

Reference number(s)
4766-A

SPECIALTY GUIDELINE MANAGEMENT

LUMAKRAS (sotorasib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Documentation of the presence of KRAS G12C mutation in tumor or plasma specimens.

III. CRITERIA FOR INITIAL APPROVAL

Non-Small Cell Lung Cancer (NSCLC)

Authorization of 12 months may be granted for treatment of KRAS G12C-mutated locally advanced or metastatic NSCLC in members who have received at least one prior systemic therapy, as a single agent.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Lumakras [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2021.