UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1157-13
Program	Prior Authorization/Notification
Medication	Lenvima® (lenvatinib)
P&T Approval Date	4/2015, 4/2016, 7/2016, 7/2017, 7/2018, 11/2018, 11/2019, 11/2020, 11/2021, 2/2022, 2/2023, 2/2024, 2/2025
Effective Date	5/1/2025

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, in combination with Afinitor (everolimus), for the treatment of patients with advanced renal cell carcinoma (RCC) following one prior anti-angiogenic therapy, in combination with Keytruda (pembrolizumab), for the first-line treatment of patients with advanced RCC, 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 (pMMR), who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.

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, and for the treatment of metastatic hepatocellular carcinoma, thymic carcinoma, and cutaneous melanoma.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. Patients less than 19 years of age

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

   a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. Thyroid Cancer

1. **Initial Authorization**

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

      (1) Diagnosis of differentiated thyroid cancer (DTC)

-AND-

      (2) Disease is locally recurrent, metastatic, progressive, or symptomatic

-AND-

      (3) Disease is radioactive iodine-refractory or ineligible

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.

C. Renal Cell Cancer

1. **Initial Authorization**

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

      (1) Diagnosis of advanced renal cell carcinoma

-AND-

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

(a) Both of the following:

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

-AND-

ii. Used in combination with Afinitor (everolimus)

-OR-

(b) Used in combination with Keytruda (pembrolizumab)

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) or Keytruda (pembrolizumab)

Authorization will be issued for 12 months.

D. Hepatocellular Cancer

1. **Initial Authorization**

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

(1) Diagnosis of hepatocellular carcinoma

-AND-

(2) Disease is unresectable or 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.

E. Endometrial Carcinoma

1. **Initial Authorization**

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

      (1) Diagnosis of endometrial carcinoma

   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.

F. 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.

G. Thymic Carcinoma

1. **Initial Authorization**

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

      (1) Diagnosis of thymic carcinoma

-AND-

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

i. Used as a single agent for those who cannot tolerate first-line combination regimens
ii. Used as a second line therapy in unresectable locally advanced disease, solitary metastasis or ipsilateral pleural metastasis, or extrathoracic metastatic disease

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.

H. Cutaneous Melanoma

1. **Initial Authorization**

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

(1) Diagnosis of cutaneous melanoma

-AND-

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

i. Disease is unresectable
ii. Disease is metastatic

-AND-

(3) 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.

I. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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.; November 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at NCCN Drugs and Biologics Compendium®. Accessed January 2, 2025.

Program	Prior Authorization/Notification – Lenvima (lenvatinib)
Change Control	
4/2015	New program.
4/2016	Annual review. Added persistent locoregional and unresectable recurrent disease to the thyroid cancer indication. Updated references.
7/2016	Added coverage criteria for advanced renal cell cancer. Updated references.
7/2017	Annual review. 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	Annual review with no change to coverage criteria. Updated references.
11/2018	Updated background and criteria to include new indication for unresectable hepatocellular carcinoma.
11/2019	Annual review. Updated background and criteria to include new indication in combination with pembrolizumab for endometrial carcinoma. Added general NCCN recommendations for use criteria. 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.
11/2021	Annual review. Updated background and criteria for new approval for use in combination with Keytruda (pembrolizumab), for treatment advanced RCC. Updated criteria per NCCN recommendations. Removed anaplastic thyroid carcinoma criteria as it is no longer recommended by NCCN. Updated references.
2/2022	Updated renal cell cancer reauthorization to include combination use of Afinitor (everolimus) or Keytruda (pembrolizumab).
2/2023	Annual review. Updated references, added state mandate footnote. Updated background and criteria to include NCCN recommended use for cutaneous melanoma.
2/2024	Annual review. Updated thyroid cancer criteria based on label and NCCN. Updated hepatobiliary and thymic cancer based on NCCN recommendations. Updated references.
2/2025	Annual review. Removed criteria for biliary cancer as it is no longer recommended by NCCN. Removed combination use with Keytruda for endometrial cancer per NCCN. Updated background and references.