

SPECIALTY GUIDELINE MANAGEMENT

LENVIMA (lenvatinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication:

1. Lenvima is indicated for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (DTC).
2. Lenvima is indicated in combination with everolimus, for the treatment of patients with advanced renal cell carcinoma (RCC) following one prior anti-angiogenic therapy.
3. Lenvima is indicated for the first-line treatment of patients with unresectable hepatocellular carcinoma (HCC).

B. Compendial Uses:

Medullary thyroid carcinoma

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. **Thyroid carcinoma**

Authorization of 12 months may be granted for the treatment of medullary, follicular, Hurthle cell, or papillary thyroid carcinoma

B. **Renal Cell Carcinoma**

Authorization of 12 months may be granted for the treatment of relapsed or advanced renal cell carcinoma.

C. **Hepatocellular Carcinoma**

Authorization of 12 months may be granted for the treatment of unresectable hepatocellular carcinoma.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

IV. REFERENCES

1. Lenvima [package insert]. Woodcliff Lake, NJ: Eisai Inc.; August 2018.
2. The NCCN Drugs & Biologics Compendium™ © 2017 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed December 5, 2017.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™ Thyroid Carcinoma (Version 1.2016). <http://www.nccn.org>. Accessed December 5, 2017.

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1865-A

4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™ Kidney Cancer (Version 2.2018). <http://www.nccn.org>. Accessed December 5, 2017.