

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.
2. Lenvima is indicated in combination with everolimus, for patients with advanced renal cell carcinoma following one prior anti-angiogenic therapy

B. Compendial Uses:

1. Differentiated thyroid carcinoma subtypes: follicular, Hürthle cell, and papillary

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 differentiated thyroid carcinoma when BOTH of the following criteria are met:

- 1.1. Member has any of the following histologic subtypes: papillary, follicular, Hürthle cell
- 1.2. Member has iodine-refractory disease

B. **Renal Cell Carcinoma**

Authorization of 12 months may be granted when Lenvima is prescribed in combination with everolimus for the treatment of relapsed or advanced disease and EITHER of the following criteria is met:

1. For disease that is of non-clear histology, Lenvima will be used as first-line systemic therapy
2. For disease that is of predominantly clear cell histology, Lenvima will be used as subsequent therapy for disease that has progressed on prior anti-angiogenic therapy (e.g., bevacizumab, sunitinib, sorafenib).

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 2016.
2. The NCCN Drugs & Biologics Compendium™ © 2016 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed December 1, 2016.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™ Thyroid Carcinoma (Version 1.2016). <http://www.nccn.org>. Accessed December 1, 2016.