Clinical Policy: Lenvatinib (Lenvima)

Reference Number: PA.CP.PHAR.138
Effective Date: 10.17.18
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Description
Lenvatinib (Lenvima®) is a kinase inhibitor.

FDA Approved Indication(s)
Lenvima is indicated:

- For the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (DTC).
- In combination with everolimus for the treatment of patients with advanced renal cell carcinoma (RCC) following one prior anti-angiogenic therapy.
- For the first-line treatment of patients with unresectable hepatocellular carcinoma (HCC).

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Lenvima is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Differentiated Thyroid Cancer (must meet all)**:**

1. Diagnosis of DTC (i.e., papillary, follicular, or Hürthle cell carcinoma);
2. Prescribed by or in consultation with an oncologist;
3. Disease is radioactive iodine-refractory and recurrent, metastatic or progressive;
4. Request meets one of the following (a or b):
   a. Dose does not exceed 24 mg per day (3 capsules per day).
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Medullary Thyroid Carcinoma (off-label) (must meet all)**:**

1. Diagnosis of medullary thyroid carcinoma (MTC);
2. Prescribed by or in consultation with an oncologist;
3. Disease is progressive or metastatic;
4. Failure of Cometriq® or Caprelsa® unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for Cometriq and Caprelsa.*
5. Request meets one of the following (a or b):
   a. Dose does not exceed 24 mg per day (3 capsules per day).
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

C. Renal Cell Carcinoma (must meet all)**:**
1. Diagnosis of advanced RCC (i.e., relapsed, metastatic or stage IV disease);
2. Prescribed by or in consultation with an oncologist;
3. Will be used in combination with Afinitor®;
   **Prior authorization may be required for Afinitor.*
4. If RCC histology is clear cell or unknown, failure of a prior RCC therapy* *(see Appendix B)* unless contraindicated or clinically adverse effects are experienced;
   **Prior authorization may be required.*
5. Request meets one of the following (a or b):
   a. Dose does not exceed 18 mg per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

D. Hepatocellular Carcinoma (must meet all):
1. Diagnosis of hepatocellular carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Request meets one of the following (a or b):
   a. Dose does not exceed 12 mg per day (if actual body weight ≥ 60 kg) or 8 mg per day (if actual body weight < 60 kg).
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

E. Other diagnoses/indications
1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b, c, or d):
   a. New dose does not exceed 24 mg per day (3 capsules per day) if DTC;
   b. New dose does not exceed 18 mg per day if RCC;
   c. New dose does not exceed 12 mg per day (actual body weight ≥ 60 kg) or 8 mg (actual body weight < 60 kg) if HCC;
   d. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DTC: differentiated thyroid cancer
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network
HCC: hepatocellular carcinoma
RCC: renal cell carcinoma
MTC: medullary thyroid cancer

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Afinitor® (everolimus)	RCC: 10 mg PO QD	10 mg/day
RCC therapeutic agents: Avastin® (bevacizumab) Cabometyx® (cabozantinib) Inlyta® (axitinib) Nexavar® (sorafenib) Opdivo® (nivolumab) Proleukin® (aldesleukin, rIL-2) Sutent® (sunitinib) Tarceva® (erlotinib) Torisel® (temsirolimus) Votrient® (pazopanib) Yervoy® (ipilimumab)	RCC: regimens vary	Varies
Caprelsa® (vandetanib)	MTC: 300 mg PO QD	300 mg/day
Cometriq® (cabozantinib)	MTC: 140 to 180 mg PO QD	180 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
DTC	24 mg PO QD	24 mg/day
RCC	18 mg PO QD	18 mg/day
HCC	12 mg PO QD (if actual body weight ≥ 60 kg) or 8 mg PO QD (if actual body weight < 60 kg)	12 mg/day

VI. Product Availability

Capsules: 4 mg, 10 mg

VII. References

1. Lenvima Prescribing Information. Woodcliff Lake, NJ: Eisai, Inc; August 2018. Available at http://www.lenvima.com/pdfs/prescribing-information.pdf. Accessed August 2018.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 2018.
3. National Comprehensive Cancer Network. Thyroid Carcinoma. 1.2015. Available at: http://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed July 2018.
4. National Comprehensive Cancer Network. Kidney Cancer. 2.2017. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed July 2018.
5. National Comprehensive Cancer Network. Hepatobiliary Cancers. 2.2018. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed August 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy Created	10/18	