Reference number(s)
3874-A

SPECIALTY GUIDELINE MANAGEMENT

RETEVMO (selpercatinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Retevmo is indicated for the treatment of adult patients with metastatic *RET* fusion-positive non-small cell lung cancer (NSCLC).
2. Retevmo is indicated 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.
3. Retevmo is indicated 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).

B. Compendial Uses
1. Recurrent, advanced or metastatic NSCLC with *RET* rearrangement-positive tumors
2. Histiocytic Neoplasms:
   a. Erdheim-Chester Disease (ECD)
   b. Langerhans Cell Histiocytosis (LCH)
   c. Rosai-Dorfman Disease

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Documentation of the presence of a *RET* gene fusion or specific *RET* gene mutation in tumor specimens or plasma (where applicable).

III. CRITERIA FOR INITIAL APPROVAL

A. Non-Small Cell Lung Cancer
Authorization of 12 months may be granted as a single agent for treatment of recurrent, advanced, or metastatic non-small cell lung cancer when the tumors have a *RET* gene fusion.

B. Medullary Thyroid Cancer
Authorization of 12 months may be granted for treatment of members 12 years of age and older with advanced or metastatic medullary thyroid cancer with a *RET* gene mutation.

C. Thyroid Cancer

Authorization of 12 months may be granted for treatment of members 12 years of age and older with advanced or metastatic radioactive iodine-refractory (if radioactive iodine is appropriate) thyroid cancer whose tumors have a *RET* gene fusion.

D. Histiocytic Neoplasms

Authorization of 12 months may be granted for the treatment of any of the following histiocytic neoplasm subtypes as a single agent in members with a *RET* gene fusion:

1. Symptomatic or relapsed/refractory Erdheim-Chester Disease (ECD)
2. Symptomatic or relapsed/refractory Rosai-Dorfman Disease
3. Langerhans Cell Histiocytosis (LCH)

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Retevmo [package insert]. Indianapolis, IN: Lilly USA, LLC; January 2021.
2. The NCCN Drugs & Biologics Compendium 2021 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 10, 2021.