



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 8/20/2020
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

RETEVMO™ (selpercatinib) oral

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

RETEVMO™ (selpercatinib) oral

Criteria:

- **Criteria for initial therapy:** Retevmo (selpercatinib) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist
 2. A confirmed diagnosis of **ONE** of the following:
 - a. Adult patient (18 years of age or older) with metastatic *RET* fusion-positive non-small cell lung cancer (NSCLC)
 - b. Adult or pediatric patient 12 years of age or older with advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC) who require systemic therapy
 - c. Adult or pediatric patient 12 years of age or 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)
 - d. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A
 3. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
 - a. Adequately controlled blood pressure
 - b. EKG to assess QT interval
 - c. Liver function tests
 - d. Electrolytes, with correction of any hypokalemia, hypomagnesemia, or hypocalcemia
 - e. TSH
 - f. Negative pregnancy test in a woman of child bearing potential
 - g. Eastern Cooperative Oncology Group (ECOG) Performance Status is ≤ 2

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Retevmo (selpercatinib) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist
 2. Individual's condition responded while on therapy
 - a. Response is defined as:
 - i. Documented evidence of disease stability
 - ii. No evidence of disease progression



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3. Individual has been adherent with the medication
4. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
 - a. Significant adverse effect such as:
 - i. Hepatotoxicity
 - ii. Life-threatening hypertension that is not controlled by antihypertensive medications
 - iii. Life-threatening QT prolongation
 - iv. Severe or life-threatening hemorrhage
5. Has not has more than 3 dose reductions due to drug toxicity
6. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Retevmo (selpercatinib) is indicated for the treatment of adult patients (18 years of age or older) with metastatic *RET* fusion-positive non-small cell lung cancer (NSCLC); for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC) who require systemic therapy; and for the treatment of 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).

These indications are 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).

Definitions:

Activities of daily living (ADL):

Instrumental ADL:

Prepare meals, shop for groceries or clothes, use the telephone, manage money, etc.

Self-care ADL:

Bathe, dress and undress, feed self, use the toilet, take medications, not bedridden

Common Terminology Criteria for Adverse Events (CTCAE) Version 4.0:

| | |
|---------|---|
| Grade 1 | Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated |
| Grade 2 | Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL* |
| Grade 3 | Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL** |
| Grade 4 | Life-threatening consequences; urgent intervention indicated |
| Grade 5 | Death related to AE |

U.S. Department of Health and Human Services, National Institutes of Health, and National Cancer Institute



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ECOG Performance status:

| Eastern Co-operative Oncology Group (ECOG) Performance Status | |
|---|---|
| Grade | ECOG description |
| 0 | Fully active, able to carry on all pre-disease performance without restriction |
| 1 | Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work |
| 2 | Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours |
| 3 | Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours |
| 4 | Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair |
| 5 | Dead |

Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982

Resources:

Retevmo (selpercatinib) product information, revised by manufacturer 05-2020, accessed 07-15-20 at DailyMed

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer. Version 06.2020, June 15, 2020. Accessed 07-15-20

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Thyroid Carcinoma. Version 02.2020, July 15, 2020. Accessed 07-15-20

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.