Sotorasib (LUMAKRAS)
Criteria for Use
July 2021

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at *www.pbm.va.gov* or *PBM INTRAnet* for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive sotorasib.

- ☐ Strong CYP 3A4 Inducers
- ☐ Proton Pump Inhibitors or H2 receptor antagonist^1
- ☐ Inability to manage CYP3A4 or P-gp substrates
- ☐ Estimated Creatinine Clearance <30 mL/min
- ☐ Moderate or Severe Hepatic Insufficiency (AST or ALT ≥2.5 X ULN [≥5 x ULN for liver metastases] or total bilirubin ≥1.5 X ULN [≥2.0 X ULN for Gilbert's syndrome])
- ☐ Untreated brain metastases
- ☐ Pregnancy (i.e. known pregnancy or positive pregnancy test)
- ☐ Breastfeeding

^1 If acid-reducing therapy required, give sotorasib 4 hours before or 10 hours after administration of a local antacid

Inclusion Criteria

The answers to ALL of the following must be fulfilled in order to meet criteria.

- ☐ Care is provided by a VA/VA Community Care oncology provider
- ☐ Eastern Cooperative Oncology Group (ECOG) performance status 0-2
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented
- ☐ Patients of child-bearing potential and patients with partners of child-bearing potential: counseling provided on contraception and risks vs. benefits of treatment. Use effective contraception and avoid breastfeeding during therapy and for 1 week after the last dose.

Additional Inclusion Criteria

The answer to the following must be fulfilled in order to meet criteria:

- ☐ Patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer who have received at least 1 prior systemic therapy.^1

^1Monitor LFTs every 3 weeks for the first 3 months then monthly as indicated

Prepared: July 2021 Contact: Mark C. Geraci, Pharm.D., BCOP, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services 10P4P