Generic Name: adagrasib

Applicable Drugs: Krazati

Preferred: N/A

Non-preferred: Krazati (adagrasib)

Date of Origin: 8/28/2023

Date Last Reviewed / Revised: 5/12/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Documented diagnosis of one of the following A or B AND must meet all criteria listed under applicable diagnosis:

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

      i. Presence of *KRAS* G12C mutation documented by an FDA-approved test.

      ii. Documentation of disease progression despite prior treatment with one systemic regimen (e.g., platinum-based chemotherapy ± immunotherapy).

   B. Locally advanced or metastatic colorectal cancer (CRC):

      i. Presence of *KRAS* G12C mutation documented by an FDA-approved test.

      ii. Documentation that adagrasib will be used in combination with cetuximab.

      iii. Documentation of disease progression despite prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

II. Age: ≥ 18 years old.

III. Medication dosage and/or dose adjustments are consistent with FDA labeling (see table 1).

IV. Treatment must be prescribed by or in consultation with an oncologist.

V. Request is for a medication with the appropriate FDA labeling and dosage, or its use is supported by current clinical practice guidelines.

VI. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Disease progression with prior treatment on Lumakras (sotorasib).

OTHER CRITERIA

- N/A

Quantity / Days Supply Restrictions

Adagrasib is available as 200 mg tablets.

- 1200 mg dose/day: 180 tablets per 30 days.
- 800 mg dose/day: 120 tablets per 30 days.
- 600 mg dose/day: 90 tablets per 30 days.

Approval Length

- **Authorization:** 6 months
- **Re-Authorization:** 6 months, with an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective and well-tolerated (e.g., no disease progression or unacceptable toxicity).

Appendix

Table 1. FDA-labeled initial dosage recommendations and dosage reductions

Initial dose	First dose reduction	Second dose reduction
600 mg orally twice daily	400 mg orally twice daily	600 mg once daily

References

1. Krazati. Prescribing information. Mirati Therapeutics, Inc.; 2024. Accessed May 12, 2025. https://www.mirati.com/krazati_uspi/
2. Jänne PA, Riely GJ, Gadgeel SM, et al. Adagrasib in non-small-cell lung cancer harboring a KRASG12C mutation. *N Engl J Med.* 2022;387(2):120-131. doi: 10.1056/NEJMoa2204619
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer (Version 3.2025). https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed May 12, 2025.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Colon Cancer (Version 3.2025). https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed May 12, 2025.