

UnitedHealthcare Pharmacy Clinical Pharmacy Programs

| Program Number | 2023 P 1404-1 |
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| Program | Prior Authorization/Notification |
| Medication | Krazati [™] (adagrasib) |
| P&T Approval Date | 2/2023 |
| Effective Date | 5/1/2023; |
| | Oxford only: 5/1/2023 |

1. Background:

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), who have received at least one prior systemic therapy.

The National Comprehensive Cancer Network (NCCN) recommends use of Krazati as subsequent therapy as a single agent for KRAS G12C mutation positive recurrent, advanced, or metastatic disease. Krazati may be used after at least one line of therapy (or second line and beyond) if no previous KRAS G12C-targeted therapy. Lumakras (sotorasib) and Krazati have a similar mechanism of action and it is not recommended to switch between these agents at the time of progression.

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria^a:

A. Patients less than 19 years of age

- 1. **Krazati** will be approved based on the following criterion:
 - a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. Non-Small Cell Lung Cancer (NSCLC)

1. Initial Authorization

- a. **Krazati** will be approved based on the following criteria:
 - (1) Diagnosis of non-small cell lung cancer (NSCLC)

-AND-



(2) Presence of KRAS G12C mutation

-AND-

- (3) Disease is **one** of the following:
 - (a) Recurrent
 - (b) Advanced
 - (c) Metastatic

-AND-

(4) Patient has received at least one prior systemic therapy

Authorization will be issued for 12 months.

2. Reauthorization

- a. **Krazati** will be approved based on the following criterion:
 - (1) Patient does not show evidence of progressive disease while on Krazati therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits and/or step therapy may be in place.

4. References:

- 1. Krazati [package insert]. San Diego, CA: Mirati Therapeutics, Inc.; December 2022.
- 2. The NCCN Drugs and Biologics Compendium (NCCN Compendium[™]). Available at https://www.nccn.org. Accessed on December 28, 2022.



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| Change Control | |
| 2/2023 | New program |