Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

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, follicular, or Hürthle cell thyroid carcinomas (NCCN 2A); **AND**

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

IV. Clinical trials or other systemic therapies are not available or appropriate (NCCN 2A);

OR

V. Medullary thyroid carcinomas in treatment of progressive disease or symptomatic distant metastases if clinical trials, cabozantinib, or vandetanib are not available or appropriate, OR if there is progression on vandetanib or cabozantinib (NCCN 2A);

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

OR

VI. Anaplastic thyroid carcinoma in those who are not responding to or cannot tolerate other available therapies (NCCN 2A);

OR

VII. Individual has a diagnosis of renal cell carcinoma; **AND**
VIII. Individual is using in combination with everolimus; **AND**
IX. Individual has received prior anti-angiogenic therapy, including but not limited to bevacizumab with interferon alfa; Sutent (sunitinib); or Votrient (pazopanib);

OR

X. Individual has a diagnosis of unresectable or advanced hepatocellular carcinoma (HCC);

OR

XI. Individual has a diagnosis of advanced or metastatic endometrial carcinoma; **AND**
XII. Individual is using in combination with pembrolizumab; **AND**
XIII. Disease is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); **AND**
XIV. Individual has confirmed disease progression after one or more prior lines of systemic therapy; **AND**
XV. Individual is not a candidate for curative surgery or radiation.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 19, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on July 19, 2019.
    a. Thyroid Carcinoma. V1.2019. Revised March 28, 2019.
    b. Kidney Cancer. V1.2020. Revised June 7, 2019.
    c. Hepatobiliary Cancers V2.2019. Revised March 6, 2019.