Clinical Policy Title:	brigatinib
Policy Number:	RxA.12
Drug(s) Applied:	Alunbrig®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Brigatinib (Alunbrig®) is a kinase inhibitor indicated for the treatment of adult 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
brigatinib (Alunbrig®)	ALK-positive NSCLC	90 mg PO once daily for the first 7 days; increase to 180 mg PO once daily	180 mg/day

Dosage Forms

- Tablets: 30 mg, 90 mg, 180 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;
4. Disease is ALK-positive;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 180 mg per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.*

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

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 documentation supports that member is currently receiving Alunbrig® 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 180 mg 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).**

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

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.
- Boxed Warning(s):
  - None.

APPENDIX D: General Information

None.

References

1. Alunbrig® Prescribing Information. Cambridge, MA: ARIAD Pharmaceuticals, Inc.; May 2020. Available at: www.alunbrig.com. Accessed January 20, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed January 20, 2021.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed January 20, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Updated references	05/2020	05/21/2020

Policy was reviewed: 1. Policy title table was updated. 2. Background and indication were updated to include updated FDA-approved indication. 3. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 4. Approval duration was updated for commercial plans for initial and continued therapy approval from length of benefit to 6 months. 5. Initial and continued therapy approval criteria were updated to include terminology "**Prescribed regimen must be FDA-approved…*". 6. References were updated.	01/20/2021	03/09/2021