VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Lenvima Prior Authorization Policy
- Lenvima® (lenvatinib capsules – Eisai)

REVIEW DATE: 06/22/2022

OVERVIEW

Lenvima, a kinase inhibitor, is indicated for the following uses:[1]

- **Differentiated thyroid cancer** for treatment of locally recurrent or metastatic, progressive, radioactive iodine refractory disease.
- **Endometrial cancer**, in combination with Keytruda® (pembrolizumab intravenous infusion), for advanced disease that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation.
- **Hepatocellular carcinoma** for first-line treatment of patients with unresectable disease.
- **Renal cell carcinoma**, advanced in combination with everolimus tablets, following one prior anti-angiogenic therapy.
- **Renal cell carcinoma,** advanced, for first-line treatment of adult patients in combination with Keytruda.

Guidelines

Lenvima is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):[2]

- **Hepatobiliary Cancers**: NCCN guidelines (version 1.2022 – March 29, 2022) recommend Lenvima as other recommended regimen for first-line systemic therapy (Child-Pugh Class A only) for hepatocellular carcinoma (category 1). It is also recommended as subsequent-line therapy upon disease progression (Child-Pugh Class A only) [category 2A].[3]
- **Kidney Cancer**: NCCN guidelines (version 4.2022 – December 21, 2021) recommend Lenvima + everolimus as a preferred regimen as subsequent therapy for relapse or stage IV disease with clear cell histology (category 1); this combination is also listed as systemic therapy, other recommended regimens, for relapsed or stage IV disease for non-clear cell histology (category 2A). Lenvima + Keytruda is listed as a preferred regimen for first-line therapy for relapsed or stage IV disease for clear cell histology (category 1); this combination is also listed as other recommended regimen for subsequent therapy for relapsed or stage IV with clear cell histology (category 2A).[4]
- **Thymomas and Thymic Carcinomas**: NCCN guidelines (version 2.2022 – May 3, 2022) recommends single-agent Lenvima (category 2A) as second-line systemic therapy for thymic carcinoma.[5]
- **Thyroid Carcinoma**: NCCN guidelines (version 2.2022 – May 5, 2022) indicate that first-line treatment for differentiated thyroid cancer is surgery, whenever possible, followed by radioactive iodine therapy in selected patients, and levothyroxine therapy in all patients.[2] Systemic therapy options include cytotoxic chemotherapy and kinase inhibitors. The guidelines state that for progressive and/or symptomatic disease, Lenvima (preferred) for locally recurrent, advanced, and/or metastatic disease not amenable to radioactive iodine therapy (category 1). There is a footnote that states that kinase inhibitor therapy may not be appropriate for patients with stable or slowly progressive indolent disease. Lenvima can be considered for treatment of progressive or symptomatic medullary thyroid disease if clinical trials or preferred systemic therapy options are not available or appropriate, or if there is progression on preferred systemic therapy options (category 2A).[6]

- **Uterine Neoplasms**: NCCN guidelines (version 1.2022– November 4, 2021) recommends Lenvima with Keytruda combination therapy for biomarker directed systemic therapy for second-line treatment for recurrent, metastatic, or high-risk endometrial carcinoma for non-MSI-high [MSI-H]/non-MMR-deficient [dMMR] tumors. This combination is a category 1 recommendation as preferred therapy.[7]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Lenvima. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Lenvima is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Endometrial Carcinoma**. Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); AND
   - **C)** The medication is used in combination with Keytruda (pembrolizumab intravenous injection); AND
   - **D)** Patient has tried at least one systemic therapy; AND
     Note: Examples of systemic therapy include carboplatin, paclitaxel, docetaxel, cisplatin, doxorubicin, or ifosfamide.
   - **E)** Patient is not a candidate for curative surgery or radiation.

2. **Hepatocellular Cancer**. Approve for 1 year if the patient meets the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has unresectable or metastatic disease.

3. **Renal Cell Cancer**. Approve for 1 year if the patient meets the following criteria (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has advanced disease; AND
   - **C)** Patient meets ONE of the following (i or ii):
     - **i.** Lenvima is being used in combination with Keytruda (pembrolizumab intravenous infusion); OR
     - **ii.** Lenvima is being used in combination with everolimus tablets/Afinitor Disperz (everolimus tablets for oral suspension) AND patient meets one of the following (a or b):
       - **a)** Patient has clear cell histology and patient has tried one antiangiogenic therapy; OR
         Note: Examples of antiangiogenic therapy include Inlyta (axitinib tablets), Votrient (pazopanib tablets), Sutent (sunitinib capsules), or Cabometyx (cabozantinib tablets).
       - **b)** Patient has non-clear cell histology.

4. **Thyroid Carcinoma, Differentiated**. Approve for 1 year if the patient meets the following criteria (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND

B) Patient has differentiated thyroid carcinoma.
Note: Examples of differentiated thyroid carcinoma include papillary, follicular, and Hürthle cell thyroid carcinoma.
C) The disease is refractory to radioactive iodine therapy.

Other Uses with Supportive Evidence

5. Thymic Carcinoma. Approve for 1 year if the patient meets the following criteria (A and B):
A) Patient is ≥ 18 years of age; AND
B) Patient has tried at least one chemotherapy regimen.
Note: Examples of a chemotherapy regimen include carboplatin plus paclitaxel, cisplatin, doxorubicin plus cyclophosphamide, cisplatin plus etoposide.

6. Thyroid Carcinoma, Medullary. Approve for 1 year if the patient meets the following criteria (A and B):
A) Patient is ≥ 18 years of age; AND
B) Patient has tried at least one systemic therapy.
Note: Examples of systemic therapy include Caprelsa (vandetanib tablets), Cometriq (carbozantinib capsules), Retevmo (selpercatinib capsules), and Gavreto (pralsetinib capsules).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Lenvima is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Lenvima® capsules [prescribing information]. Woodcliff Lake, NJ: Eisai; December 2021.
2. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 14, 2022. Search term: lenvatinib.
3. The NCCN Hepatobiliary Cancers Clinical Practice Guidelines in Oncology (version 1.2022 – March 29, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 14, 2022.
4. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 4.2022– December 21, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 14, 2022.
5. The NCCN Thymomas and Thymic Carcinoma Clinical Practice Guidelines in Oncology (version 2.2022 – May 3, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 14, 2022.
6. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 2.2022 – May 5, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 14, 2022.
7. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 1.2022 – November 4, 2021). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 14, 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Endometrial Carcinoma:** A requirement was added that the patient is ≥ 18 years of age. The phrase "disease has progressed on one prior systemic therapy" was reworded to "patient has tried one systemic therapy." **Hepatocellular Cancer:** A requirement was added that the patient is ≥ 18 years of age. The requirement of "unresectable" was moved from the condition of approval into the criteria section and additional qualifier of "metastatic disease" was added. **Renal Cell Cancer:** A requirement was added that the patient is ≥ 18 years of age. "Clear cell or non-clear cell" was moved from the condition of approval and added into the criteria section. "Stage IV" disease was reworded to "advanced" disease. The qualifier was added that Lenvima is being used in combination with Keytruda (pembrolizumab intravenous infusion) for clear cell renal cell carcinoma. A qualifier was added that for non-clear cell renal cell carcinoma, Lenvima is used in combination with Afinitor (everolimus)/Afinitor Disperz (everolimus tablets for oral suspension) therapy. **Thyroid Carcinoma, Differentiated:** A requirement was added that the patient is ≥ 18 years of age. The requirement that patient has "differentiated" thyroid carcinoma was added into the criteria section. A note was added with examples of differentiated thyroid carcinoma. **Anaplastic Thyroid Carcinoma:** Indication was deleted from other uses with supportive evidence based on NCCN guidelines. **Thymic Carcinoma:** Indication and criteria were added to other uses with supportive evidence based on NCCN guideline recommendations. A requirement was added that the patient is ≥ 18 years of age. **Thyroid Carcinoma, Medullary:** A requirement was added that the patient is ≥ 18 years of age. The requirement for previous therapy was changed from "Patient has tried Caprelsa or Cometriq" to "Patient has tried at least one systemic therapy" and a note was added with examples of systemic therapy.	06/02/2021
Selected Revision	**Renal Cell Cancer:** The criteria qualifier of relapsed disease was removed. The requirement that "Lenvima is being used in combination with Keytruda (pembrolizumab intravenous infusion) for patients with clear cell histology" was changed to "Lenvima is being used in combination with Keytruda (pembrolizumab intravenous infusion)" based on new FDA labeled indication.	08/18/2021
Annual Revision	**Endometrial Carcinoma:** The approval duration was changed from 3 years to 1 year. **Hepatocellular Cancer:** The approval duration was changed from 3 years to 1 year. **Renal Cell Cancer:** The approval duration was changed from 3 years to 1 year. **Thyroid Carcinoma, Differentiated:** The approval duration was changed from 3 years to 1 year. **Thymic Carcinoma:** The approval duration was changed from 3 years to 1 year. **Thyroid Carcinoma, Medullary:** The approval duration was changed from 3 years to 1 year.	06/22/2022