BlueCross BlueShield Federal Employee Program

AUGTYRO
(repotrectinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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 2025. National Comprehensive Cancer Network, Inc. Accessed on January 15, 2025.