RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	Revetmo
Policy Number:	RxA.636
Drug(s) Applied:	Revetmo ®(selpercatinib)
Original Policy Date:	09/14/2020
Last Review Date:	07/01/2020
Line of Business Policy Applies to:	Commercial, Medicaid

Background

RETEVMO is a kinase inhibitor indicated for the treatment of:

- Adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC)1 (1.1)
- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy1 (1.2)
- 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)

Thyroid cancer is the most common type of endocrine cancer.. There are many types of thyroid cancer including medullary thyroid cancer (MTC). MTC accounts for about 4% of thyroid cancers. Medullary cancers are categorized as familial when acquired through inheritance, or as sporadic, a nonhereditary form that occurs more frequently. RET-positive thyroid cancer is found in 60% of sporadic MTC and over 90% in familial MTC.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Selpercatinib (Revetmo)	• Adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC)1 (1.1) • Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy1 (1.2) • 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)	Orally: twice a day Based upon body weight: • <50kg: 120mg/dose • ≥50kg: 160mg/dose	160mg orally twice daily

Dosage Forms

- Capsules: 40 mg, 80 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer or Medullary Thyroid Cancer

1. The member must have one of the following disease states:
    i. Adult patients with metastatic RET fusion-positive NSCLC
    ii. Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy
    iii. 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).
2. Prescribed by or in consultation with an oncologist
3. The member must have an ECOG score of 0 or 1
4. The member is 12 years of age or older

Approval Duration: 3 months
Commercial: 3 months
Medicaid: 3 months

II. Continued Therapy Approval

A. Non-Small Cell Lung Cancer

1. The member is currently receiving Retevmo as authorized by RxAdvance or member has previously met initial approval criteria.
2. The member is responding positively to therapy
3. The member is 12 years of age or older

Approval Duration: 6 months
Commercial: 6 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

1. ECOG: Eastern Cooperative Oncology Group
2. NSCLC: Non-Small Cell Lung Cancer
3. MTC: medullary thyroid cancer

APPENDIX B: Therapeutic Alternatives

RET-Positive NSCLC: Alecensa (alectinib) has been tried, along with Caprelsa (vandetanib) and Cometriq (cabozantinib S-malate). None are FDA-approved for RET NSCLC.

RET-Positive Thyroid Cancer and Medullary Thyroid Cancer: Caprelsa (vandetanib), Cometriq (cabozantinib S-malate), Lenvima (lenvatinib), and Nexavar (sorafenib) are used. Off label, Sutent (sunitinib) has been used.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
    - None

- Boxed Warning(s):
  - None

References

1. Phase 1/2 Study of LOXO-292 in Patients With Advanced Solid Tumors, RET Fusion-Positive Solid Tumors, and Medullary Thyroid Cancer
2. Bongarzone I, et al. RET/NTRK1 Rearrangements in Thyroid Gland Tumors of the Papillary Carcinoma Family: Correlation with Clinicopathological Features.
3. Retevmo Prescribing Information. Indianapolis, IN; Lilly: May 2020. Available at www.retevmo.com. Accessed January 7, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	07/07/2020	09/14/2020