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 pembrolizumab for the first line treatment of adult patients with advanced renal cell carcinoma.
3. Lenvima is indicated in combination with everolimus, for the treatment of adult patients with advanced renal cell carcinoma (RCC) following one prior anti-angiogenic therapy.
4. Lenvima is indicated for the first-line treatment of patients with unresectable hepatocellular carcinoma (HCC).
5. Lenvima is indicated in combination with pembrolizumab, for the treatment of patients with advanced endometrial carcinoma (EC) that is mismatch repair proficient (pMMR), as determined by an FDA-approved test, or not microsatellite instability-high (MSI-H), who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.

B. Compendial Uses
1. Medullary, follicular, oncocytic/Hurthle cell, or papillary thyroid carcinoma
2. HCC
3. Relapsed RCC
4. Recurrent endometrial carcinoma
5. Thymic carcinoma
6. Cutaneous melanoma

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: Documentation of laboratory report confirming mismatch repair (MMR) tumor status, where applicable.

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, oncocytic/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. The requested drug 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. The requested drug will be used in combination with pembrolizumab (Keytruda).

C. Hepatocellular Carcinoma

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

1. Member has unresectable disease and is not a transplant candidate
2. Member has local disease, inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease
3. Member has metastatic disease or extensive liver tumor burden

D. Endometrial Carcinoma

Authorization of 12 months may be granted for treatment of advanced, metastatic or recurrent endometrial carcinoma when used in combination with pembrolizumab (Keytruda) when either of the following are met:

1. The disease is mismatch repair proficient (pMMR)
2. The disease is mismatch repair deficient (dMMR) and has progressed following prior platinum-based chemotherapy

E. Thymic Carcinoma

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

F. Cutaneous Melanoma

Authorization of 12 months may be granted for treatment of metastatic or unresectable cutaneous melanoma that has progressed following treatment with an anti-PD-1/PD-L1-based therapy, in combination with pembrolizumab.

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]. Nutley, NJ: Eisai Inc.; November 2022.
2. The NCCN Drugs & Biologics Compendium 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed August 21, 2023.

3. National Comprehensive Cancer Network (NCCN) Guidelines: Thyroid Carcinoma V4.2023. National Comprehensive Cancer Network, Inc. https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed August 21, 2023.
4. Micromedex (electronic version). Truven Health Analytics. Greenwood Village, Colorado, USA https://www.micromedexsolutions.com/. Accessed August 21, 2023.