UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1404-2
Program	Prior Authorization/Notification
Medication	Krazati™ (adagrasib)
P&T Approval Date	2/2023, 2/2024
Effective Date	5/1/2024

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 for *KRAS G12C*-mutated recurrent, advanced, or metastatic NSCLC. The NCCN also recommends the use of Krazati as subsequent therapy for the treatment of *KRAS G12C*-mutated recurrent, advanced or metastatic colon cancer, rectal cancer, and pancreatic adenocarcinoma as well as for the treatment of brain metastases in *KRAS G12C*-mutated NSCLC and *KRAS G12C* mutation positive ampullary adenocarcinoma.

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. <u>Patients less than 19 years of age</u>

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. <u>Non-Small Cell Lung Cancer (NSCLC)</u>

1. **<u>Initial Authorization</u>**

   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. Colon Cancer

1. **Initial Authorization**

a. **Krazati** will be approved based on the following criteria:

(1) Diagnosis of colon cancer

-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.

D. Rectal Cancer

1. **Initial Authorization**

a. **Krazati** will be approved based on the following criteria:

(1) Diagnosis of rectal cancer

-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.

E. Ampullary Adenocarcinoma

1. **Initial Authorization**

a. Krazati will be approved based on the following criteria:

(1) Diagnosis of ampullary adenocarcinoma

-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.

F. Pancreatic Adenocarcinoma

1. **Initial Authorization**

a. **Krazati** will be approved based on the following criteria:

(1) Diagnosis of pancreatic adenocarcinoma

-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.

G. 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 26, 2023.

Program	Prior Authorization/Notification – Krazati (adagrasib)
Change Control	
2/2023	New program
2/2024	Annual review. Added criteria for NCCN recommended use of Krazati in colon cancer, rectal cancer, ampullary adenocarcinoma and pancreatic adenocarcinoma. Updated background and references.