STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LENVATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LENVATINIB MESYLATE	LENVIMA	41756		GPI-10 (2133505420)	

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
   - The thyroid cancer is refractory to radioactive iodine therapy

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   - **10 mg daily dose: #1 per day.**
   - **14 mg daily dose: #2 per day.**
   - **20 mg daily dose: #2 per day.**
   - **24 mg daily dose: #3 per day.**

   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?
   - The patient is 18 years of age or older
   - Lenvima will be used as a first-line treatment
   - Lenvima will be used in combination with pembrolizumab (Keytruda)

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   - **8 mg daily dose: #2 per day.**
   - **10 mg daily dose: #1 per day.**
   - **14 mg daily dose: #2 per day.**
   - **20 mg daily dose: #2 per day.**

   If no, continue to #3.

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GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of advanced renal cell cancer (RCC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lenvima will be used in combination with everolimus
   - The patient has tried one anti-angiogenic therapy (e.g., Sutent [sunitinib], Votrient [pazopanib], Inlyta [axitinib], Nexavar [sorafenib])

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   - **8 mg daily dose: #2 per day.**
   - **10 mg daily dose: #1 per day.**
   - **14 mg daily dose: #2 per day.**
   - **18 mg daily dose: #3 per day.**

   If no, continue to #4.

4. Does the patient have a diagnosis of unresectable hepatocellular carcinoma (HCC) **AND** meet the following criterion?
   - Lenvima is being used as a first-line treatment

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   - **4 mg every other day: #1 per 2 days.**
   - **4 mg daily dose: #1 per day.**
   - **8 mg daily dose: #2 per day.**
   - **12 mg daily dose: #3 per day.**

   If no, continue to #5.

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GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of advanced endometrial carcinoma (EC) and meet **ALL** of the following criteria?
   - Lenvima is used in combination with pembrolizumab (Keytruda)
   - The patient's cancer is mismatch repair proficient (pMMR), as determined by an FDA-approved test, or is not microsatellite instability-high (MSI-H)
   - 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 or GPI-14 based on the following daily dose requirements:**
   - **8 mg daily dose: #2 per day.**
   - **10 mg daily dose: #1 per day.**
   - **14 mg daily dose: #2 per day.**
   - **20 mg daily dose: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LENVATINIB (Lenvima)** requires the following rule(s) be met for approval:
   A. You have **ONE** of the following diagnoses:
      1. Differentiated thyroid cancer (DTC: cancer cells look/act like normal thyroid cells)
      2. Advanced renal cell cancer (RCC: kidney cancer)
      3. Unresectable hepatocellular carcinoma (HCC: liver cancer that cannot be removed by surgery)
      4. Advanced endometrial carcinoma (EC: type of cancer that starts in the uterus)

   B. **If you have differentiated thyroid cancer, approval also requires:**
      1. Your thyroid cancer is locally recurrent (re-appears in the same spot) or metastatic (has spread to other parts of the body)
      2. Your thyroid cancer is progressive (getting worse)
      3. Your thyroid cancer is refractory (has not responded) to radioactive iodine therapy

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LENVATINIB

GUIDELINES FOR USE (CONTINUED)

C. **If you have advanced renal cell cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Lenvima will be used as first-line treatment in combination with pembrolizumab (Keytruda)
      b. Lenvima is used in combination with everolimus AND you have tried one prior anti-angiogenic therapy (treatment that stop tumors from growing their own blood vessels, such as Sutent [sunitinib], Votrient [pazopanib], Inlyta [axitinib], Nexavar [sorafenib])

D. **If you have unresectable hepatocellular carcinoma, approval also requires:**
   1. Lenvima is being used as a first-line treatment

E. **If you have advanced endometrial carcinoma, approval also requires:**
   1. Lenvima is used in combination with pembrolizumab (Keytruda)
   2. Your cancer is mismatch repair proficient (pMMR), as determined by a Food and Drug Administration (FDA)-approved test, or is not microsatellite instability-high (MSI-H) (markers of the cancer to help determine what treatment options are appropriate)
   3. You have experienced disease progression (worsening) following prior systemic therapy (treatment that targets the entire body)
   4. You are not a candidate for curative surgery or radiation

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

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

REFERENCES

- Lenvima [Prescribing Information]. Nutley, NJ: Eisai, Inc.; November 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/09/23
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