Augtyro™ (repotrectinib)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC)

Treatment of 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 and have progressed following treatment or have not satisfactory alternative therapy

Compendial Uses
NSCLC, recurrent, advanced or metastatic NTRK1/2/3 gene fusion-positive or ROS1 rearrangement-positive tumors

Histiocytic neoplasms with NTRK gene fusion including Erdheim-Chester Disease (ECD), Langerhans Cell Histiocytosis (LCH), and Rosai-Dorfman Disease

POLICY

Required Documentation
Submission of the following information is necessary to initiate the prior authorization review:

1. NTRK gene fusion status or ROS1 status (where applicable)

Criteria for Initial Approval

1. **Non-Small Cell Lung Cancer (NSCLC)**
   Authorization of 12 months may be granted for treatment of recurrent, advanced, or metastatic ROS1-positive or NTRK gene fusion-positive non-small cell lung cancer as a single agent.

2. **Solid tumors with NTRK gene fusion**
   Authorization of 12 months may be granted for treatment of members 12 years of age and older with solid tumors that have an NTRK gene fusion, as demonstrated by laboratory testing (e.g., next-generation sequencing [NGS] or fluorescence in situ hybridization [FISH]).

3. **Histiocytic Neoplasms with NTRK gene fusion**
   Authorization of 12 months may be granted for the treatment of any of the following NTRK gene fusion-positive histiocytic neoplasm subtypes as a single agent:
   - Symptomatic or relapsed/refractory Erdheim-Chester Disease (ECD)
   - Langerhans Cell Histiocytosis (LCH)
   - Symptomatic or relapsed/refractory Rosai-Dorfman Disease

Continuation of Therapy

1. **ROS1- positive Non-Small Cell Lung Cancer (NSCLC) and NTRK gene-fusion positive gastrointestinal stromal tumor**
   Authorization of 12 months may be granted for continued treatment of ROS1-positive non-small cell lung cancer (NSCLC) in members requesting reauthorization when there is no evidence of unacceptable toxicity while on the current regimen.

2. **All other indications**
   Authorization of 12 months may be granted for continued treatment of solid tumors that have an NTRK gene fusion when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Augtyro (repotrectinib) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Augtyro (repotrectinib) 40 mg capsules	240 per 30 days	160 mg orally once daily for 14 days, then increase dose to 160 mg orally twice daily Dose adjustments due to adverse reactions: 160 mg once daily • First reduction: 120 mg orally once daily • Second reduction: 80 mg orally once daily

Augtyro (repotrectinib) 160 mg capsules	60 per 30 days	160 mg twice daily • First reduction: 120 mg twice daily • Second reduction: 80 mg twice daily Continue until disease progression or unacceptable toxicity.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

Augtyro [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; June 2024.

The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed July 14, 2025.

POLICY HISTORY

Policy #: 05.05.30

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