Applicable Drugs: Lorbrena (lorlatinib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 11/17/2025

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met.)

I. Documentation the following diagnoses AND must meet all criteria listed under the applicable diagnosis:

II. FDA-Approved Indication(s)

A. Non-small cell lung cancer (NSCLC)

i. Documentation disease is anaplastic lymphoma kinase positive (ALK)-positive as detected by an FDA-approved test.

ii. Documentation of advanced or metastatic disease.

iii. Lorbrena will be used as a single agent.

iv. Minimum age requirement: 18 years old or older

Other Uses With Supportive Evidence

B. B-Cell lymphomas

C. Central nervous system cancers

D. Histiocytic neoplasms

E. NSCLC – ROS1 rearrangement positive tumors

F. Pediatric central nervous system cancers

G. Soft tissue sarcomas

H. T-Cell lymphomas

I. Uterine neoplasms

III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

Exclusion Criteria

- N/A

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Tablets: 25 mg and 100 mg
- Maximum dose: 100 mg once daily
- Quantity limit: 30-day supply

Approval Length

- **Authorization:** 1 year
- **Re-Authorization:** 1 year - An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of symptomatic systemic disease with multiple lesions.

Appendix

N/A

References

1. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer. Version 8.2025. Updated August 15, 2025. Accessed September 18, 2025. www.nccn.org/professionals/physician_gls/pdf/nscl.pdf
2. Lorbrena. Prescribing Information. Pfizer US., 2024. Accessed September 4, 2025. https://labeling.pfizer.com/ShowLabeling.aspx?id=11140
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. B-Cell Lymphomas. Version 3.2025. Updated August 18, 2025. Accessed September 18, 2025. www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Central Nervous System Cancers. Version 2.2025. Updated August 28, 2025. Accessed September 18, 2025. www.nccn.org/professionals/physician_gls/pdf/cns.pdf
5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Histiocytic Neoplasms. Version 1.2025. Updated June 20, 2025. Accessed September 18, 2025. www.nccn.org/professionals/physician_gls/pdf/histiocytic_neoplasms.pdf

6. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Pediatric Central Nervous System Cancers. Version 3.2025. Updated September 2, 2025. Accessed September 18, 2025. www.nccn.org/professionals/physician_gls/pdf/ped_cns.pdf
7. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Soft Tissue Sarcoma. Version 1.2025. Updated May 2, 2025. Accessed September 18, 2025. www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf
8. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. T-Cell Lymphomas. Version 2.2025. Updated May 28, 2025. Accessed September 18, 2025. www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf
9. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Uterine Neoplasms. Version 3.2025. Updated March 7, 2025. Accessed September 18, 2025. www.nccn.org/professionals/physician_gls/pdf/uterine.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.