

PHARMACY COVERAGE GUIDELINE

AUGTYRO™ (repotrectinib) oral Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

Scope

- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance

- To determine whether a member is eligible for the Service, read the entire PCG.
 - This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
 - Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
 - The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
 - The “Description” section describes the Service.
 - The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
 - The “Resources” section lists the information and materials we considered in developing this PCG
 - **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
 - Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.
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Medical Necessity Requirements for AUGTYRO (repotrectinib)

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a physician specializing in the diagnosis or in consultation with an Oncologist

Indication

- Locally advanced or metastatic ROS1 positive non small cell lung cancer (NSCLC) in individuals 18 years of age or older
- Solid tumors in individuals 12 years of age or older with **ALL** of the following:
 - Neurotrophic tyrosine receptor kinase (NTRK) gene fusion

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- Locally advanced or metastatic disease or where surgical resection is likely to result in severe morbidity
- Disease progression following treatment or no satisfactory alternative therapy
- Other oncologic direct treatment uses listed in National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

Age Requirement

- Age is dependent upon diagnosis

Baseline Clinical Evaluation

- For non small cell lung cancer (NSCLC): Documentation of ROS1 rearrangement(s) in tumor specimens
- For solid tumors: Documentation of neurotrophic tyrosine receptor kinase (NTRK) gene fusion
- Eastern Cooperative Oncology Group (ECOG) status of 0 to 1
- Liver function tests including bilirubin
- Uric acid level
- Negative pregnancy test in a woman of childbearing potential

Alternative Therapies

- For non small cell lung cancer (NSCLC): Failure (trial for at least three months duration), contraindication, intolerance, or is not a candidate for **ONE** of the following:
 - Xalkori (crizotinib)
 - Rozlytrek (entrectinib)

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- No concomitant use with:
 - Moderate and strong CYP3A inhibitors (e.g., fluconazole, erythromycin, ketoconazole, itraconazole, nelfinavir, telaprevir, boceprevir)
 - P glycoprotein (P gp) inhibitors (e.g., amiodarone, clarithromycin, cyclosporine, diltiazem, propafenone, quinidine)
 - Moderate and strong CYP3A inducers (e.g., armodafinil, bexarotene, nafcillin, rifampin, rifabutin, phenobarbital, carbamazepine)
 - Hormonal contraceptives

Documentation Requirements

- A completed request form must be submitted including:
 - Chart notes
 - Lab results (ROS1 or NTRK gene fusion, ECOG status, liver function, uric acid, pregnancy test)
 - Supporting clinical documentation

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Additional Requirements

- Does not have symptomatic brain metastases
- Does not have severe renal impairment or kidney failure (estimated glomerular filtration rate less than 30 mL/min) and is not on dialysis
- Does not have moderate (total bilirubin greater than 1.5 to 3 times upper limit of normal with any aspartate aminotransferase) or severe (total bilirubin greater than 3 times upper limit of normal with any aspartate aminotransferase) hepatic impairment

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year
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Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification

- Continues to be seen by a physician specializing in or is in consultation with an Oncologist

Clinical Response

- No documentation of disease progression
- No documentation of unacceptable drug toxicity

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- No development of contraindications or significant adverse drug effects such as:
 - Life threatening central nervous system effects requiring urgent intervention (e.g., dizziness, ataxia, cognitive impairment, gait or balance disorder, mood disorders)
 - Interstitial lung disease/pneumonitis
 - Life threatening hepatotoxicity unresolved in 4 weeks or if it recurs
 - Hyperuricemia
 - Other adverse reactions unresolved in 4 weeks or if it recurs
- No concomitant use with:
 - Moderate and strong CYP3A inhibitors (e.g., fluconazole, erythromycin, ketoconazole, itraconazole, nelfinavir, telaprevir, boceprevir)
 - P glycoprotein (P gp) inhibitors (e.g., amiodarone, clarithromycin, cyclosporine, diltiazem, propafenone, quinidine)
 - Moderate and strong CYP3A inducers (e.g., armodafinil, bexarotene, nafcillin, rifampin, rifabutin, phenobarbital, carbamazepine)
 - Hormonal contraceptives

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Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in given indication
- Lab values that confirm safe use

Additional Requirements

- Does not have symptomatic brain metastases
- Does not have severe renal impairment or kidney failure (estimated glomerular filtration rate less than 30 mL/min) and is not on dialysis
- Does not have moderate (total bilirubin greater than 1.5 to 3 times upper limit of normal with any aspartate aminotransferase) or severe (total bilirubin greater than 3 times upper limit of normal with any aspartate aminotransferase) hepatic impairment

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year
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Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications
 2. Off-Label Use of Cancer Medications
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Description:

Augtyro (repotrectinib) is a kinase inhibitor indicated for the treatment of adult individuals with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC). Augtyro (repotrectinib) is also indicated for the treatment of adult and pediatric individuals 12 years of age and older with solid tumors that: have a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion; are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity; and have progressed following treatment or have no satisfactory alternative therapy. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
[MedWatch Forms for FDA Safety Reporting | FDA](#)



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Resources:

Augtyro (repotrectinib) product information, revised by E.R. Squibb & Sons, L.L.C. 06-2024. Available at [label \(fda.gov\)](#). Accessed October 24, 2025.

Neal JW, Lovly CM. Personalized, genotype-directed therapy for advanced non-small cell lung cancer. In: UpToDate, Lilenbaum RC, Vora SR (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through November 2025. Topic last updated October 22, 2025. Accessed December 02, 2025.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Non-Small Cell Lung Cancer Version 2.2026 –Updated December 02, 2025. Available at <https://www.nccn.org>. Accessed December 02, 2025.

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT03093116: A Phase 1/2, Open-Label, Multi-Center, First-in-Human Study of the Safety, Tolerability, Pharmacokinetics, and Anti-Tumor Activity of TPX-0005 in Patients With Advanced Solid Tumors Harboring ALK, ROS1, or NTRK1-3 Rearrangements (TRIDENT-1). Available from: <http://clinicaltrials.gov>. Last update posted November 09, 2023. Last verified November 2023. Accessed December 06, 2023. Re-evaluated December 02, 2025.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.

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