UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Lenvima

Program	Prior Authorization
Medication	Lenvima™ (lenvatinib)
Issue Date	6/2015
Pharmacy and Therapeutics Approval Date	7/2017
Effective Date	9/2017

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. Lenvima is also indicated 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. [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).[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) **All of the following**

(a) Diagnosis of **<u>one</u>** of the following:
- i. Follicular carcinoma
- ii. Hürthle cell carcinoma
- iii. Papillary carcinoma

-AND-

(b) **<u>One</u>** 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) Disease is refractory to radioactive iodine

-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)

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

Authorization will be issued for 12 months.

3. References:

1. Lenvima [package insert]. Woodcliff Lake, NJ: Eisai Inc.; February 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed, June 6, 2017.

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.