

STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

SELPERCATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELPERCATINIB	RETEVMO	46525		GPI-10	
				(2153577900)	

GUIDELINES FOR USE

- 1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient's cancer has a RET gene fusion, as detected by an FDA-approved test

If yes, approve for 12 months by GPID or GPI-14 for all strengths as follows:

40mg: #6 per day.80mg: #4 per day.

If no, continue to #2.

- 2. Does the patient have a diagnosis of advanced or metastatic medullary thyroid cancer (MTC) and meet **ALL** of the following criteria?
 - The patient is 12 years of age or older
 - The patient's cancer has a RET-mutation, as detected by an FDA-approved test
 - The patient requires systemic therapy

If yes, approve for 12 months by GPID or GPI-14 for all strengths as follows:

40mg: #6 per day.80mg: #4 per day.

If no, continue to #3.

- 3. Does the patient have a diagnosis of advanced or metastatic thyroid cancer and meet **ALL** of the following criteria?
 - The patient is 12 years of age or older
 - The patient's cancer has a RET gene fusion, as detected by an FDA-approved test
 - The patient requires systemic therapy
 - The thyroid cancer is refractory to radioactive iodine therapy (if radioactive iodine is appropriate)

If yes, approve for 12 months by GPID or GPI-14 for all strengths as follows:

40mg: #6 per day.

• 80mg: #4 per day.

If no, continue to #4.

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GUIDELINES FOR USE (CONTINUED)

- 4. Does the patient have a diagnosis of locally advanced or metastatic solid tumors and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient's tumor has a *RET* gene fusion
 - The tumor has progressed on or following prior systemic treatment OR the patient has no satisfactory alternative treatment options

If yes, approve for 12 months by GPID or GPI-14 for all strengths as follows:

- 40mg: #6 per day.
- 80mg: #4 per day.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SELPERCATINIB** (**Retevmo**) requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
 - 1. Locally advanced or metastatic non-small cell lung cancer (a type of lung cancer that has spread to nearby tissue or lymph nodes, or has spread to other parts of the body)
 - 2. Advanced or metastatic medullary thyroid cancer (a type of thyroid cancer that has progressed or has spread to other parts of the body)
 - 3. Advanced or metastatic thyroid cancer (thyroid cancer that has progressed or has spread to other parts of the body)
 - 4. Locally advanced or metastatic solid tumors (abnormal mass that has spread to nearby tissue or lymph nodes, or has spread to other parts of the body)
- B. If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:
 - 1. You are 18 years of age or older
 - 2. Your cancer has a rearranged during transfection (*RET*: type of gene) gene fusion, as detected by a Food and Drug Administration (FDA) approved test
- C. If you have advanced or metastatic medullary thyroid cancer, approval also requires:
 - 1. You are 12 years of age or older
 - 2. Your cancer has a rearranged during transfection (*RET*: type of gene) mutation, as detected by a Food and Drug Administration (FDA) approved test
 - 3. You require systemic therapy (treatment that travels through the entire body)

(Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

- D. If you have advanced or metastatic thyroid cancer, approval also requires:
 - 1. You are 12 years of age or older
 - 2. You require systemic therapy (treatment that travels through the entire body)
 - 3. Your cancer has a rearranged during transfection (*RET*: type of gene) gene fusion, as detected by a Food and Drug Administration (FDA) approved test
 - 4. Your thyroid cancer is refractory (has not responded) to radioactive iodine therapy, if radioactive iodine is appropriate
- E. If you have locally advanced or metastatic solid tumors, approval also requires:
 - 1. You are 18 years of age or older
 - 2. Your tumor has a rearranged during transfection (*RET*: type of gene) gene fusion
 - 3. Your tumor has progressed on or following prior systemic treatment OR you have no satisfactory alternative treatment options

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Retevmo.

REFERENCES

Retevmo [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; September 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A Created: 07/20

Commercial Effective: 10/17/22 Client Approval: 09/22 P&T Approval: 10/22

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