

## Clinical Policy: Lorlatinib (Lorbrena)

Reference Number: ERX.SPA.320

Effective Date: 03.01.19

Last Review Date: 05.21

Line of Business: Commercial, Medicaid

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

### Description

Lorlatinib (Lorbrena<sup>®</sup>) is a kinase inhibitor.

### FDA Approved Indication(s)

Lorbrena is indicated for the treatment of adults patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Lorbrena is **medically necessary** when the following criteria are met:

#### 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 or ROS1 positive;
5. If disease is ROS1 positive, failure of Rozlytrek™, Xalkori<sup>®</sup>, or Zykadia<sup>®</sup>, unless clinically significant adverse effects are experienced or all are contraindicated;  
*\*Prior authorization may be required for Rozlytrek, Xalkori, and Zykadia*
6. Request meets one of the following (a or b):\*
  - a. Dose does not exceed 100 mg (3 tablets) 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:

**Medicaid** – 6 months

**Commercial** – Length of Benefit

##### B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

#### II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Lorbrena 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 (3 tablets) 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:**

**Medicaid** – 12 months

**Commercial** – Length of Benefit

**B. Other diagnoses/indications** (must meet 1 or 2):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

**Approval duration: Duration of request or 6 months (whichever is less);** or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

**IV. Appendices/General Information**

*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
Rozlytrek (entrectinib)	600 mg PO QD	600 mg/day
Zykadia (ceritinib)	450 mg PO QD	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 reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
ALK-positive NSCLC	100 mg PO QD	100 mg/day

**VI. Product Availability**

Tablets: 25 mg, 100 mg

**VII. References**

1. Lorbrera Prescribing Information. New York, NY: Pfizer Inc; May 2020. Available at: [www.pfizer.com](http://www.pfizer.com). Accessed January 14, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [http://www.nccn.org/professionals/drug\\_compendium](http://www.nccn.org/professionals/drug_compendium). Accessed January 14, 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](https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf). Accessed January 14, 2021.

4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed January 14, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	12.11.18	02.19
2Q 2019 annual review: no significant changes; references reviewed and updated.	02.19.19	05.19
2Q 2020 annual review: added Medicaid line of business with 6/12 month initial/continued authorization duration; per NCCN Compendium added Xalkori as a possible redirect option for ALK-positive disease; added Rozlytrek as a possible redirect option for ROS1-positive disease; added quantity limit of 3 tablets to allow for dose adjustments; references reviewed and updated.	02.12.20	05.20
2Q 2021 annual review: per NCCN Compendium which supports Lorbrina as first-line therapy in ALK positive NSCLC, removed requirement for use of prior therapies; RT4: updated FDA-approved indication for NSCLC removing disease progression on specific prior therapies; references reviewed and updated.	03.23.21	05.21

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

This policy is the property of Envolve Pharmacy Solutions. Unauthorized copying, use, and distribution of this Policy or any information contained herein is strictly prohibited. By accessing this policy, you agree to be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.

©2018 Envolve Pharmacy Solutions. All rights reserved. All materials are exclusively owned by Envolve Pharmacy Solutions and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Envolve Pharmacy Solutions. You may not alter or remove any trademark, copyright or other notice contained herein.