Medica Coverage Policy

Policy Name: KRAS Mutation Analysis for Predicting Response to Drug Therapy
Effective Date: 9/20/2021

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy
KRAS mutation analysis COVERED for:

- Predicting response to anti-epidermal growth factor receptor (EGFR) monoclonal antibodies for patients with non-small cell lung cancer (NSCLC).
- **Note:** Appropriate use of KRAS mutation analysis for individuals with metastatic colorectal cancer is addressed in Medica’s position statement, *Genetic Testing for Colorectal Cancer*.

KRAS mutation analysis for all other indications is considered investigative and unproven and therefore NOT COVERED. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the safety and efficacy or effects on health care outcomes.

**Note:** Pharmacogenetic testing is not investigative when testing for a specific gene biomarker is required by the U.S. Food and Drug Administration (FDA) prior to initiating drug therapy for treatment of colorectal cancer. A list of FDA required tests (by test name and manufacturer) can be found on the FDA’s site, List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools), located at: [https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools](https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools).

**Note:** See also related Medica coverage policies; *Genetic Testing for Colorectal Cancer (CRC)* and *Liquid Biopsy: Testing of Circulating Tumor Cells or Cell-Free Tumor DNA*; and *Genetic and Pharmacogenetic Testing*.

Description
KRAS is in an oncogene that plays an important role in regulating the epidermal growth factor receptor (EGFR) pathway. It acts as an on and off switch for cell division. Mutations in the KRAS gene interrupt this pathway and may affect a patient’s response to anti-EGFR monoclonal antibodies and chemotherapies. Associations between mutations in the KRAS gene and effectiveness of therapy have been found in patients with metastatic colorectal cancer receiving the anti-EGFR monoclonal antibodies cetuximab (Erbitux®) and panitumumab (Vectibix®). It has been suggested that non-small cell lung cancer (NSCLC) patients with KRAS mutations do not respond to treatment with EGFR tyrosine kinase inhibitors such as erlotinib (Tarceva®) and gefitinib (Iressa®). The influence of KRAS mutations on the effectiveness of treatments for other cancers, including pancreatic and ovarian cancer, is under study. KRAS mutation testing is performed on biopsied tumor tissue and is available commercially at several laboratories regulated by the Clinical Laboratory Improvement Amendments (CLIA).
FDA Approval
Genetic tests are regulated under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. Premarket approval from the FDA is not required as long as the assay is performed in a laboratory facility that observes CLIA regulations.

Prior Authorization
Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:
- 81275 - KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis, variants in codons 12 and 13
- 81276 - KRAS (Kirsten rat sarcoma viral oncogene homolog) (eg, carcinoma) gene analysis; additional variant(s) (eg, codon 61, codon 146)
- 0111U – Praxis (TM) Extended RAS Panel [Illumina, Illumina]

Original Effective Date: 8/1/2009

Re-Review Date(s): 6/26/2012
7/15/2015
1/21/2016 – administrative update; code 81276 added
7/18/2018
11/1/2019 – administrative update; code 0111U added
2/17/2020 – administrative update; format
8/19/2020 – administrative update; coverage policy language
7/21/2021

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