RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	lorlatinib
Policy Number:	RxA.407
Drug(s) Applied:	Lorbrena®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Lorlatinib (Lorbrena®) is a kinase inhibitor.

Lorbrena is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)- positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on

- Crizotinib and at least one other ALK inhibitor for metastatic disease; or
- Alectinib as the first ALK inhibitor therapy for metastatic disease; or
- Ceritinib as the first ALK inhibitor therapy for metastatic disease.

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Lorlatinib (Lorbrena®)	ALK-positive NSCLC	100 mg PO once daily	100 mg/day

Dosage Forms

- Tablets: 25 mg, 100 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 ALK or ROS1 positive;
5. If disease is ALK positive, failure of Alecensa®, Alunbrig®, or Zykadia® unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for Alecensa, Alunbrig, and Zykadia.*
6. If disease is ROS1 positive, failure of Xalkori® or or Zykadia® unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for Xalkori and Zykadia.*
7. Request meets one of the following (a or b):
   a. Dose does not exceed 100 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).*

Approval Duration
Commercial: 6 months
Medicaid/HIM: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria approved 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 100 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).*

Approval Duration
Commercial: 12 months
Medicaid/HIM: 12 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
This table provides a listing of preferred alternative therapy recommended in the approval criteria.
The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Alecensa® (alectinib)	600 mg PO BID	1,200 mg/day
Alunbrig® (brigatinib)	90 mg PO once daily for the first 7 days; if tolerated, increase to 180 mg PO once daily	180 mg/day

Zykadia® (ceritinib)	450 mg PO once daily	450 mg/day
Xalkori® (crizotinib)	250 mg PO BID	500 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Concomitant use with strong CYP3A inducers.

- Boxed Warning(s):
  - None.

References

1. Lorbrena Prescribing Information. New York, NY: Pfizer Inc; May 2020. Available at: www.pfizer.com. Accessed July 14, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 15, 2020.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 6.2020 – June 15, 2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed July 15, 2020.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/. Accessed July 15, 2020.
5. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed July 15, 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.** Dosing information was updated **3.** Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". **4.** References were updated.	07/14/2020	09/14/2020