

POLICY NUMBER UM_Onc_1405	SUBJECT Retevmo™ (selpercatinib)	DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 06/10/20	APPROVAL DATE June 10, 2020	EFFECTIVE DATE June 26, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 06/10/20
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee	
URAC STANDARDS	NCQA STANDARDS	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS	APPLICABLE LINES OF BUSINESS All	

I. PURPOSE

To define and describe the accepted indications for Retevmo (selpercatinib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

- a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies **AND**
- d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
- e. When available, generic alternatives are preferred over brand-name drugs.

2. Non-Small Cell Lung Cancer

- a. Member has advanced or metastatic Non-Small Cell Lung Cancer that is positive for a RET-genomic alteration (fusion or mutation, confirmed by a gene sequencing test) **AND**
- b. Retevmo (selpercatinib) will be used as a single agent as first or subsequent line of therapy.

3. Thyroid Cancer



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- a. Adult and pediatric members ≥ 12 years of age with advanced/metastatic RET-mutation /RET-fusion positive Medullary Thyroid Cancer who require systemic therapy **OR**
- b. Adult and pediatric members ≥ 12 years of age with RET- fusion/RET-mutation positive thyroid cancer (all non-Medullary histologies are included) who require systemic therapy, and have disease that is refractory to radioactive iodine (if radioactive iodine is appropriate therapy for their thyroid cancer- their cancer is positive for radioactive iodine uptake on appropriate scanning) **AND**
- c. Retevmo (selpercatinib) will be used as a single agent.

III. EXCLUSION CRITERIA

1. Lack of confirmation of a positive RET- genomic alteration (fusion or mutation).
2. Disease progression while receiving Retevmo or another MET inhibitor e.g. vandetinib/cabozantinib.
3. Concurrent use with other anti-cancer therapy including targeted therapy, immunotherapy and/or chemotherapy.
4. Dosing exceeds single dose limit of Retevmo (selpercatinib) 320 mg.
5. Treatment exceeds the maximum limit of 180 (40 mg) or 120 (80 mg) tablets/month.
6. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Retevmo PI prescribing information. Lilly USA, LLC, Indianapolis, IN 2020.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.