

Drug Policy:

Alecensa™ (alectinib)

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| POLICY NUMBER UM ONC_1277 | SUBJECT Alecensa™ (alectinib) | | DEPT/PROGRAM UM Dept | PAGE 1 of 3 |
| DATES COMMITTEE REVIEWED 03/23/16, 01/05/17, 01/10/18, 02/13/19, 12/11/19, 02/12/20, 11/11/20, 10/13/21, 11/15/21, 05/11/22, 10/12/22, 07/12/23, 05/08/24 | APPROVAL DATE May 08, 2024 | EFFECTIVE DATE May 31, 2024 | COMMITTEE APPROVAL DATES 03/23/16, 01/05/17, 01/10/18, 02/13/19, 12/11/19, 02/12/20, 11/11/20, 10/13/21, 11/15/21, 05/11/22, 10/12/22, 07/12/23, 05/08/24 | |
| PRIMARY BUSINESS OWNER: UM | | COMMITTEE/BOARD APPROVAL Utilization Management Committee | | |
| NCQA STANDARDS UM 2 | | ADDITIONAL AREAS OF IMPACT | | |
| CMS REQUIREMENTS | STATE/FEDERAL REQUIREMENTS | | APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid | |

I. PURPOSE

To define and describe the accepted indications for Alecensa (alectinib) 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 requested medication was used within the last year, **AND**
2. The member has not experienced disease progression and/or no intolerance to the requested medication, **AND**
3. Additional medication(s) are not being added to the continuation request.

B. Non-Small Cell Lung Cancer (NSCLC)

1. The member has recurrent or metastatic NSCLC and Alecensa (alectinib) is being used as a single agent for **ALL** of the following:
 - a. The tumor is ALK positive **AND**
 - b. Alecensa (alectinib) is being used as first line therapy **OR**

- c. Alecensa (alectinib) is being used as subsequent therapy.
2. Alecensa (alectinib) may be used as adjuvant treatment following tumor resection in adult members with ALK-positive metastatic NSCLC.

III. EXCLUSION CRITERIA

- A. Concurrent use with chemotherapy.
- B. Lack of documentation of ALK rearrangement in tumor tissue
- C. Dosing exceeds single dose limit of Alecensa (alectinib) 600 mg.
- D. Treatment exceeds the maximum limit of 240 (150 mg) capsules/month.
- E. Investigational use of Alecensa (alectinib) 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 less than 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. Mok T, et al. Updated overall survival and final progression-free survival data for patients with treatment-naïve advanced ALK-positive non-small-cell lung cancer in the ALEX study. *Ann Oncol*. 2020 Aug;31(8):1056-1064.
- B. Solomon B, et al. ALINA: A phase III study of alectinib versus chemotherapy as adjuvant therapy in patients with stage IB–IIIA anaplastic lymphoma kinase-positive (*ALK+*) non-small cell lung cancer (NSCLC). *Journal of Clinical Oncology* 2023; 37(15): TPS8569-TPS8569(2019). DOI:[10.1200/JCO.2019.37.15_suppl.TPS8569](https://doi.org/10.1200/JCO.2019.37.15_suppl.TPS8569)
- C. Alecensa Prescribing Information. Genentech, Inc. South San Francisco, CA 2024.
- D. Clinical Pharmacology Elsevier Gold Standard 2023.
- E. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2023.
- F. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.
- G. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2023.
- 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>.