Reference number
1865-A

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).
4. Lenvima is indicated in combination with pembrolizumab, for the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.
5. Lenvima is indicated in combination with pembrolizumab for the first line treatment of patients with advanced renal cell carcinoma.

B. Compendial Uses

1. Medullary, follicular, Hurthle cell, or papillary thyroid carcinoma
2. HCC: inoperable by performance status or comorbidity, local disease, metastatic disease or extensive liver tumor burden
3. Relapsed RCC
4. Recurrent endometrial carcinoma
5. Thymic carcinoma

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review for endometrial carcinoma:
Documentation of laboratory report confirming MSI-H or mismatch repair deficient (dMMR) tumor status.

III. CRITERIA FOR INITIAL APPROVAL

A. Thyroid carcinoma

Authorization of 12 months may be granted for treatment of thyroid carcinoma when any of the following criteria are met:

1. Member has follicular, Hürthle cell, or papillary thyroid carcinoma not amenable to radioactive iodine therapy (RAI).

2. Member has medullary thyroid carcinoma and has progressed on vandetanib (Caprelsa) or cabozantinib (Cometriq) OR these therapies are inappropriate

B. Renal Cell Carcinoma

Authorization of 12 months may be granted for treatment of advanced, relapsed or stage IV renal cell carcinoma when used in any of the following settings.

1. Lenvima will be used in combination with everolimus (Afinitor) and either of the following is met:
   i. The disease histology is predominantly clear cell and the member has used prior therapy OR
   ii. The disease histology is non-clear cell
2. Lenvima will be used in combination with pembrolizumab (Keytruda).

C. Hepatocellular Carcinoma

Authorization of 12 months may be granted for treatment of hepatocellular carcinoma when any of the following criteria are met:

1. Member has unresectable disease or inoperable by performance status or comorbidity
2. Member has local disease
3. Member has metastatic disease or extensive liver tumor burden

D. Endometrial Carcinoma

Authorization of 12 months may be granted for treatment of endometrial carcinoma when used in combination with pembrolizumab for advanced, metastatic or recurrent endometrial carcinoma that is not MSI-H or dMMR when the member has disease progression following prior systemic therapy and is not a candidate for curative surgery or radiation.

E. Thymic Carcinoma

Authorization of 12 months may be granted for treatment of thymic carcinoma when used as a single agent.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Lenvima [package insert]. Woodcliff Lake, NJ: Eisai Inc.; August 2021.
2. The NCCN Drugs & Biologics Compendium 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed November 8, 2021.