

Lenvima™ (lenvatinib) (Oral)

Document Number: IC-0232

Last Review Date: 01/07/2019

Date of Origin: 03/31/2015

Dates Reviewed: 03/2015, 01/2016 05/2016, 01/2017, 01/2018, 09/2018, 01/2019

I. Length of Authorization

Coverage is provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

LENVIMA capsules are supplied in cartons of 6 cards. Each card is a 5-day blister card as follows:	
Strength	Quantity Limit
24 mg (ten 10 mg capsules and five 4 mg capsules per card)	1 carton every 30 days
20 mg (ten 10 mg capsules per card)	1 carton every 30 days
18 mg (five 10 mg capsules and ten 4 mg capsules per card)	1 carton every 30 days
14 mg (five 10 mg capsules and five 4 mg capsules per card)	1 carton every 30 days
12 mg (fifteen 4 mg capsules per card)	1 carton every 30 days
10 mg (five 10 mg capsules per card)	1 carton every 30 days
8 mg (ten 4 mg capsules per card)	1 carton every 30 days
4 mg (five 4 mg capsules per card)	1 carton every 30 days

B. Max Units (per dose and over time) [Medical Benefit]:

- N/A

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient age 18 years or older; **AND**

Thyroid Carcinoma (Follicular/Hürthle Cell/Papillary) †

- Patient's cancer is locally recurrent or unresectable, persistent or metastatic; **AND**
- Patient's cancer is progressive and/or symptomatic; **AND**
- Patient has failed prior treatment with radioactive iodine; **AND**
- Not in combination with other chemotherapy

Thyroid Carcinoma (Medullary) ‡

- Patient's has recurrent, persistent or distant metastatic disease that is progressive or symptomatic; **AND**
 - Patient has failed prior treatment with vandetanib or cabozantinib; **OR**
 - Clinical trials or other systemic therapies with vandetanib or cabozantinib is not available and/or appropriate for the patient

Renal Cell Cancer (RCC) †

- Must be used in combination with everolimus; **AND**
- Patient must have advanced, relapsed or unresectable metastatic disease; **AND**
 - Used as subsequent therapy; **OR**
 - Patient has predominantly non-clear cell histology

Hepatocellular Carcinoma (HCC) †

- Used as a single agent therapy; **AND**
- Patient has Child-Pugh Class A disease (i.e., excludes Child-Pugh Class B or C disease); **AND**
 - Patient has unresectable disease **AND** used as first-line therapy or is not a transplant candidate; **OR**
 - Patient is not a candidate for surgery or has local disease; **OR**
 - Patient has metastatic disease or has an extensive liver tumor burden

† FDA-labeled indication(s), ‡ Compendia recommended indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Tumor response with 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: life-threatening hypertension, severe cardiac dysfunction, hepatotoxicity, nephrotic syndrome, renal failure/impairment, gastrointestinal perforation/fistula formation, severe/recurrent diarrhea, severe QT prolongation (grade 3 or 4), Reversible Posterior Leukoencephalopathy Syndrome (RPLS), arterial thromboembolic events and severe hemorrhage, severe hypocalcemia, impaired wound healing.

V. Dosage/Administration

Indication	Dose
Thyroid Carcinoma	24 mg (two 10 mg capsules and one 4 mg capsule) orally once daily until disease progression or unacceptable toxicity

RCC	18 mg (one 10 mg capsule and two 4 mg capsules) orally once daily (in combination with everolimus 5 mg orally once daily) until disease progression or unacceptable toxicity
HCC	Recommended dose is based on actual body weight taken orally, once daily until disease progression or unacceptable toxicity: <ul style="list-style-type: none"> • 12 mg for patients greater than or equal to 60 kg or • 8 mg for patients less than 60 kg.

VI. Billing Code/Availability Information

Jcode:

- J8999 – Prescription drug, oral, chemotherapeutic, nos
- C9399 – Unclassified drugs or biologicals. (*Hospital Outpatient Use ONLY*)

NDC:

LENVIMA capsules are supplied in cartons of 6 cards. Each card is a 5-day blister card as follows:	
NDC	Strength
62856-724-xx	24 mg (ten 10 mg capsules and five 4 mg capsules per card)
62856-720-xx	20 mg (ten 10 mg capsules per card)
62856-718-xx	18 mg (five 10 mg capsules and ten 4 mg capsules per card)
62856-714-xx	14 mg (five 10 mg capsules and five 4 mg capsules per card)
62856-712-xx	12 mg (fifteen 4 mg capsules per card)
62856-710-xx	10 mg (five 10 mg capsules per card)
62856-708-xx	8 mg (ten 4 mg capsules per card)
62856-704-xx	4 mg (five 4 mg capsules per card)

VII. References

1. Lenvima [package insert]. Eisai, Woodcliff Lake, NJ; August 2018. Accessed December 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for lenvatinib. National Comprehensive Cancer Network, 2018. 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 December 2018.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Thyroid Carcinoma. Version 2.2018. National Comprehensive Cancer Network, 2018. 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 December 2018.

Appendix 1 – Covered Diagnosis Codes

ICD-10	Description
C22.0	Liver cell carcinoma
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C73	Malignant neoplasm of thyroid gland
Z85.528	Personal history of other malignant neoplasm of kidney

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) and Local Coverage Determinations (LCDs) 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): 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 (WPS)
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 (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
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