Clinical Policy: Sotorasib (Lumakras)

Reference Number: ERX.SPA.443
Effective Date: 09.01.21
Last Review Date: 08.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Sotorasib (Lumakras™) is an inhibitor of $KRAS^{G12C}$, a tumor-restricted, mutant-oncogenic form of the RAS GTPase, KRAS.

FDA Approved Indication(s)
Lumakras is 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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Lumakras is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of recurrent, locally advanced or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is positive for KRAS G12C mutation;
5. Member has received at least one systemic therapy *(see Appendix B)*;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 960 mg (8 tablets) per day;
   b. Dose is supported by practice guideline or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Lumakras for a covered indication 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, request meets one of the following (a or b):*
   a. New dose does not exceed 960 mg (8 tablets) per day;
   b. New dose is supported by practice guideline or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*
Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
NSCLC: non-small cell lung cancer

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
cisplatin- or carboplatin-containing chemotherapy	Varies	Varies
Imfinzi® (durvalumab)	10 mg/kg IV every 2 weeks or 1,500 mg every 4 weeks	1,500 mg every 4 weeks
Keytruda® (pembrolizumab)	200 mg IV every 3 weeks OR 400 mg every 6 weeks up to 24 months	400 mg every 6 weeks
Libtayo® (cemiplimab-rwlc)	350 mg IV every 3 weeks	350 mg every 3 weeks
Opdivo® (nivolumab)	240 mg IV every 2 weeks or 480 mg IV every 4 weeks	480 mg every 4 weeks
Tecentriq® (atezolizumab)	840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks	1,680 mg every 4 weeks
Yervoy® (ipilimumab)	In combination with Opdivo: 1 mg/kg IV every 6 weeks	1 mg/kg every 6 weeks

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
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NSCLC	960 mg PO QD	960 mg/day

VI. Product Availability

Tablet: 120 mg

VII. References

1. Lumakras Prescribing Information. Thousand Oaks, CA: Amgen Inc.; May 2021. Available at: www.lumakras.com. Accessed April 14, 2022.
2. National Comprehensive Cancer Network. Non-small cell lung cancer Version 3.2022. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed April 14, 2022.
3. Skoulidis F, Li BT, Dy GK, et al. Sotorasib for lung cancers with KRAS p.G12C mutation. N Engl J Med 2021 Jun 4; 384:2371-2381.doi: 10.1056/NEJMoa2103695. Accessed June 14, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	06.14.21	08.21
3Q 2022 annual review: no significant changes; added option for recurrent disease per NCCN; removed option to bypass failure of at least one systemic therapy if contraindicated or clinically significant adverse effects are experienced per prescribing information; references reviewed and updated.	04.14.22	08.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.