PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Augtyro Prior Authorization Policy
- Augtyro™ (repotrectinib capsules – Bristol-Myers Squibb Company)

REVIEW DATE: 07/03/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Augtyro, a kinase inhibitor, is indicated for the following uses[1]:
- **Non-small cell lung cancer (NSCLC),** for the treatment of locally advanced or metastatic *ROS1*-positive, disease in adults.
- **Solid tumors,** in adults and pediatric patients ≥ 12 years of age:
  - Have neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion-positive tumor; AND
  - For the treatment of locally advanced or metastatic disease or where surgical resection is likely to result in severe morbidity; AND
  - For disease that have progressed following treatment or have no satisfactory alternative therapy.

The NTRK gene fusion-positive solid tumor 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.

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.

The NTRK gene fusion-positive solid tumor indication is not yet addressed in the NCCN guidelines/compendium.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Augtyro. All approvals are provided for the duration noted below.

- **Augtyro™ (repotrectinib capsules – Bristol-Myers Squibb Company) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

FDA-Approved Indication

1. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of 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.

2. **Solid Tumors.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   Note: Examples of solid tumors include breast cancer, cholangiocarcinoma, colorectal cancer, esophageal cancer, glioblastoma, head/neck cancer, non-small cell lung cancer (*NTRK* gene fusion-positive), peripheral nerve sheath tumor, salivary gland tumor, soft tissue sarcoma, thyroid cancer.
   A) Patient is ≥ 12 years of age; AND
   B) The tumor is positive for neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion; AND
   C) Patient meets ONE of the following (i or ii):
      i. The tumor is locally advanced or metastatic; OR
      ii. Surgical resection of tumor will likely result in severe morbidity; AND
   D) Patient meets ONE of the following (i or ii):
      i. The disease has progressed following treatment; OR
      ii. There are no satisfactory alternative therapies.

CONDITIONS NOT COVERED

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

is(are) considered experimental, investigational or unproven for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Augtyro™ capsules [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; November 2023.
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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy		11/29/2023
Update	01/05/2024: Updated guidelines section addressing Augtyro.	--
Early annual revision	Solid Tumors: Added new FDA-approval condition and criteria	07/03/2024