Clinical Policy: Selpercatinib (Retevmo)

Reference Number: CP.PHAR.478
Effective Date: 09.01.20
Last Review Date: 05.21
Line of Business: Commercial, HIM, Medicaid Revision Log

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

Description

Selpercatinib (Retevmo™) is a kinase inhibitor.

FDA Approved Indication(s)

Retevmo is indicated for the treatment of:

- Adult patients with metastatic *RET* fusion-positive non-small cell lung cancer (NSCLC)
- *RET*-mutant medullary thyroid cancer (MTC)
  - Adult and pediatric patients 12 years of age and older with advanced or metastatic *RET*-mutant MTC who require systemic therapy
- *RET* fusion-positive thyroid cancer
  - Adult and pediatric patients 12 years of age and older with advanced or metastatic *RET* fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)*

**This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).*

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 Centene Corporation® that Retevmo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (must meet all)**:**

1. Diagnosis of recurrent, advanced, or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Documentation of *RET* fusion-positive disease (e.g., KIF5B-RET);
5. Retevmo is not prescribed concurrently with Gavreto™;
6. Member has not received prior *RET* targeted therapy (e.g., Gavreto);
7. For brand Retevmo requests, member must use generic selpercatinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
8. Request meets one of the following (a, b, or c):*
   a. Weight < 50 kg: Dose does not exceed 120 mg (2 capsules) twice daily;
   b. Weight ≥ 50 kg: Dose does not exceed 160 mg (2 capsules) twice daily;

c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – Length of Benefit

B. Thyroid Cancer (must meet all)**:**

1. Diagnosis of one of the following (a, b, or c):
   a. MTC;
   b. Differentiated thyroid carcinoma (DTC; Hurthle cell, papillary, follicular);
   c. Anaplastic thyroid carcinoma (ATC);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 12 years;
4. Disease is advanced or metastatic;
5. For MTC, documentation of mutant-positive disease (e.g., RET M918T);
6. For DTC or ATC, documentation of fusion-positive disease (e.g., CCDC6-RET), and member is radioactive iodine-refractory (if radioactive iodine is appropriate);
7. Retevmo is not prescribed concurrently with Gavreto;
8. Member has not received prior *RET* targeted therapy (e.g., Gavreto);
9. For brand Retevmo requests, member must use generic selpercatinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
10. Request meets one of the following (a, b, or c):*
    a. Weight < 50 kg: Dose does not exceed 120 mg (2 capsules) twice daily;
    b. Weight ≥ 50 kg: Dose does not exceed 160 mg (2 capsules) twice daily;
    c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – Length of Benefit

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Retevmo for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Retevmo is not prescribed concurrently with Gavreto;
4. Member has not received prior *RET* targeted therapy (e.g., Gavreto);

5. For brand Retevmo requests, member must use generic selpercatinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. If request is for a dose increase, request meets one of the following (a, b, or c):*
   a. Weight < 50 kg: New dose does not exceed 120 mg twice (2 capsules) daily;
   b. Weight ≥ 50 kg: New dose does not exceed 160 mg twice (2 capsules) daily;
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 12 months
Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 of 2):
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
MTC: medullary thyroid cancer
NCCN: National Comprehensive Cancer Network
NSCLC: non-small cell lung cancer

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NSCLC, thyroid cancer	Weight < 50 kg: 120 mg PO BID Weight ≥ 50 kg: 160 mg PO BID	Weight < 50 kg: 240 mg/day Weight ≥ 50 kg: 320 mg/day

VI. Product Availability

Capsules: 40 mg, 80 mg

VII. References

1. Retevmo Prescribing Information. Indianapolis, IN: Lilly USA, LLC; May 2020. Available at http://pi.lilly.com/us/retevmo-uspi.pdf. Accessed January 26, 2021.
2. Selpercatinib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed January 26, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively.	03.10.20	05.20
Drug is now FDA approved - criteria updated per FDA labeling: For NSCLC, failure of platinum-based chemotherapy and PD-1/PD-L1 therapy removed per FDA; recurrent, advanced or metastatic replaces advanced per FDA and NCCN; dosing added; for thyroid cancer, MTC restricted to mutant-positive rather than also fusion-positive; failure of systemic therapy removed per FDA; dosing added; references reviewed and updated.	06.02.20	08.20
Updated criteria to prevent concurrent use of Gavreto as well as history of RET target therapy.	09.23.20	11.20
2Q 2021 annual review: no significant changes; added generic redirection language to "must use" since oral oncology product; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	01.26.21	05.21

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.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.