Reference number(s)
5699-A

Specialty Guideline Management
Krazati

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Krazati	adagrasib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

- Krazati is indicated as a single agent for the treatment of adult patients with Kirsten rat sarcoma (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.
- Krazati is indicated in combination with cetuximab for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic colorectal cancer (CRC), as determined by an FDA-approved test, who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

Compendial Uses[2-4]

- Non-small cell lung cancer
- Pancreatic adenocarcinoma
- Colorectal cancer
- Ampullary adenocarcinoma

- Biliary tract cancers
- Small bowel adenocarcinoma

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Documentation of the presence of KRAS G12C mutation

Coverage Criteria

NSCLC[1,2]

Authorization of 12 months may be granted for treatment of recurrent, advanced, or metastatic KRAS G12C mutation positive NSCLC as a single agent when either of the following criteria are met:

- The member has received at least one prior systemic therapy and has not experienced disease progression on KRAS G12C-targeted therapy.
- The member has brain metastases.

Pancreatic Adenocarcinoma[2]

Authorization of 12 months may be granted for treatment of recurrent, locally advanced or metastatic pancreatic adenocarcinoma when all of the following criteria are met:

- The tumor or plasma specimen is positive for the KRAS G12C mutation.
- Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2.
- The requested medication will be used as a single agent.

Colorectal Cancer[1-4]

Authorization of 12 months may be granted for treatment of advanced or metastatic colorectal cancer, including appendiceal adenocarcinoma, and anal adenocarcinoma when all of the following criteria are met:

- The tumor or plasma specimen is positive for the KRAS G12C mutation.
- The requested medication will be used as a single agent, or in combination with cetuximab (Erbitux) or panitumumab (Vectibix).
- The member previously received treatment with chemotherapy.

Ampullary Adenocarcinoma[2]

Authorization of 12 months may be granted for treatment of progressive ampullary adenocarcinoma when both of the following criteria are met:

- The requested medication will be used as a single agent.
- The tumor or plasma specimen is positive for the KRAS G12C mutation.

Biliary Tract Cancers[2]

Authorization of 12 months may be granted for subsequent treatment of unresectable, gross residual (R2), or metastatic biliary tract cancers (including intrahepatic and extrahepatic cholangiocarcinoma and gallbladder cancer), when both of the following criteria are met:

- The requested medication will be used as a single agent.
- The tumor or plasma specimen is positive for the KRAS G12C mutation.

Small Bowel Adenocarcinoma[2]

Authorization of 12 months may be granted for subsequent treatment of advanced or metastatic small bowel adenocarcinoma when both of the following criteria are met:

- The requested medication will be used as a single agent.
- The tumor or plasma specimen is positive for the KRAS G12C mutation.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Krazati [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; July 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed July 10, 2025.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Colon Cancer. Version 4.2025. Accessed July 10, 2025. https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf.
4. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Anal Carcinoma. Version 4.2025. Accessed July 10, 2025. https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf.