Clinical Policy Title:	sotorasib
Policy Number:	RxA.695
Drug(s) Applied:	Lumakras™
Original Policy Date:	8/18/2021
Last Review Date:	9/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Sotorasib (Lumakras™) is an inhibitor of the RAS GTPase family indicated for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy.

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
sotorasib (Lumakras™)	Non-small cell lung cancer	960 mg orally once daily	960 mg orally once daily

Dosage Forms

- Tablets: 120 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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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. Prescribed by or in consultation with oncologist;
3. Age ≥ 18 years;
4. Member has KRAS G12C–mutated NSCLC as determined by an FDA-approved test;
5. Failure of at least one (1) systemic therapy (cisplatin-based therapy, carboplatin-based therapy, anthracyclines, taxanes) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;

6. Dose does not exceed 960 mg orally once daily.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Non-small cell lung cancer (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, dose does not exceed 960 mg orally once daily.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
NSCLC: non-small cell lung cancer
ORR: overall response rate
DOR: duration of response
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives
N/A

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported

- Boxed Warning(s):
  - None reported

APPENDIX D: General Information

- Lumakras™ has drug interactions, and providers should avoid coadministration with proton pump inhibitors, H2 receptor antagonists, and strong cytochrome P450 3A4 (CYP3A4) inducers, and certain CYP3A4 substrates and P-gp substrates. If an acid-reducing agent cannot be avoided, Lumakras™ must be taken either 4 hours before or 10 hours after the antacid.

References

1. Lumakras™ prescribing information. Thousand Oaks, CA; Amgen Inc.; May 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214665s000lbl.pdf. Accessed August 18, 2021.
2. IPD Analytics IPD Analytics Rx Insights_New Drug Review_Lumakras_06 2021.pdf. Available at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=lumakras. Accessed August 18, 2021.
3. National Comprehensive Cancer Network. Non-small cell lung cancer. Version 5.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed August 18, 2021.
4. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 18, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	8/18/2021	09/14/2021