Clinical Policy: Lenvatinib (Lenvima)

Reference Number: HIM.PA.SP50
Effective Date: 12.01.17
Last Review Date:
Line of Business: Health Insurance Marketplace

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria

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

1. Diagnosis of DTC (i.e., papillary, follicular, or Hürthle cell carcinoma);
2. Disease has all of the following characteristics (a-c):
   a. Locally recurrent or metastatic;
   b. Progressive;
   c. Radioactive iodine-refractory;
3. Dose does not exceed 24 mg/day (3 capsules/day).

Approval duration: 6 months

B. Renal Cell Carcinoma (must meet all)**:**

1. Diagnosis of RCC;
2. Disease is advanced (relapsed or stage IV);
3. Lenvima is prescribed in combination with everolimus;
4. Meets a or b:
   a. FDA recommended use: Member has received one prior anti-angiogenic therapy (e.g., pazopanib, sunitinib, bevacizumab, temsirolimus, axitinib, sorafenib);
   b. Off-label NCCN recommended use (i or ii):
      i. RCC histology is characterized as predominant clear cell, and member has received prior therapy with interleukin-2;
      ii. RCC histology is characterized as non-clear cell;
5. Request meets one of the following (a or b):

a. Dose does not exceed 18 mg/day (3 capsules/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. Medullary Thyroid Carcinoma (off-label) (must meet all)**:**
1. Diagnosis of medullary thyroid carcinoma;
2. Disease is progressive, or there are symptomatic distant metastases;
3. Meets a or b:
   a. Clinical trials, vandetanib, and cabozantinib are not available or appropriate;
   b. Disease has progressed on vandetanib or cabozantinib;
4. 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. Other diagnoses/indications
1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy (e.g., no disease progression or unacceptable toxicity);
3. If request is for a dose increase, request meets one of the following (a, b, or c):
   a. For DTC: New dose does not exceed 24 mg/day (3 capsules/day);
   b. For RCC: New dose does not exceed 18 mg/day (3 capsules/day);
   c. For RCC or medullary thyroid carcinoma: 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 health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – HIM.PHAR.21 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
RCC: renal cell carcinoma

V. References

1. Lenvima Prescribing Information. Woodcliff Lake, NJ: Eisai Inc.; July 2017. Available at: www.lenvima.com. Accessed August 29, 2017.
2. Lenvatinib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed August 29, 2017.
3. Thyroid cancer (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed August 29, 2017.
4. Kidney cancer (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed August 29, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.29.17	11.17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or

regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.