New Century Health

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, 05/11/22, 07/13/22, 09/20/22, 07/12/23, 10/11/23	APPROVAL DATE October 11, 2023	EFFECTIVE DATE October 27, 2023	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, 05/11/22, 07/13/22, 09/20/22, 07/12/23, 10/11/23	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
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. Continuation requests for a not-approvable medication shall be exempt from this NCH policy provided:

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

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.

C. Renal Cell Carcinoma (RCC)

1. The member has advanced or metastatic RCC and Lenvima (lenvatinib) may be used in combination with Keytruda (pembrolizumab) as first line therapy OR
2. 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.

D. Hepatocellular Carcinoma (HCC)

1. Lenvima (lenvatinib) will be used as monotherapy for members with unresectable or metastatic hepatocellular cancer AND
2. 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.

E. Endometrial Cancer

1. 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.

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 90 (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 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.
4. 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).
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

A. None

VII. REFERENCES

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G. Clinical Pharmacology Elsevier Gold Standard 2023.

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I. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.

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K. Lexicomp Online®, Pediatric & Neonatal Lexi-Drugs® , Hudson, Ohio: Lexi-Comp, Inc. 2023.

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

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