Drug Policy:

Lenvima™ (lenvatinib)

POLICY NUMBER UM ONC_1283	SUBJECT Lenvima™ (lenvatinib)		DEPT/PROGRAM UM Dept	PAGE 1 of 4
DATES COMMITTEE REVIEWED 03/23/16, 05/20/16, 06/29/17, 07/26/17, 07/06/18, 06/12/19, 12/11/19, 04/08/20, 03/10/21, 11/15/21, 03/09/22	APPROVAL DATE March 9, 2022	EFFECTIVE DATE March 25, 2022	COMMITTEE APPROVAL DATES 03/23/16, 05/20/16, 06/29/17, 07/26/17, 07/06/18, 06/12/19, 12/11/19, 04/08/20, 03/10/21, 11/15/21, 03/09/22	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1	NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. 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.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR
2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR

3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When applicable, generic alternatives are preferred over brand-name drugs.

B. Thyroid Cancer

1. 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 OR
2. The member has anaplastic thyroid carcinoma and Lenvatinib is being used as monotherapy as first or subsequent line therapy.

C. Renal Cell Carcinoma (RCC)

1. Lenvima (lenvatinib) may be used in metastatic renal cell carcinoma as a single agent OR with Afinitor (everolimus) 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
2. NOTE: Keytruda (pembrolizumab) + Lenvima (lenvatinib) is a Non-Preferred regimen per NCH Policy for any line of therapy for metastatic renal cell carcinoma. This position is based on the lack of Level 1 evidence (randomized trials and or meta-analyses) showing superior outcomes with the above regimen compared to the regimens recommended per NCH Policy and NCH Pathway.

D. Hepatocellular Carcinoma (HCC)

1. Lenvima (lenvatinib) will be used as monotherapy for members with unresectable or metastatic hepatocellular cancer.

E. Endometrial Cancer

1. Lenvima (lenvatinib) is being used in combination with Keytruda (pembrolizumab) as subsequent line therapy after disease progression on prior chemotherapy, if not a candidate for curative surgery or radiotherapy, in members with recurrent/metastatic endometrial cancer whose tumors are MSI-Stable.

III. EXCLUSION CRITERIA

A. Disease progression while taking Lenvima (lenvatinib) or on a prior lenvatinib containing regimen.

B. The max 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.

C. Treatment exceeds the maximum monthly limit of 60 (10 mg) or 30 (4 mg).

D. 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:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.

2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, in light of 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).
5. 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.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. 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.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

C. None

VII. REFERENCES

D. Makker V, et al. Lenvatinib Plus Pembrolizumab in Patients With Advanced Endometrial Cancer. J Clin Oncol. 2020;38(26):2981.

E. Kudo M, et al. Lenvatinib versus sorafenib in first-line treatment of patients with unresectable hepatocellular carcinoma: a randomised phase 3 non-inferiority trial. Lancet 2018; 391:1163.

F. Motzer RJ, et al. Lenvatinib, everolimus, and the combination in patients with metastatic renal cell carcinoma: a randomised, phase 2, open-label, multicentre trial. Lancet Oncol 2015; 16:1473.

G. Lenvima prescribing information. Eisai Inc. Woodcliff Lake, NJ 2021.

H. Clinical Pharmacology Elsevier Gold Standard 2022.

I. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2022.

J. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2022.

K. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2022.

L. Lexicomp Online®, Pediatric & Neonatal Lexi-Drugs® , Hudson, Ohio: Lexi-Comp, Inc. 2022.

M. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

N. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.