Evolent Clinical Guideline 3195 for Lenvima™ (lenvatinib)

Guideline Number:	Applicable Codes	
Evolent_CG_3195		
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Original Date:	**Last Revised Date:**	**Implementation Date:**
March 2016	October 2025	October 2025

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STATEMENT

Purpose

To define and describe the accepted indications for Lenvima (lenvatinib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Endometrial Cancer

- Lenvima (lenvatinib) may be used in combination with Keytruda (pembrolizumab) as subsequent line therapy, in members with MSI-stable/MMR-proficient (not MSI-High/deficient MMR) metastatic endometrial cancer who have experienced disease progression on one line of chemotherapy.

Hepatocellular Carcinoma (HCC)

- Lenvima (lenvatinib) will be used as monotherapy for members with unresectable or metastatic hepatocellular cancer AND
- The member has Child-Pugh Class score A (on initial request only).

CHILD-PUGH SCORE

Chemical and Biochemical Parameters	Scores (Points) for Increasing Abnormality		
	1	2	3
Encephalopathy (grade)[1]	None	1–2	3–4
Ascites	Absent	Slight	Moderate
Albumin (g/dL)	>3.5	2.8–3.5	<2.8
Prothrombin time[2] Seconds over control INR	 <4 <1.7	 4–6 1.7–2.3	 >6 >2.3
Bilirubin (mg/dL) • For primary biliary cirrhosis	<2 <4	2–3 4–10	>3 >10

Class A = 5–6 points; Class B = 7–9 points; Class C = 10–15 points.

Renal Cell Carcinoma (RCC)

- The member has advanced or metastatic RCC and Lenvima (lenvatinib) may be used in combination with Keytruda (pembrolizumab) as first line therapy OR
- Lenvima (lenvatinib) may be used in advanced/metastatic renal cell carcinoma, as a single agent as subsequent therapy in members who have experienced disease progression on prior therapy with an anti-angiogenesis agent (an oral TKI and/or bevacizumab) AND an immune checkpoint inhibitor.

Thyroid Cancer

- Lenvima (lenvatinib) will be used as monotherapy in members with locally recurrent or metastatic differentiated thyroid cancer (subtypes include papillary carcinoma, follicular carcinoma or Hürthle cell carcinoma) AND the disease is refractory to radioactive Iodine.

CONTRAINDICATIONS/WARNINGS

- None

EXCLUSION CRITERIA

- Disease progression while taking Lenvima (lenvatinib) or on a prior lenvatinib containing regimen.
- The maximum dose should not exceed 24 mg/day for thyroid cancer, 20 mg/day for renal cell cancer, 12 mg/day for hepatocellular cancer, and 20 mg/day for endometrial cancer.
- Treatment exceeds the maximum monthly limit of 60 (10 mg) or 90 (4 mg) capsules.
- Investigational use of Lenvima (lenvatinib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

- Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
- Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
- Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
- Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
- That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
- That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
- That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

CODING AND STANDARDS

Codes

- J8999 - lenvatinib

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
October 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1283 Lenvima (lenvatinib) • Updated exclusion criteria • Updated references
October 2024	• Updated NCH verbiage to Evolent

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

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