



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LENVATINIB

Generic	Brand	HICL	GCN	Exception/Other
LENVATINIB MESYLATE	LENVIMA	41756		ROUTE = ORAL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of differentiated thyroid cancer (DTC) and meet **ALL** of the following criteria; (**NOTE:** Differentiated thyroid cancer (DTC) can be classified as papillary (PTC), follicular (FTC), or Hurthle cell)?
 - The thyroid cancer is locally recurrent or metastatic
 - The thyroid cancer is progressive
 - Patient has tried or has a contraindication to radioactive iodine therapy

If yes, **approve for 12 months by GPID based on the following daily dose requirements:**

- For a daily dose of 10mg, approve for 30 blisters per 30 days.
- For a daily dose of 14mg, approve for 60 blisters per 30 days.
- For a daily dose of 20mg, approve for 60 blisters per 30 days.
- For a daily dose of 24mg, approve for 90 blisters per 30 days.

If no, continue to #2.

2. Does the patient have a diagnosis of advanced renal cell cancer (RCC) and meet **ALL** of the following criteria?
 - Lenvima will be used in combination with everolimus
 - Patient has previously tried one anti-angiogenic therapy (e.g., Sutent (sunitinib), Votrient (pazopanib), Inlyta (axitinib), Nexavar (sorafenib))

If yes, **approve for 12 months by GPID based on the following daily dose requirements:**

- For a daily dose of 8mg, approve for 60 blisters per 30 days.
- For a daily dose of 10mg, approve for 30 blisters per 30 days.
- For a daily dose of 14mg, approve for 60 blisters per 30 days.
- For a daily dose of 18mg, approve for 90 blisters per 30 days.

If no, continue to #3.

3. Does the patient have a diagnosis of unresectable hepatocellular carcinoma (HCC)?

If yes, **approve for 12 months by GPID based on the following daily dose requirements:**

- For a dose of 4mg every other day, approve for 15 blisters per 30 days.
- For a daily dose of 4mg, approve for 30 blisters per 30 days.
- For a daily dose of 8mg, approve for 60 blisters per 30 days.
- For a daily dose of 12mg, approve for 90 blisters per 30 days.

If no, continue to #4.

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GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of advanced endometrial carcinoma and meet **ALL** of the following criteria?

- The medication is used in combination with pembrolizumab (Keytruda)
- The patient does not have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) biomarkers
- The patient has experienced disease progression following prior systemic therapy
- The patient is not a candidate for curative surgery or radiation

If yes, **approve for 12 months by GPID based on the following daily dose requirements:**

- **For a daily dose of 8mg, approve for 60 blisters per 30 days.**
- **For a daily dose of 10mg, approve for 30 blisters per 30 days.**
- **For a daily dose of 14mg, approve for 60 blisters per 30 days.**
- **For a daily dose of 20mg, approve for 60 blisters per 30 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **LENVATINIB (Lenvima)** requires a diagnosis of differentiated thyroid cancer, advanced renal cell cancer, unresectable hepatocellular carcinoma, or advanced endometrial carcinoma. In addition, the following criteria must be met:

For the diagnosis of differentiated thyroid cancer, approval requires:

- Thyroid cancer is progressive and is locally recurrent **or** metastatic
- Patient has tried or has contraindication to radioactive iodine therapy

For the diagnosis of advanced renal cell cancer, approval requires:

- Lenvima will be used in combination with everolimus
- Patient has previously tried one anti-angiogenic therapy

For the diagnosis of advanced endometrial carcinoma, approval requires:

- The medication is used in combination with pembrolizumab (Keytruda)
- The patient does not have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) biomarkers
- The patient has experienced disease progression following prior systemic therapy
- The patient is not a candidate for curative surgery or radiation

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lenvima.

REFERENCES

- Lenvima [Prescribing Information]. Woodcliff Lake, NJ: Eisai, Inc. September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

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