Lorbrena® (lorlatinib)
(Oral)

Document Number: IC-0410

Last Review Date: 05/01/2020
Date of Origin: 12/04/2018
Dates Reviewed: 12/2018, 05/2019, 05/2020

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Lorbrena 25 mg tablets: 3 tablets per day
- Lorbrena 100 mg tablets: 1 tablet per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- 100 mg daily

III. Initial Approval Criteria[1,2]

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**

Universal Criteria

- Therapy will not be used in combination with strong CYP3A inducers (e.g., apalutamide, carbamazepine, rifampin, etc.); **AND**
- Baseline electrocardiogram (ECG) has been obtained prior to initiating therapy and will be monitored periodically while on therapy; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, nivolumab, atezolizumab, durvalumab, etc.) unless otherwise specified; **AND**

Non-Small Cell Lung Cancer (NSCLC) † Φ

- Used as a single agent; **AND**
- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
    - Patient's disease is anaplastic lymphoma kinase (ALK)-positive as detected by FDA-approved or CLIA-compliant test § and has progressed on at least one of the following:

- Crizotinib and at least one other prior ALK-inhibitor (i.e., alectinib, brigatinib, or ceritinib); **OR**
- Alectinib or ceritinib as the first ALK-inhibitor therapy with or without prior chemotherapy; **OR**
- First-line therapy with an ALK-inhibitor (i.e., alectinib, brigatinib, ceritinib, or crizotinib) and subsequent therapy with continuation of the same ALK-inhibitor for asymptomatic disease or for symptomatic disease with isolated lesions ‡; **OR**
- First-line therapy with alectinib, brigatinib, or ceritinib for patients with multiple lesions ‡; **OR**

o Patient's disease is ROS1 rearrangement-positive as detected by FDA-approved or CLIA-compliant test §; **AND**

- Disease has progressed on crizotinib, entrectinib, or ceritinib as first line therapy ‡

§*If confirmed using an FDA approved assay - http://www.fda.gov/companiondiagnostics*

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Φ Orphan Drug

IV. Renewal Criteria[1]

Authorizations can be renewed based on the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: hepatotoxicity, CNS effects (i.e., seizures, hallucinations, mood and cognitive function changes), AV-block, hyperlipidemia, interstitial lung disease (ILD)/pneumonitis, etc.

V. Dosage/Administration

Indication	Dose
NSCLC	100 mg orally once daily until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code:

- J8999 – Prescription drug, oral, chemotherapeutic. Not Otherwise Specified
- C9399 – Unclassified drugs or biologicals

NDC:

- Lorbrena 25 mg tablet: 00069-0227-xx
- Lorbrena 100 mg tablet: 00069-0231-xx

VII. References

1. Lorbrena [package insert]. New York, NY: Pfizer, November 2018. Accessed March 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for lorlatinib. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2020.
3. Shaw AT, Kim DW, Mehra R, et al. Ceritinib in ALK-rearranged non-small-cell lung cancer. N Engl J Med. 2014 Mar 27;370(13):1189-97. doi: 10.1056/NEJMoa1311107.
4. Solomon BJ, Besse B, Bauer TM, et al. Lorlatinib in patients with ALK-positive non-small-cell lung cancer: results from a global phase 2 study. Lancet Oncol. 2018 Dec;19(12):1654-1667. doi: 10.1016/S1470-2045(18)30649-1.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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
C34.80	Malignant neoplasm of overlapping sites of unspecified 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
Z85.118	Personal history of other malignant neoplasm of bronchus and lung

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Article (LCAs) may exist and

compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC