# Drug Policy:
# Augtyro™ (repotrectinib)

| | | | |
|---|---|---|---|
| **POLICY NUMBER**<br>UM ONC_1490 | **SUBJECT**<br>Augtyro™ (repotrectinib)™ | **DEPT/PROGRAM**<br>UM Dept | **PAGE 1 OF 3** |
| **DATES COMMITTEE REVIEWED**<br>12/13/23, 08/14/24 | **APPROVAL DATE**<br>August 14, 2024 | **EFFECTIVE DATE**<br>August 30, 2024 | **COMMITTEE APPROVAL DATES**<br>12/13/23, 08/14/24 |
| **PRIMARY BUSINESS OWNER:** UM | | **COMMITTEE/BOARD APPROVAL**<br>Utilization Management Committee | |
| **NCQA STANDARDS**<br>UM 2 | | **ADDITIONAL AREAS OF IMPACT** | |
| **CMS REQUIREMENTS** | **STATE/FEDERAL REQUIREMENTS** | **APPLICABLE LINES OF BUSINESS**<br>Commercial, Exchange, Medicaid | |

## I. PURPOSE

To define and describe the accepted indications for Augtyro (repotrectinib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

## II. INDICATIONS FOR USE/INCLUSION CRITERIA

### A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The member has not experienced disease progression on the requested medication AND
2. The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
3. Additional medication(s) are not being added to the continuation request.

### B. Non-Small Cell Lung Cancer

1. Augtyro (repotrectinib) may be used as initial or subsequent line therapy for locally advanced or metastatic Non Small Cell Lung Cancer that is positive for a ROS-1 rearrangement.

### C. Solid Tumors

1. Augtyro (repotrectinib) may be used in adult and pediatric members 12 years 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 that have progressed following treatment or have no satisfactory alternative therapy.

## III. EXCLUSION CRITERIA

A. Disease progression while taking Augtyro (repotrectinib).

B. Concurrent use with other anticancer therapies.

C. Dosing exceeds single dose limit of Augtyro (repotrectinib) 160 mg.

D. Investigational use of Augtyro (repotrectinib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

## IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

## V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

## VI. ATTACHMENTS

A. None

## VII. REFERENCES

A. Augtyro prescribing information 2024. Bristol-Myers Squibb Company Princeton, NJ 08543

B. Drilon A, et al; TRIDENT-1 Investigators. Repotrectinib in *ROS1* Fusion-Positive Non-Small-Cell Lung Cancer. N Engl J Med. 2024 Jan 11;390(2):118-131. doi: 10.1056/NEJMoa2302299

C. Solomon, BJ, et al. Repotrectinib in patients (pts) with NTRK fusion-positive (NTRK+) advanced solid tumors, including NSCLC: Update from the phase I/II TRIDENT-1 trial. Annals of Oncology. October 2023; Abstract 1372P: 34 (2): S787-S788. DOI: https://doi.org/10.1016/j.annonc.2023.09.2405

D. Updates Results Support Repotrectinib in ROS1+ NSCLC. https://www.targetedonc.com/view/updates-results-support-repotrectinib-in-ros1-nsclc. Accessed 29 November 2023.

E. Clinical Pharmacology Elsevier Gold Standard 2024.

F. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2024.

G. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2024.

H. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

I. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.