

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Krazati Prior Authorization Policy

- Krazati™ (adagrasib tablets – Mirati Therapeutics)

REVIEW DATE: 12/14/2022

OVERVIEW

Krazati, a Kirsten RAf Sarcoma virus (*KRAS*) inhibitor, is indicated for the treatment of adults 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.¹ This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of a clinical benefit in a confirmatory trial(s).

Mutations in the *KRAS* gene most commonly occur at codon 12.² Data suggest that approximately 30% of patients with NSCLC have *KRAS* mutations. The prognosis of survival of patients with tumors with *KRAS* mutation is poorer compared with that of patients with tumors without *KRAS* mutation.

Guidelines

National Comprehensive Cancer Network (NCCN) NSCLC guidelines (version 1.2023 – December 22, 2022) recommend Krazati as a subsequent treatment option, for use after at least one prior systemic treatment (i.e., second-line and beyond) if the patient has not received previous *KRAS G12C*-targeted therapy [category 2A]. Patients who progressed on Lumakras™ (sotorasib tablets), another *KRAS* inhibitor directed at *KRAS G12C*-mutated NSCLC, should not be treated with Krazati; and vice-versa.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Krazati. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Krazati is recommended in those who meet the following criteria:

FDA-Approved Indication

1. Non-Small Cell Lung Cancer (NSCLC). Approve for 1 year if the patient meets the following criteria (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) Patient has *KRAS G12C*-mutated locally advanced or metastatic NSCLC, as determined by an approved test; AND

C) Patient has been previously treated with at least one systemic regimen.

Note: Examples of systemic regimens include those containing one or more of the following products: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous

infusion), Tecentriq (atezolizumab intravenous infusion), Alimta (pemetrexed intravenous infusion), Yervoy (ipilimumab intravenous infusion), Abraxane (albumin-bound paclitaxel intravenous infusion), bevacizumab, cisplatin, carboplatin, docetaxel, gemcitabine, paclitaxel, vinorelbine.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Krazati is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Krazati™ tablets [prescribing information]. San Diego, CA: Mirati Therapeutics; December 2022.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 1.2023 - December 22, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 22, 2022.