

Clinical Policy Title:	sotorasib
Policy Number:	RxA.695
Drug(s) Applied:	Lumakras®
Original Policy Date:	8/18/2021
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 (must meet all):

1. Diagnosis of locally advanced or metastatic non-small cell lung cancer;
2. Diagnosis is positive for KRAS G12C mutation as detected by an FDA-approved test;
3. Member has received at least one prior systemic therapy;
4. Prescribed as a single agent.

B. Colorectal Cancer (must meet all):

1. Diagnosis of metastatic colorectal cancer;
2. Diagnosis is positive for KRAS G12C mutation as detected by an FDA-approved test;
3. Prescribed in combination with panitumumab;
4. Member has received prior fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indication 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 3.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed March 31, 2025.
2. John H. Strickler, Hironaga Satake, Thomas J. George et.al. Sotorasib in KRAS p.G12C–Mutated Advanced Pancreatic Cancer. N Engl J Med 2023; 388:33-43. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMoa2208470#:~:text=Mutations%20in%20the%20Kirsten%20rat%20sarcoma%20viral%20oncogene,molecule%20that%20specifically%20and%20irreversibly%20inhibits%20KRAS%20G12C>. Accessed March 31, 2025.

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.	8/18/2021	09/14/2021
Policy was reviewed: 1. References were reviewed and updated.	4/21/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, Pancreatic Adenocarcinoma (Off-label). 2. Continued Therapy Approval criteria, II.B: Updated to include approval criteria for indication, Pancreatic Adenocarcinoma (Off-label). 3. References were reviewed and updated.	05/29/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 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 reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. Reauthorization criteria for all the diagnosis merged under "All Indications in Section I". 8. References were reviewed and updated.	8/28/2024	9/13/2024
Policy was reviewed: 1. Added new indication, mCRC. 2. Added prescribed as single agent for NSCLC.	03/31/2025	04/10/2025

3. References were reviewed and updated.		
Policy reviewed.	12/11/2025	12/11/2025