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| **Clinical Policy Title:** | alectinib |
| **Policy Number:** | RxA.335 |
| **Drug(s) Applied:** | Alecensa® |
| **Original Policy Date:** | 03/06/2020 |
| **Last Review Date:** | 09/14/2021 |
| **Line of Business Policy Applies to:** | All lines of business |

## Background

Alectinib (Alecensa®)is a kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

## Dosing Information

| Drug Name | Indication | Dosing Regimen | Maximum Dose |
|---|---|---|---|
| alectinib (Alecensa®) | ALK-positive NSCLC | 600 mg orally twice daily with meal. | 1,200 mg/day |

## Dosage Forms

- Capsules: 150 mg

## Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

**I. Initial Approval Criteria**

**A. Non-Small Cell Lung Cancer** (must meet all)**:**

1. Diagnosis of recurrent, advanced or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age 18 years of age or older;
4. Disease is ALK rearrangement positive;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 1,200 mg (8 capsules) per day;
   b. Requested dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

**Approval duration**
**Commercial:** 6 months
**Medicaid:** 6 months

**B. CNS Cancer (Limited & Extensive Brain Metastases) (Off -Label)** (must meet all):

1. Diagnosis of limited or extensive brain metastases;
2. Prescribed by or in consultation with an oncologist;

3. Age 18 years of age or older;
4. Request is for one of the following (a or b):
   a. Used as a single-agent treatment for limited brain metastases in patients with ALK rearrangement-positive non-small cell lung cancer:
   b. Single-agent treatment for extensive brain metastases in patients with ALK rearrangement-positive non-small cell lung cancer:
5. Prescribed for one of the following (a, b, or c):
   a. As initial treatment in select patient (e.g., patients with small asymptomatic brain metastases);
   b. As treatment for recurrent brain metastases;
   c. As treatment of relapsed/recurrent disease with either stable systemic disease or reasonable systemic treatment options;
6. Request meets one of the following (a or b):
   a. Dose does not exceed 1,200 mg (8 capsules) per day;
   b. Requested dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

**Approval duration**
**Commercial**: 6 months
**Medicaid**: 6 months

## II. Continued Therapy Approval

**A. All indications in Section I** (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance benefit, or documentation supports that member is currently receiving Alecensa® for NSCLC and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 1,200 mg (8 capsules) per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

**Approval duration**
**Commercial:** 6 months
**Medicaid:** 6 months

## III. Appendices

**APPENDIX A: Abbreviation/Acronym Key**

ALK: anaplastic lymphoma kinase
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network
NSCLC: non-small cell lung cancer
ILD: Interstitial Lung Disease
CNS: Central Nervous System
ALT: Alanine transaminase
AST: Aspartate aminotransferase

**APPENDIX B: Therapeutic Alternatives**

- Not applicable

**APPENDIX C: Contraindications/Boxed Warnings**

- Contraindication(s):
  - None reported.

- Boxed Warnings
  - None reported.

**APPENDIX D: General Information**

- Hepatotoxicity: Monitor liver laboratory tests every 2 weeks during the first 3 months of treatment, then once a month and as clinically indicated, with more frequent testing in patients who develop transaminase and bilirubin elevations. In case of severe ALT, AST, or bilirubin elevations, withhold, then reduce dose, or permanently discontinue Alecensa®.
- Interstitial Lung Disease (ILD)/Pneumonitis: Immediately withhold Alecensa® in patients diagnosed with ILD/pneumonitis and permanently discontinue if no other potential causes of ILD/pneumonitis have been identified.
- Renal Impairment: Withhold Alecensa® for severe renal impairment, then resume Alecensa® at reduced dose upon recovery or permanently discontinue.
- Bradycardia: Monitor heart rate and blood pressure regularly. If symptomatic, withhold Alecensa® then reduce dose, or permanently discontinue.

**References**


1. Alecensa® Prescribing Information. South San Francisco, CA: Genentech USA, Inc. January 2021. Available at https://www.gene.com/download/pdf/alecensa_prescribing.pdf. Accessed May 28, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 28, 2021.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 4.2021. Available at https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf . Accessed May 28, 2021.
4. National Comprehensive Cancer Network Guidelines. Central Nervous System Cancers Version 5.2020. Available at https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf . Accessed May 28, 2021.


| Review/Revision History | Review/Revised Date | P&T Approval Date |
|---|---|---|
| Policy established. | 01/2020 | 03/06/2020 |
| Policy was reviewed:<br>1. Policy title table was updated.<br>2. Line of Business Policy Applies to was updated to “All lines of business”.<br>3. The Commercial approval duration for Initial and Continued Therapy Approval criteria was updated from Length of benefit “ to “6 months”.<br>4. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”<br>5. References were updated. | 07/29/2020 | 09/14/2020 |
| Policy was reviewed: | 05/28/2021 | 09/14/2021 |

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| 1. Background was rephrased to “Alectinib (Alecensa®)is a kinase inhibitor indicated for the treatment…”.<br>2. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy.<br>3. Initial Approval Criteria I.B was updated to include off-label indication, “CNS Cancer (Limited & Extensive Brain Metastases) (Off -Label) …”<br>4. Continued Therapy Approval Criteria II.A was updated from “Non Small Cell Lung Cancer” to “All indications in Section I…”<br>5. Continued Therapy Approval Criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…”<br>6. Appendix A was updated to include abbreviations ILD, CNS, ALT, and AST.<br>7. Appendix D was updated to include Warnings and Precautions regarding “Hepatotoxicity…”, “Interstitial Lung Disease…”, “Renal impairment…”, “and “Bradycardia…”.<br>8. References were reviewed and updated. | | |