



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

PRALSETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PRALSETINIB	GAVRETO	46818		GPI-10 (2153575000)	

**GUIDELINES FOR USE**

1. Does the patient have a diagnosis of 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 has a *RET* fusion-positive tumor as detected by an FDA-approved test

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**  
If no, continue to #2.

2. 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 has a *RET* fusion-positive tumor
  - The patient requires systemic therapy
  - The patient is radioactive iodine-refractory (if radioactive iodine is appropriate)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #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 **PRALSETINIB (Gavreto)** requires the following rule(s) be met for approval:

A. You have ONE of the following:

1. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
2. Advanced or metastatic thyroid cancer (thyroid cancer that has spread to other parts of the body)

B. **If you have metastatic non-small cell lung cancer, approval also requires:**

1. You are 18 years of age or older
2. You have a rearranged during transfection (*RET*) fusion-positive (a type of gene mutation) tumor that has been detected by a Food and Drug Administration (FDA)-approved test

**(Denial text continued on next page)**

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GUIDELINES FOR USE (CONTINUED)

C. If you have advanced or metastatic thyroid cancer, approval also requires:

1. You are 12 years of age or older
2. You have a rearranged during transfection (*RET*) fusion-positive (a type of gene mutation) tumor
3. You need systemic therapy (treatment that targets the entire body)
4. You have received treatment with radioactive iodine, and it did not work or is no longer working (if radioactive iodine is an appropriate treatment option)

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 Gavreto.

REFERENCES

- Gavreto [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 09/11/23

Created: 10/20

Client Approval: 08/23

P&T Approval: 10/23