Overview
LENVIMA is a prescription medicine that is used to treat the following kinds of cancer:
- Differentiated thyroid cancer (DTC), a type of thyroid cancer that can no longer be treated with radioactive iodine and is progressing
- Advanced renal cell carcinoma (RCC), a type of kidney cancer, after one course of treatment with another anti-cancer medicine
- Hepatocellular carcinoma (HCC) when it cannot be removed by surgery

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with Lenvima, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs

OR
Authorization may be granted if the member meets ALL following criteria and documentation has been submitted:

Advanced renal cell carcinoma
Prescriber provides documentation of ALL of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing (quantity requested is ≤ 3 capsules/day) *
4. Requested regimen includes everolimus
5. ONE of the following:

* Valid only when obtained as samples or via manufacturer’s patient assistance programs

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Specialty Medications
- All Plans
  - Phone: 866-814-5506
  - Fax: 866-249-6155

Non-Specialty Medications
- MassHealth
  - Phone: 877-433-7643
  - Fax: 866-255-7569
- Commercial
  - Phone: 800-294-5979
  - Fax: 888-836-0730
- Exchange
  - Phone: 855-582-2022
  - Fax: 855-245-2134

Medical Specialty Medications (NLX)
- All Plans
  - Phone: 844-345-2803
  - Fax: 844-851-0882

Exceptions
N/A
a. Tumor is clear cell histology and physician documented inadequate response or adverse reaction to ONE or contraindication to ALL first-line therapies (pazopanib, sunitinib, temsirolimus, axitinib monotherapy or in combination with pembrolizumab, ipilimumab + nivolumab, cabozantinib, high-dose IL-2, sorafenib)

b. Tumor is non-clear cell histology and physician documented inadequate response or adverse reaction to ONE or contraindication to ALL systemic therapies (e.g., sunitinib, axitinib, bevacizumab or biosimilar, cabozantinib, erlotinib, everolimus, nivolumab, pazopanib, sorafenib, temsirolimus)

**Differentiated thyroid cancer (DTC)**
Prescriber provides documentation of ALL of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing (quantity requested is ≤ 3 capsules/day) *

**Endometrial Carcinoma**
Prescriber provides documentation of ALL of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing (quantity requested is ≤ 2 capsules/day) *
4. Inadequate response or adverse reaction to one prior line of systemic therapy or contraindication to systemic therapy (Examples of systemic therapy for endometrial carcinoma include carboplatin, paclitaxel, doxorubicin, docetaxel, cisplatin, ifosfamide, and bevacizumab. These may be used as monotherapy or as combination therapy)
5. Requested agent will be used in combination with Keytruda® (pembrolizumab)

**Unresectable Hepatocellular Carcinoma (HCC)**
Prescriber provides documentation of ALL of the following:
1. Diagnosis of unresectable and metastatic HCC
2. Prescriber is an oncologist
3. Appropriate dosing (quantity requested is ≤ 3 capsules/day) *

**Continuation of Therapy**
Reauthorization requires physician attestation of continuation of therapy and positive response to therapy.

**Limitations**
1. Initial approvals and reauthorizations will be granted for 12 months
2. The following quantity limits apply:

| Lenvima 4 mg | 30 capsules per 30 days |
| Lenvima 8 mg | 60 capsules per 30 days |
| Lenvima 10 mg | 30 capsules per 30 days |
| Lenvima 12 mg | 90 capsules per 30 days |
| Lenvima 14 mg | 60 capsules per 30 days |
| Lenvima 18 mg | 90 capsules per 30 days |
| Lenvima 20 mg | 60 capsules per 30 days |
| Lenvima 24 mg | 90 capsules per 30 days |

*Any requests for over the quantity limit must be reviewed against the Global Quantity Limit criteria.*
References

Review History
10/9/2020: Created criteria to be in compliance with the Masshealth partial unified formulary requirements effective 1/1/21.

Disclaimer
AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.