

## 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 Indications

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, follicular, Hurthle cell or papillary 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 2018 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed November 5, 2018.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology Thyroid Carcinoma (Version 1.2018). <http://www.nccn.org>. Accessed November 5, 2018.

Reference number
1865-A

4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology Kidney Cancer (Version 2.2019). <http://www.nccn.org>. Accessed November 5, 2018.