALL of the following for **ALL** indications:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor uric acid level and liver function tests (LFTs) including bilirubin
c. Female patients of reproductive potential **only**: patient will be advised to use effective non-hormonal contraception during treatment with Augtyro and for 2 months after the last dose
d. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Augtyro and for 4 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 320 mg per day

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Augtyro (repotrectinib) is a kinase inhibitor indicated for the treatment of ROS1-positive non-small cell lung cancer (NSCLC) and for the treatment of patients with solid tumors. Treatment with Augtyro should continue until disease progression or unacceptable toxicity. The safety and effectiveness of Augtyro in pediatric patients less than 18 years of age with ROS1-positive NSCLC have not been established. The safety and effectiveness of Augtyro in pediatric patients less than 12 years of age with solid tumors who have an NTRK gene fusion have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Augtyro while maintaining optimal therapeutic outcomes.

References

1. Augtyro [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; June 2024.
2. NCCN Drugs & Biologics Compendium® Repotrectinib 2024. National Comprehensive Cancer Network, Inc. Accessed on August 6, 2024.

Policy History

Date	Action
December 2023	Addition to PA
March 2024	Annual review and reference update
July 2024	Per PI update, added indication of solid tumors with NTRK gene fusion
September 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.