

Clinical Policy Title:	pralsetinib
Policy Number:	RxA.657
Drug(s) Applied:	Gavreto®
Original Policy Date:	11/18/2020
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (NSCLC) (must meet all):

1. Diagnosis of recurrent, advanced or metastatic NSCLC;
2. Member has RET fusion-positive disease (e.g., CCDC6-RET, KIF5B-RET);
3. Gavreto™ will be used as a single agent;
4. Gavreto is not prescribed concurrently with Retevmo™;
5. Member has not received prior RET targeted therapy (e.g., Retevmo™).

Approval Duration

All Lines of Business (except Medicare): 6 months

B. Thyroid Cancer (must meet all):

1. The member must have one of the following disease states (a or b):
 - a. Diagnosis of advanced or metastatic RET-mutant medullary thyroid cancer (MTC);
 - b. Diagnosis of advanced or metastatic RET fusion positive thyroid cancer who are radioactive iodine-refractory (if radioactive iodine is appropriate).
2. Gavreto™ will be used as a single agent as first or subsequent line of therapy;
3. Gavreto™ is not prescribed concurrently with Retevmo™;
4. Member has not received prior RET targeted therapy (e.g., Retevmo™).

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 8.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed August 28, 2024.
2. National Comprehensive Cancer Network. Thyroid Carcinoma Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed August 28, 2024.

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	11/18/2020	12/07/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Initial Approval Criteria I.B. was updated to include a new indication, " Thyroid Cancer". Continued Approval Criteria for thyroid cancer was also added. 2. References were reviewed and updated. 	10/19/2021	12/07/2021
Policy was reviewed: <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of recurrent, advanced or metastatic disease with RET rearrangement positive tumors NSCLC to Diagnosis of recurrent, advanced or metastatic NSCLC. 2. Initial Approval Criteria, I.A.4: Updated to remove prior diagnostic criteria "Member have an ECOG performance status of 0–1". 3. Initial Approval Criteria, I.A.4: Updated to include new diagnostic criteria Member has RET fusion-positive disease (e.g., CCDC6-RET, KIF5B-RET). 4. Initial Approval Criteria, I.A.5: Updated to remove prior diagnostic criteria "Member does not have another known mutation or primary driver alteration". 5. Initial Approval Criteria, I.A.5: Updated prescribing criteria from Gavreto™ will be used as a single agent as first or subsequent line of therapy to Gavreto™ will be used as a single agent. 6. Initial Approval Criteria, I.A.6 and I.B.5: Updated to include new combination therapy criteria Gavreto is not prescribed concurrently with Retevmo™. 7. Initial Approval Criteria, I.A.7 and I.B.6: Updated to include prior 	09/01/2022	10/19/2022

<p>therapy criteria Member has not received prior RET targeted therapy (e.g., Retevmo™).</p> <p>8. Continued Therapy Approval Criteria, II.A.3: Updated to include new combination therapy criteria Gavreto is not prescribed concurrently with Retevmo™.</p> <p>9. Continued Therapy Approval Criteria, II.A.4: Updated to include prior therapy criteria Member has not received prior RET targeted therapy (e.g., Retevmo™).</p> <p>10. Continued Therapy Approval Criteria, II.A: Updated approval duration criteria from 6 months to 12 months.</p> <p>11. Reference were reviewed and updated.</p>		
Policy was reviewed.	10/19/2023	10/19/2023
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed other reauthorization requirements including positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated. 	08/28/2024	09/13/2024
Policy was reviewed.	12/05/2024	N/A
Policy reviewed.	12/11/2025	12/11/2025