Clinical Policy Title:	pralsetinib
Policy Number:	RxA.657
Drug(s) Applied:	Gavreto™
Original Policy Date:	11/18/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Gavreto™ (pralsetinib) is a kinase inhibitor indicated for the treatment of adult patients with metastatic rearranged during transfection (RET) fusion- positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s)

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
pralsetinib (Gavreto™)	Metastatic RET fusion positive NSCLC	400 mg PO once daily on an empty stomach	400 mg PO once daily.

Dosage Forms

- Capsules: 100 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 (must meet al):

1. Diagnosis of recurrent, advanced or metastatic disease with RET rearrangement positive tumors NSCLC;
2. Age > 18;
3. Prescribed by or in consultation with an oncologist;
4. Member have an ECOG performance status of 0–1;
5. Member does not have another known mutation or primary driver alteration;
6. Gavreto™ will be used as a single agent as first or subsequent line of therapy.
7. Dose does not exceed 400 mg PO once daily.

Approval Duration

Commercial: 6 months

Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria for the covered indications and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 400 mg PO once daily.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
NSCLC: non-small cell lung cancer
RET: rearranged during transfection
ECOG: Eastern Cooperative Oncology Group

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Retevmo™ (selpercatinib)	Weight < 50 kg: 120 mg PO BID Weight ≥ 50 kg: 160 mg PO BID	Weight < 50 kg: 240 mg/day Weight ≥ 50 kg: 320 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None
- Boxed Warning(s):
  - None

APPENDIX D: General Information

- Gavreto is a once-daily oral targeted therapy for people living with RET-positive non–small cell lung cancer (NSCLC) that has spread to other parts of the body, or metastasized

References

1. Gavreto (pralsetinib) [prescribing information]. Cambridge, MA: Blueprint Medicines Corporation; September 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213721s000lbl.pdf . Accessed on November 18, 2020.
2. Gainor JF, Curigliano G, Kim DW, et al. Registrational dataset from the phase I/II ARROW trial of pralsetinib (BLU-667) in patients (pts) with advanced RET fusion+ non-small cell lung cancer (NSCLC). J Clin Oncol. 2020;38(suppl):9515. doi: 10.1200/JCO.2020.38.15_suppl.9515. Accessed on November 18, 2020
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 8.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf . Accessed on November 18, 2020

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	11/18/2020	12/07/2020