UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Lenvima

Program	Prior Authorization
Medication	Lenvima™ (lenvatinib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	6/2015
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

1. Background:

Lenvima (lenvatinib) is a kinase inhibitor indicated for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer, for the treatment of patients with renal cell cancer in combination with Afinitor (everolimus), for patients with advanced disease following one prior anti-angiogenic therapy, for the first-line treatment of patients with unresectable hepatocellular carcinoma, and in combination with pembrolizumab, for the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation.[1]

In addition, the National Cancer Comprehensive Network (NCCN) also recommends Lenvima for the treatment of medullary thyroid carcinoma in patients who have experienced disease progression while on Caprelsa (vandetanib) or Cometriq (cabozantinib), as a systemic therapy for recurrent adenoid cystic carcinoma, anaplastic thyroid carcinoma, and for the treatment of metatstatic hepatocellular carcinoma.[2]

2. Coverage Criteria:

A. <u>Thyroid Cancer</u>

1. **<u>Initial Authorization</u>**

   a. **Lenvima** will be approved based on **<u>one</u>** of the following criteria:

      (1) **<u>All</u>** of the following

         (a) Diagnosis of **<u>one</u>** of the following:

i. Follicular carcinoma
ii. Hürthle cell carcinoma
iii. Papillary carcinoma

-AND-

(b) **One** of the following:

i. Unresectable or locally recurrent disease
ii. Metastatic disease
iii. Persistent locoregional disease

-AND-

(c) **One** of the following:

i. Patient has symptomatic disease
ii. Patient has progressive disease

-AND-

(d) One of the following:

i. Disease is refractory to radioactive iodine
ii. Distant metastatic disease not amenable to radioactive iodine treatment

-OR-

(2) **All** of the following:

(a) Diagnosis of medullary thyroid carcinoma

-AND-

(b) **One** of the following:

i. Disease is progressive
ii. Disease is symptomatic with distant metastases

-AND-

(c) History of failure, contraindication, or intolerance to **one** of the following:

i. Caprelsa (vandetanib)
ii. Cometriq (cabozantinib)

-OR-

(3) **Both** of the following:

(a) Diagnosis of anaplastic thyroid carcinoma

-AND-

(b) Disease is metastatic

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Lenvima** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Lenvima therapy

Authorization will be issued for 12 months.

B. Renal Cell Cancer

1. **Initial Authorization**

a. **Lenvima** will be approved based on **all** of the following criteria:

(1) Diagnosis of advanced renal cell cancer

-AND-

(2) History of failure, contraindication, or intolerance to prior anti-angiogenic therapy [e.g., Avastin (bevacizumab), Votrient (pazopanib), Sutent (sunitinib), Nexavar (sorafenib)]

-AND-

(3) Used in combination with Afinitor (everolimus)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Lenvima** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Lenvima therapy

AND-

(2) Used in combination with Afinitor (everolimus)

Authorization will be issued for 12 months.

C. Hepatocellular Carcinoma

1. Initial Authorization

a. **Lenvima** will be approved based on **both** of the following criteria:

(1) Diagnosis of hepatocellular carcinoma

-AND-

(2) Disease is **one** of the following:

(a) Unresectable
(b) Metastatic

Authorization will be issued for 12 months.

2. Reauthorization

a. **Lenvima** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Lenvima therapy

Authorization will be issued for 12 months.

D. Endometrial Carcinoma

1. **Initial Authorization**

a. **Lenvima** will be approved based on **both** of the following criteria:

(1) Diagnosis of endometrial carcinoma

-AND-

(2) Used in combination with Keytruda (pembrolizumab)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Lenvima** will be approved based on **both** of the following criteria:

(1) Patient does not show evidence of progressive disease while on Lenvima therapy

-AND-

(2) Used in combination with Keytruda (pembrolizumab)

Authorization will be issued for 12 months.

E. Adenoid Cystic Carcinoma

1. **Initial Authorization**

a. **Lenvima** will be approved based on the following criteria:

(1) Diagnosis of recurrent adenoid cystic carcinoma

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Lenvima** will be approved based on the following criteria:

(1) Patient does not show evidence of progressive disease while on Lenvima therapy

Authorization will be issued for 12 months.

F. NCCN Recommended Regimens

1. **Initial Authorization**

   a. **Lenvima** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

   Authorization will be issued for 12 months.

2. **Reauthorization**

   a. **Lenvima** will be approved based on the following criterion:

      (1) Documentation of positive clinical response to Lenvima therapy

   Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Lenvima [package insert]. Woodcliff Lake, NJ: Eisai Inc.; September 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed October 5, 2020.

Program	Prior Authorization -Lenvima (lenvatinib)
Change Control	
Date	Change
6/2015	New program.
4/2016	Updated clinical criteria to align with Employer and Individual and updated policy template.
7/2016	Added coverage criteria for advanced renal cell cancer. Updated references.
7/2017	Updated background and criteria to include NCCN recommended off label utilization for medullary thyroid carcinoma in patients

	with after Caprelsa or Cometriq. Updated formatting of criteria for differentiated thyroid cancer to align with NCCN guidelines. Updated references.
7/2018	Added NCCN recommended regimen criteria. Updated references.
11/2018	Updated background and criteria to include new indication for unresectable hepatocellular carcinoma. Updated references.
11/2019	Annual review. Updated background and criteria to include new indication in combination with pembrolizumab for endometrial carcinoma. Updated references.
11/2020	Annual review. Updated background and criteria to include NCCN recommended use for recurrent adenoid cystic carcinoma and anaplastic thyroid carcinoma. Added concurrent use with everolimus to the reauthorization criteria for renal cell cancer. Updated references. Added Additional Clinical Rules section.