

LENVIMA (lenvatinib)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

- 1. Differentiated thyroid cancer (DTC)
 - a. Locally recurrent or metastatic disease
 - b. Progression after radioactive iodine therapy (radioactive iodinerefractory)
- 2. Advanced renal cell carcinoma (RCC) **AND ONE** of the following:
 - a. Used in combination with pembrolizumab as first-line treatment
 - b. Used in combination with everolimus
 - i. Progression after one prior anti-angiogenic therapy
- 3. Unresectable hepatocellular carcinoma (HCC) AND ONE of the following:
 - a. Used as first-line treatment
 - b. Used as subsequent-line therapy
 - i. Patient must be Child-Pugh Class A
- 4. Advanced endometrial carcinoma (EC)
 - a. Used in combination with pembrolizumab
 - b. Patient is **ONE** of the following:
 - i. Mismatch repair proficient (pMMR), as determined by an FDAapproved test
 - ii. **NOT** microsatellite instability-high (MSI-H)
 - c. Disease progression following prior systemic therapy
 - d. NOT a candidate for curative surgery or radiation

Prior - Approval Limits

Reference

| Diagnosis | Recommended Dosing |
|---|---|
| Differentiated Thyroid Cancer (DTC) | 24 mg once daily |
| Renal Cell Carcinoma (RCC) - First-Line | 20 mg orally once daily, in combination |

Lenvima FEP Clinical Criteria

BlueCross. BlueShield

LENVIMA

| Federal Employee Program. (lenvatinib) | |
|---|--|
| Treatment of Patients with Advanced | with 200 mg pembrolizumab administered |
| RCC | as IV infusion over 30 minutes every 3 |
| | weeks |
| Renal Cell Carcinoma (RCC) – Previously | 18 mg in combination with 5 mg |
| Treated RCC | everolimus once daily |
| Hepatocellular Carcinoma (HCC) | 12 mg once daily for patients greater than |
| | or equal to 60 kg or 8 mg once daily for |
| | patients less than 60 kg |
| Endometrial carcinoma | 20 mg orally once daily, in combination |
| | with 200 mg pembrolizumab administered |
| | as IV infusion over 30 minutes every 3 |
| | weeks |

Lenvima comes in cartons of 6 blister cards. Each card contains a 5 day supply of medication. Each carton therefore contains a 30 day supply.

| Strength | How Supplied |
|----------|--|
| 4 mg | One 4 mg capsule / Five 4 mg capsules per card |
| 8 mg | Two 4 mg capsules / Ten 4 mg capsules per card |
| 10 mg | One 10 mg capsule / Five 10 mg capsules per card |
| 12 mg | Three 4 mg capsules / Fifteen 4 mg capsules per card |
| 14 mg | One 10 mg capsule and one 4 mg capsule / Five 10 mg |
| | capsules and five 4 mg capsules per card |
| 18 mg | One 10 mg capsule and two 4 mg capsules / Five 10 mg |
| | capsules and ten 4 mg capsules per card |
| 20 mg | Two 10 mg capsules / Ten 10 mg capsules per card |
| 24 mg | Two 10 mg capsules and one 4 mg capsule / Ten 10 mg |
| | capsules and five 4 mg capsules per card |

Duration 12 months

Prior – Approval Renewal Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

- 1. Differentiated Thyroid Cancer (DTC)
- 2. Advanced Renal Cell Carcinoma (RCC)
- 3. Unresectable hepatocellular carcinoma (HCC)



LENVIMA (lenvatinib)

Federal Employee Program.

- 4. Advanced endometrial carcinoma (EC)
 - a. Used in combination with (pembrolizumab)

AND ALL of the following:

- a. **NO** disease progression
- b. **NO** unacceptable toxicity. Examples include: i.life-threatening hypertension
 - ii.severe cardiac dysfunction
 - iii.hepatotoxicity
 - iv.nephrotic syndrome
 - v.renal failure/impairment
 - vi.gastrointestinal perforation/fistula formation
 - vii.severe QT prolongation (grade 3 or 4)
 - viii.Reversible Posterior Leukoencephalopathy Syndrome (RPLS) ix.arterial thromboembolic events and severe hemorrhage

Prior - Approval Renewal Limits

Same as above