Clinical Policy: Lenvatinib (Lenvima)
Reference Number: HIM.PA.SP50
Effective Date: 12.01.17
Last Review Date:
Line of Business: Health Insurance Marketplace

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):
CLINICAL POLICY

Lenvatinib

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


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<th>Reviews, Revisions, and Approvals</th>
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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
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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.

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