LORBRENA®
LORLATINIB | 100 mg tablets

LORBRENA® Formulary Exception Toolkit

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This LORBRENA® Formulary Exception Toolkit aims to help prescribers and office staff to accurately navigate the formulary exception process to help appropriate patients start and stay on LORBRENA®.

If a formulary exception is needed, please use these resources to support the exception process.

This Toolkit includes the following resources:

- **Medical Necessity Checklist**
- **Sample Letter of Medical Necessity**
- **Prior Authorization Checklist**
- **Appeals Checklist**
- **Sample Letter of Formulary Exception**
- **Reimbursement Guide**

Pfizer Oncology together™

Visit **www.pfizeroncologytogether.com/hcp/products/** and scroll down to LORBRENA® to download digital versions of these resources

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Accurate completion of reimbursement-related or coverage-related documentation is the responsibility of the provider and patient. This information is general in nature and is not intended to be exhaustive. Pfizer makes no guarantee regarding reimbursement for any service or item.

NOTE: Retain a copy of all submissions for your personal records.

The information contained in this checklist is provided by Pfizer for informational purposes for patients who have been prescribed LORBRENA®. There is no requirement that any patient or healthcare provider use LORBRENA® in exchange for this information, and this checklist is not meant to substitute for a prescriber's independent medical decision-making.

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Medical Necessity Checklist

A Letter of Medical Necessity may help support clinical decision-making at initial precertification or appeals for your patient receiving treatment with LORBRENA®. To support the development of the letter of medical necessity for appropriate patients, please include the following information.

Medical History

- ❑ Patient name, date of birth, gender
- ❑ Insurance policy/ID number
- ❑ Diagnosis (ICD-10-CM) and dates of initial diagnosis and recurrence *(see Reimbursement Guide in Toolkit)*
- ❑ Laboratory/imaging results and pathology reports
- ❑ Previously administered treatments (if applicable)
- ❑ Current condition, comorbidities, and intolerance to other therapies
- ❑ Biomarker status via FDA-approved test

Current Treatment

- ❑ Concise medical rationale for LORBRENA®
- ❑ Recommended treatment plan
  - ➢ LORBRENA® dosage, quantity, and days supplied

Treatment History (if applicable)

- ❑ Prior treatments and procedures for the disease
  - ➢ Treatment dosage and frequency
  - ➢ Treatment duration
  - ➢ Clinical response
  - ➢ Reason(s) for discontinuation
- ❑ Physician opinion of patient prognosis or disease progression

Supporting documentation to include with letter of medical necessity

- LORBRENA® Full Prescribing Information
- Published articles and clinical guidelines (e.g., ASCO and NCCN)
- Laboratory/imaging results and pathology reports, including confirmation of biomarker status via FDA-approved test
- Medical records documenting treatment history

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Sample Letter of Medical Necessity

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[Insert Physician Letterhead]

Attn: [Insert Name of Pharmacy Director]
[Insert Insurer/Health Plan Name]
[Insert Address]
[Insert City, State, ZIP]

RE: [Insert Patient Full Name]
[Insert Gender and Date of Birth]
[Insert Policy Number]
[Insert Group Number]

REQUEST: Authorization for treatment with LORBRENA® (lorlatinib)
DIAGNOSIS: [placeholder for diagnosis] [Insert ICD-10-CM]
DOSAGE: [Insert dose, frequency, and days supplied]
REQUEST TYPE: ☐ Standard ☐ Expedited

[Insert Date]

Dear [Insert name]:
I am writing on behalf of my patient, [insert patient name], to document the medical necessity of LORBRENA®. My request is supported by the following:

Summary of Patient's Diagnosis
[Insert patient's diagnosis, date of diagnosis, lab results and date, and current medical condition]

Summary of Treatment History [Exercise medical judgement and discretion when inserting the following:
- Diagnosis (ICD-10-CM) and dates of initial diagnosis and recurrence (if applicable)
- Confirmed biomarker status via FDA-approved test
- Laboratory/imaging results and pathology reports
- If applicable, prior treatments and procedures for the cancer (dosage, duration, clinical response, and reasons for discontinuation)
- Current condition, comorbidities, and intolerance to other therapies
- Physician opinion of patient prognosis or disease progression]

Rationale for Treatment

Considering the patient's medical history, current medical condition, and the supporting use of LORBRENA®, I believe treatment with LORBRENA® at this time is warranted, appropriate, and medically necessary for this patient.

The following documentation is enclosed:
- LORBRENA® full Prescribing Information
- [Insert published articles and clinical guidelines (e.g., ASCO and NCCN)]
- [Insert laboratory/imaging results and pathology reports]
- [Insert medical records documenting treatment history]

Please contact me at [insert phone number or e-mail address] if you require any additional information or documentation. I look forward to your timely response.

Sincerely,
[Insert physician name and participating provider number]

If this request is denied, I am requesting an expedited review of appeal by a professional in my specialty.

Enclosure: [Include full Prescribing Information and any additional supporting documentation]

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Prior Authorization Checklist

Correct submission of a **Prior Authorization (PA)** (coverage determination) form may help expedite approval of LORBRENA® for appropriate patients. Providers must submit evidence of medical necessity and why covered alternatives are clinically unacceptable. Poorly documented requests may be denied, resulting in treatment delay and additional work for an appeal.

PA requirements vary among healthcare insurers. If available, completion of an insurer-specific PA form is recommended. The following information may need to be included:

Patient Information

- ❑ Name
- ❑ Date of birth
- ❑ Social Security number
- ❑ Copy of front and back of patient's insurance card

Insurance Information

- ❑ Name of insurance
- ❑ Phone number
- ❑ Name of policy holder
- ❑ Plan ID number
- ❑ Group number
- ❑ Plan address

Healthcare Provider Information

- ❑ Name
- ❑ Tax ID number
- ❑ Address
- ❑ Phone/fax
- ❑ NPI number
- ❑ Provider number

Patient Clinical Diagnosis

- ❑ Diagnosis (ICD-10-CM) and dates of initial diagnosis/recurrence *(see Reimbursement Guide in Toolkit)*
- ❑ Biomarker status via FDA-approved test
- ❑ If applicable, prior treatments and procedures for the cancer (dosage, duration, clinical response, and reasons for discontinuation)
- ❑ Concise medical rationale for LORBRENA®
- ❑ Recommended treatment plan
  - ➢ LORBRENA® dosage, quantity, start date and days supplied

Supporting documentation

- LORBRENA® Full Prescribing Information
- Published articles and clinical guidelines (e.g., ASCO and NCCN)
- Laboratory/imaging results and pathology reports, including confirmation of biomarker status via FDA-approved test
- Medical records documenting treatment history (if applicable)
- Letter of medical necessity

FOR EXPEDITED REQUESTS, SUPPORT THE URGENCY WITH ADEQUATE INFORMATION

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Appeals Checklist

Before submitting an appeal (reconsideration), review the reason for LORBRENA® denial. Verify that LORBRENA® is FDA-approved for the patient's diagnosis, and prior authorization (PA), patient information, and coding were submitted correctly.

If the claim was submitted correctly, you and/or the patient may decide to appeal the denied claim. Please check with your patient on documents they received from the insurer. Submit relevant information from below, per insurer-specific requirements, before the filing deadline.

Insurer-specific form, if required

- Insurer-specific guidance, forms, and resources can typically be found on insurer websites on a tools, resources, or forms page, by searching for appeals, or by logging into the provider portal.
- 'Model Coverage Redetermination Request' form can be used for Medicare

Letter of formulary exception, including the following information:

Medical History

- ❑ Patient name, date of birth, gender
- ❑ Insurance policy/ID number
- ❑ Diagnosis (ICD-10-CM) and dates of initial diagnosis and recurrence *(see Reimbursement Guide in Toolkit)*
- ❑ Laboratory/imaging results and pathology reports
- ❑ Previously administered treatments (if applicable)
- ❑ Current condition, comorbidities, and intolerance to other therapies
- ❑ Biomarker status via FDA-approved test

Treatment History (if applicable)

- ❑ Prior treatments and procedures for the disease
  - ➢ Treatment dosage and frequency
  - ➢ Treatment duration
  - ➢ Clinical response
  - ➢ Reason(s) for discontinuation
- ❑ Physician opinion of patient prognosis or disease progression

Current Treatment

- ❑ Concise medical rationale for LORBRENA®
- ❑ Recommended treatment plan
  - ➢ LORBRENA® dosage, quantity, and days supplied

Supporting documentation to include with letter of formulary exception

- LORBRENA® Full Prescribing Information
- Published articles and clinical guidelines (e.g., ASCO and NCCN)
- Laboratory/imaging results and pathology reports, including confirmation of biomarker status via FDA-approved test
- Medical records documenting treatment history

Accurate completion of reimbursement-related or coverage-related documentation is the responsibility of the provider and patient. This information is general in nature and is not intended to be exhaustive. Pfizer makes no guarantee regarding reimbursement for any service or item.

NOTE: Retain a copy of all submissions for your personal records.

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Sample Letter of Formulary Exception

Accurate completion of reimbursement-related or coverage-related documentation is the responsibility of the provider and patient. Pfizer makes no guarantee regarding reimbursement for any service or item.

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[Insert Physician Letterhead]

Attn: [Insert Name of Pharmacy Director]
[Insert Insurer/Health Plan Name]
[Insert Address]
[Insert City, State, ZIP]

RE: [Insert Patient Full Name]
[Insert Gender and Date of Birth]
[Insert Policy Number]
[Insert Group Number]
[Insert Claim Number]

REQUEST: Authorization for treatment with LORBRENA® (lorlatinib)
DIAGNOSIS: [placeholder for diagnosis] [Insert ICD-10-CM]
DOSAGE: [Insert dose, frequency, and days supplied]
REQUEST TYPE: ☐ Standard ☐ Expedited
APPEAL LEVEL: ☐ First Level (Ref. #:) ☐ Second Level (Ref. #:) ☐ Third Level (Ref. #:)

[Insert Date]

Dear [Insert name]:
I am writing on behalf of my patient, [insert patient name], to request a formulary exception for LORBRENA®. My request is supported by the following:

Summary of Patient's Diagnosis
[Insert patient's diagnosis, date of diagnosis, lab results and date, and current medical condition]

Summary of Treatment History [Exercise medical judgement and discretion when inserting the following:
- Diagnosis (ICD-10-CM) and dates of initial diagnosis and recurrence (if applicable)
- Confirmed biomarker status via FDA-approved test
- Laboratory/imaging results and pathology reports
- If applicable, prior treatments and procedures for the cancer (dosage, duration, clinical response, and reasons for discontinuation)
- Current condition, comorbidities, and intolerance to other therapies
- Physician opinion of patient prognosis or disease progression]

Rationale for Treatment

Considering the patient's medical history, current medical condition, and the supporting use of LORBRENA®, I believe treatment with LORBRENA® at this time is warranted, appropriate, and medically necessary for this patient. For LORBRENA® clinical information, please see the accompanying full Prescribing Information [and additional supporting documentation].

Please contact me at [insert phone number or e-mail address] if you require any additional information or documentation. I look forward to your timely response.

Sincerely,
[Insert physician name and participating provider number]

If this request is denied, I am requesting an expedited review of appeal by a professional in my specialty.

Enclosure:
- LORBRENA® full Prescribing Information
- [Insert any additional supporting documentation: e.g., published articles and clinical guidelines from ASCO or NCCN, laboratory/imaging results and pathology reports, and medical records documenting treatment history]

LORBRENA® Reimbursement Guide

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

ICD-10-CM

ICD-10-CM is a statistical classification system created by the Center for Disease Control and Prevention Act, which arranges diseases and injuries into groups according to predetermined criteria.

ICD-10-CM codes may include, but are not limited to, the following codes listed below. Reporting the medical necessity for LORBRENA® may require a primary as well as secondary diagnosis, in some cases.

ICD-10-CM Code	Descriptor
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

References:
1. CMS, 2023 ICD-10-CM tabular list of disease and injuries, https://www.cms.gov/medicare/icd-10/2021-icd-10-cm, Accessed June 8, 2023.
2. CMS, MLN Fact Sheet: Health Care Code Sets: ICD-10, June 2022, Available at https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/icd9-10cm-icd10pcs-cpt-hcpcs-code-sets-educational-tool-icn900943.pdf

LORBRENA® Indication and Important Safety Information

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

IMPORTANT SAFETY INFORMATION

Contraindications: LORBRENA is contraindicated in patients taking strong CYP3A inducers, due to the potential for serious hepatotoxicity.

Risk of Serious Hepatotoxicity with Concomitant Use of Strong CYP3A Inducers: Severe hepatotoxicity occurred in 10 of 12 healthy subjects receiving a single dose of LORBRENA with multiple daily doses of rifampin, a strong CYP3A inducer. Grade 4 ALT or AST elevations occurred in 50% of subjects, Grade 3 in 33% of subjects, and Grade 2 in 8% of subjects. ALT or AST elevations occurred within 3 days and returned to within normal limits after a median of 15 days (7 to 34 days); median time to recovery in subjects with Grade 3 or 4 or Grade 2 ALT or AST elevations was 18 days and 7 days, respectively. LORBRENA is contraindicated in patients taking strong CYP3A inducers. Discontinue strong CYP3A inducers for 3 plasma half-lives of the strong CYP3A inducer prior to initiating LORBRENA.

Central Nervous System (CNS) Effects: A broad spectrum of CNS effects can occur; overall, CNS effects occurred in 52% of the 476 patients receiving LORBRENA. These included seizures (1.9%, sometimes in conjunction with other neurologic findings), psychotic effects (7%; 0.6% severe [Grade 3 or 4]), and changes in cognitive function (28%; 2.9% severe), mood (including suicidal ideation) (21%; 1.7% severe), speech (11%; 0.6% severe), mental status (1.3%; 1.1% severe), and sleep (12%). Median time to first onset of any CNS effect was 1.4 months (1 day to 3.4 years). Overall, 2.1% and 10% of patients required permanent or temporary discontinuation of LORBRENA, respectively, for a CNS effect; 8% required dose reduction. Withhold and resume at same or reduced dose or permanently discontinue based on severity.

Hyperlipidemia: Increases in serum cholesterol and triglycerides can occur. Grade 3 or 4 elevations in total cholesterol occurred in 18% and Grade 3 or 4 elevations in triglycerides occurred in 19% of the 476 patients who received LORBRENA. Median time to onset was 15 days for both hypercholesterolemia and hypertriglyceridemia. Approximately 4% and 7% of patients required temporary discontinuation and 1% and 3% of patients required dose reduction of LORBRENA for elevations in cholesterol and in triglycerides in Study B7461001 and Study B7461006, respectively. Eighty-three percent of patients required initiation of lipid-lowering medications, with a median time to onset of start of such medications of 17 days. Initiate or increase the dose of lipid-lowering agents in patients with hyperlipidemia. Monitor serum cholesterol and triglycerides before initiating LORBRENA, 1 and 2 months after initiating LORBRENA, and periodically thereafter. Withhold and resume at same dose for the first occurrence; resume at same or reduced dose of LORBRENA for recurrence based on severity.

Atrioventricular (AV) Block: PR interval prolongation and AV block can occur. In 476 patients who received LORBRENA at a dose of 100 mg orally once daily and who had a baseline electrocardiography (ECG), 1.9% experienced AV block and 0.2% experienced Grade 3 AV block and underwent pacemaker placement. Monitor ECG prior to initiating LORBRENA and periodically thereafter. Withhold and resume at reduced or same dose in patients who undergo pacemaker placement. Permanently discontinue for recurrence in patients without a pacemaker.

Interstitial Lung Disease (ILD)/Pneumonitis: Severe or life-threatening pulmonary adverse reactions consistent with ILD/pneumonitis can occur. ILD/pneumonitis occurred in 1.9% of patients, including Grade 3 or 4 ILD/pneumonitis in 0.6% of patients. Four patients (0.8%) discontinued LORBRENA for ILD/pneumonitis. Promptly investigate for ILD/pneumonitis in any patient who presents with worsening of respiratory symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, and fever). Immediately withhold LORBRENA in patients with suspected ILD/pneumonitis. Permanently discontinue LORBRENA for treatment-related ILD/pneumonitis of any severity.

Hypertension: Hypertension can occur. Hypertension occurred in 13% of patients, including Grade 3 or 4 in 6% of patients. Median time to onset of hypertension was 6.4 months (1 day to 2.8 years), and 2.3% of patients temporarily discontinued LORBRENA for hypertension. Control blood pressure prior to initiating LORBRENA. Monitor blood pressure after 2 weeks and at least monthly thereafter. Withhold and resume at reduced dose or permanently discontinue based on severity.

Hyperglycemia: Hyperglycemia can occur. Hyperglycemia occurred in 9% of patients, including Grade 3 or 4 in 3.2% of patients. Median time to onset of hyperglycemia was 4.8 months (1 day to 2.9 years), and 0.8% of patients temporarily discontinued LORBRENA for hyperglycemia. Assess fasting serum glucose prior to initiating LORBRENA and monitor periodically thereafter. Withhold and resume at reduced dose or permanently discontinue based on severity.

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LORBRENA® Indication and Important Safety Information (continued)

Embryo-fetal Toxicity: LORBRENA can cause fetal harm. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use an effective non-hormonal method of contraception, since LORBRENA can render hormonal contraceptives ineffective, during treatment with LORBRENA and for at least 6 months after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with LORBRENA and for 3 months after the final dose.

Adverse Reactions: In the pooled safety population of 476 patients who received 100 mg LORBRENA once daily, the most frequent (≥ 20%) adverse reactions were edema (56%), peripheral neuropathy (44%), weight gain (31%), cognitive effects (28%), fatigue (27%), dyspnea (27%), arthralgia (24%), diarrhea (23%), mood effects (21%), and cough (21%). The most frequent (≥ 20%) Grade 3-4 laboratory abnormalities in patients receiving LORBRENA were hypercholesterolemia (21%) and hypertriglyceridemia (21%).

In previously untreated patients, serious adverse reactions occurred in 34% of the 149 patients treated with LORBRENA; the most frequently reported serious adverse reactions were pneumonia (4.7%), dyspnea (2.7%), respiratory failure (2.7%), cognitive effects (2.0%), and pyrexia (2.0%). Fatal adverse reactions occurred in 3.4% of patients and included pneumonia (0.7%), respiratory failure (0.7%), cardiac failure acute (0.7%), pulmonary embolism (0.7%), and sudden death (0.7%). In the Phase 1/2 study, serious adverse reactions occurred in 32% of the 295 patients; the most frequently reported serious adverse reactions were pneumonia (3.4%), dyspnea (2.7%), pyrexia (2%), mental status changes (1.4%), and respiratory failure (1.4%). Fatal adverse reactions occurred in 2.7% of patients and included pneumonia (0.7%), myocardial infarction (0.7%), acute pulmonary edema (0.3%), embolism (0.3%), peripheral artery occlusion (0.3%), and respiratory distress (0.3%).

Drug Interactions: LORBRENA is contraindicated in patients taking strong CYP3A inducers. Avoid concomitant use with moderate CYP3A inducers, strong CYP3A inhibitors, and fluconazole. If concomitant use of moderate CYP3A inducers cannot be avoided, increase the LORBRENA dose as recommended. If concomitant use with a strong CYP3A inhibitor or fluconazole cannot be avoided, reduce the LORBRENA dose as recommended. Avoid concomitant use of LORBRENA with CYP3A substrates and P-gp substrates, which may reduce the efficacy of these substrates.

Lactation: Because of the potential for serious adverse reactions in breastfed infants, instruct women not to breastfeed during treatment with LORBRENA and for 7 days after the final dose.

Hepatic Impairment: No dose adjustment is recommended for patients with mild hepatic impairment. The recommended dose of LORBRENA has not been established for patients with moderate or severe hepatic impairment.

Renal Impairment: Reduce the dose of LORBRENA for patients with severe renal impairment. No dose adjustment is recommended for patients with mild or moderate renal impairment.