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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	January 6, 2023
Subject:	Krazati	**Page:**	1 of 4

Last Review Date: March 8, 2024

Krazati

Description

Krazati (adagrasib)

Background
Krazati (adagrasib) is an irreversible inhibitor of KRAS G12C that covalently binds to the mutant cysteine in KRAS G12C and locks the mutant KRAS protein in its inactive state and prevents downstream signaling without affecting wild-type KRAS protein. Krazati inhibits tumor cell growth and viability in cells harboring KRAS G12C mutations and results in tumor regression in KRAS G12C-mutated tumor xenograft models with minimal off-target activity (1).

Regulatory Status
FDA-approved indication: Krazati 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 (1).

Krazati has warnings regarding gastrointestinal adverse reaction, QTc interval prolongation, hepatotoxicity, and interstitial lung disease (ILD)/pneumonitis. Liver function tests (ALT, AST, alkaline phosphatase, and total bilirubin) should be monitored prior to the start of Krazati and monthly for 3 months or as clinically indicated (1).

The safety and effectiveness of Krazati in pediatric patients less than 18 years of age have not been established (1).

Related policies

Lumakras

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Krazati may be considered **medically necessary** if the conditions indicated below are met.

Krazati may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Locally advanced or metastatic non-small cell lung cancer (NSCLC)

AND ALL of the following:

1. Presence of KRAS G12C mutation as determined by an FDA-approved test
2. Patient has received at least one prior systemic therapy
3. Prescriber agrees to monitor AST, ALT, alkaline phosphatase, and total bilirubin
4. Prescriber agrees to monitor for QTc prolongation as clinically indicated

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Locally advanced or metastatic non-small cell lung cancer (NSCLC)

AND ALL of the following:

1. **NO** disease progression or unacceptable toxicity
2. Prescriber agrees to monitor AST, ALT, alkaline phosphatase, and total

bilirubin

3. Prescriber agrees to monitor for QTc prolongation as clinically indicated

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Strength	Quantity
200 mg	540 tablets per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Krazati (adagrasib) 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). Krazati contains warnings regarding gastrointestinal adverse reactions, QTc interval prolongation, hepatotoxicity, and interstitial lung disease (ILD)/pneumonitis. The safety and effectiveness of Krazati in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Krazati while maintaining optimal therapeutic outcomes.

References

1. Krazati [package insert]. San Diego, CA: Mirati Therapeutics. Inc.; December 2022.
2. NCCN Drugs & Biologics Compendium® Adagrasib 2024. National Comprehensive Cancer Network, Inc. Accessed on January 29, 2024.

Policy History

Date	Action
January 2023	Addition to PA
March 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.