POLICY NUMBER UM ONC_1283	SUBJECT Lenvima™ (lenvatinib)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
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	APPROVAL DATE April 8, 2020	EFFECTIVE DATE April 24, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 03/23/16, 05/20/16, 06/29/17, 07/26/17, 07/06/18, 06/12/19, 12/11/19, 04/08/20	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		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 All	

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

1. **PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:**
    a. 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**
    b. 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**
    c. 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: Error! Hyperlink reference not valid. **AND**
    d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
    e. When available, generic alternatives are preferred over brand-name drugs.
2. **Thyroid Cancer**
    a. The member has locally recurrent or metastatic differentiated thyroid cancer (subtypes include papillary carcinoma, follicular carcinoma or Hürthle cell carcinoma) **AND** the disease is refractory to radiactive Iodine **OR**
    b. The member has anaplastic thyroid carcinoma and Lenvatinib is being used as first or subsequent line therapy.
3. **Renal Cell Carcinoma (RCC)**

a. **NOTE: The preferred tyrosine kinase inhibitor, per NCH Policies & NCH Pathway, for first line metastatic RCC is:**

i. **Pazopanib for good risk disease**

ii. **Cabozantinib for intermediate or poor risk disease**.

b. Lenvatinib may be used in metastatic renal cell carcinoma as a single agent for any line of therapy for non-clear cell carcinoma **OR** with everolimus as subsequent therapy for clear cell carcinoma.

4. **Hepatocellular Carcinoma (HCC)**

a. **NOTE: The preferred agent, per NCH Policies & NCH Pathway, for first line therapy of unresectable or metastatic HCC is LENVATINIB.**

b. The member has unresectable or metastatic hepatocellular cancer **AND**

c. Lenvima (lenvatinib) is being used as a single agent for members with Child-Pugh Class A only.

5. **Endometrial Cancer**

a. The member has advanced, or recurrent microsatellite stable endometrial cancer **AND**

b. Lenvima (lenvatinib) is being used in combination with pembrolizumab as subsequent line therapy after disease progression on prior chemotherapy, in members whose tumors are MSI-Stable (for members with tumors that are MSI-High.

III. EXCLUSION CRITERIA

1. Disease progression while taking Lenvima (lenvatinib).
2. Prior therapy of lenvatinib or (mTOR) inhibitor.
3. Member with grade 3 or 4 renal failure/impairment or hepatotoxicity.
4. The max dose should not exceed 24 mg/day for thyroid cancer, 18 mg/day for renal cell cancer, 12 mg/day for hepatocellular cancer, and 20 mg/day for endometrial cancer.
5. Treatment exceeds the maximum monthly limit of 90 (24 mg per day carton); 60 (20 mg per day carton); 90 (18 mg per day carton); 60 (14 mg per day carton); 30 (10 mg per day carton); 60 (8 mg per day carton), 30 (4 mg per day carton).
6. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

1. Review – UM Department
2. Final Approval – UM Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Lenvima prescribing information. Eisai Inc. Woodcliff Lake, NJ. 2020.

2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.
6. Lexicomp Online®, Pediatric & Neonatal Lexi-Drugs® , Hudson, Ohio: Lexi-Comp, Inc. 2020.