RXADVANCE
2 Park Central Drive
Southborough, MA 01772

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

Background

Alectinib (Alecensa®) is a tyrosine kinase inhibitor that targets the activity of anaplastic lymphoma kinase. It is indicated for the treatment of 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 PO BID 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.

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

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;

2. Currently receiving medication that has been authroized by RxAdvance benefit, or documentation supports that member is currently receiving Alecensa for NSCLC and has received this medication for at least 30 days;
3. Member is responding positively to therapy;
4. 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

APPENDIX B: Therapeutic Alternatives
- Not applicable

APPENDIX C: Contraindications/Boxed Warnings
- Contraindication(s):
  - None reported
- Boxed Warnings
  - None reported

APPENDIX D: General Information
- Not applicable

References

1. Alecensa Prescribing Information. South San Francisco, CA: Genentech USA, Inc. June 2018. Available at https://www.gene.com/download/pdf/alecensa_prescribing.pdf. Accessed July 29, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 29, 2020.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 6.2020. Available at http://www.nccn.org. Accessed July 29, 2020.
4. National Comprehensive Cancer Network Guidelines. Central Nervous System Cancers Version 2.2020. Available at www.nccn.org. Accessed July 29, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. 2. Line of Business Policy Applies to was updated to	07/29/2020	09/14/2020

"All lines of business". 3. The Commercial approval duration for Initial and Continued Therapy Approval criteria was updated from Length of benefit **"** to "6 months". 4. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…" 5. References were updated.		