Lenvima (lenvatinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Lenvima (lenvatinib) 4mg daily dose pack	1 pack per 30 days (30 capsules)
Lenvima (lenvatinib) 8mg daily dose pack	1 pack per 30 days (60 capsules)
Lenvima (lenvatinib) 10mg daily dose pack	1 pack per 30 days (30 capsules)
Lenvima (lenvatinib) 12mg daily dose pack	1 pack per 30 days (90 capsules)
Lenvima (lenvatinib) 14mg daily dose pack	1 pack per 30 days (60 capsules)
Lenvima (lenvatinib) 18mg daily dose pack	1 pack per 30 days (90 capsules)
Lenvima (lenvatinib) 20mg daily dose pack	1 pack per 30 days (60 capsules)
Lenvima (lenvatinib) 24mg daily dose pack	1 pack per 30 days (90 capsules)

APPROVAL CRITERIA

Requests for Lenvima (lenvatinib) may be approved if the following criteria are met:

I. Individual has a diagnosis of locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (DTC);

OR

II. Individual has a diagnosis of papillary or follicular thyroid carcinomas (NCCN 2A); **AND**

III. Individual has progressive and/or symptomatic disease that is iodine-refractory (NCCN 2A);

OR

IV. Individual has a diagnosis of oncocytic thyroid carcinoma (NCCN 2A); **AND**

V. Individual has progressive and/or symptomatic disease (NCCN 2A);

OR

VI. Individual has a diagnosis of medullary thyroid carcinomas in treatment of progressive disease or symptomatic distant metastases if clinical trials or systemic therapy options are not available or appropriate, OR if there is progression on systemic therapy options (NCCN 2A);

OR

VII. Individual has a diagnosis of metastatic anaplastic thyroid carcinoma (ATC); **AND**

VIII. Individual is using in combination with pembrolizumab;

OR

IX. Individual has a diagnosis of thymic carcinoma (NCCN 2A); **AND**
X. Individual is using Lenvima (lenvatinib) as a single agent; **AND**
XI. Lenvima (lenvatinib) is being used for one of the following:
    A. Postoperative or preoperative treatment for resectable disease in individuals who cannot tolerate alternative first-line regimens; **OR**
    B. As first-line therapy for individuals who cannot tolerate alternative first-line regimens; **OR**
    C. As subsequent therapy for unresectable, locally advanced, or metastatic disease;

OR

XII. Individual has a diagnosis of advanced, relapsed, or stage IV renal cell carcinoma (RCC) (Label, NCCN 2A); **AND**
XIII. Individual is using in combination with everolimus;

OR

XIV. Individual has a diagnosis of advanced renal cell carcinoma (RCC) (Label, NCCN 1); **AND**
XV. Individual is using in combination with pembrolizumab;

OR

XVI. Individual has a diagnosis of unresectable, advanced, or metastatic hepatocellular carcinoma (HCC) (Label, NCCN 1); **AND**
XVII. Individual is using Lenvima (lenvatinib) as a single agent;

OR

XVIII. Individual has a diagnosis of advanced or metastatic, or recurrent endometrial carcinoma (Label, NCCN 1); **AND**
XIX. Individual is using in combination with pembrolizumab; **AND**
XX. Disease is mismatch repair proficient (pMMR) (Label, NCCN 1) or not microsatellite instability-high (MSI-H) (Label); **AND**
XXI. Individual has confirmed disease progression after one or more prior lines of systemic therapy; **OR**
XXII. Individual has recurrent disease after prior platinum-based therapy in any setting, including neoadjuvant and adjuvant therapy;

OR

XXIII. Individual has a diagnosis of recurrent endometrial carcinoma (NCCN 2A); **AND**
XXIV. Individual is using Lenvima (lenvatinib) as a single agent; **AND**
XXV. Individual is using as second-line or subsequent therapy for recurrent or metastatic disease;

OR

XXVI. Individual has a diagnosis of cutaneous Melanoma (NCCN 2A); **AND**
XXVII. Individual is using in combination with pembrolizumab; **AND**
XXVIII. Individual has metastatic or unresectable disease that has progressed following

treatment with anti-PD-1/PD-L1-based therapy, including after anti-PD-1/PD-L1-based therapy that was used in combination with an anti-CTLA-4 for ≥2 doses.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 16, 2025.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
4. Sato J, Satouchi M, Itoh S, et al. Lanvatinib in patients with advanced or metastatic thymic carcinoma (REMORA): a multicentre, phase 2 trial. Lancet Oncol 2020; 21: 843-50.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 16, 2025.
    a. Thymomas and Thymic Carcinomas. V2.2025. Revised May 19, 2025.
    b. Melanoma: Cutaneous. V2.2025. Revised January 28, 2025.
    c. Thyroid Carcinoma V1.2025. Revised March 27, 2025.
    d. Kidney Cancer. V3.2025. Revised January 9, 2025.
    e. Hepatobiliary Cancers V1.2025. Revised March 20, 2025.
    f. Uterine Neoplasms. V3.2025. Revised March 7, 2025.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.