Applicable To:
- ☑ Medicare
- ☑ Medicaid – excluding Nebraska, Arizona, and Kentucky

Claims and Payment Policy: Screening for Colorectal cancer Using Cologuard™ – A Multitarget Stool DNA Test

Policy Number: CPP- 103

Original Effective Date: 8/1/2018
Revised Effective Date(s): 2/18/2020

BACKGROUND

Evidence exists that reductions in colorectal cancer (CRC) mortality can be achieved through detection and treatment of early-stage CRCs and the identification and removal of adenomatous polyps, the precursor to these cancers. Colorectal cancer (CRC) is the second leading cause of death from cancer in the United States (Edwards et al., 2002). Research has shown that screening adults for early cancers or their precursor lesions, followed by appropriate therapy and continued surveillance, can reduce CRC incidence and mortality (Curry, 2003). A general consensus has emerged that periodic screening of adults is a valuable preventive intervention (United States General Accounting Office, 2004).

Screening stool or fecal DNA (deoxyribonucleic acid, sDNA) testing detects molecular markers of altered DNA that are contained in the cells shed by colorectal cancer and pre-malignant colorectal epithelial neoplasia into the lumen of the large bowel. Through the use of selective enrichment and amplification techniques, sDNA tests are designed to detect very small amounts of DNA markers to identify colorectal cancer or pre-malignant colorectal neoplasia. The Cologuard™ – multitarget sDNA test is a proprietary in vitro diagnostic device that incorporates both sDNA and fecal immunochemical test techniques and is designed to analyze patients' stool samples for markers associated with the presence of colorectal cancer and pre-malignant colorectal neoplasia.

The American Cancer Society 2018 guideline for colorectal cancer screening recommends that average-risk adults aged 45 years to 85 years of age undergo regular screening with either a high-sensitivity stool-based test or a structural (visual) exam, based on personal preferences and test availability. As a part of the screening process, all positive results on non-colonoscopy screening tests should be followed up with timely colonoscopy.

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POSITION STATEMENT

Per CMS National Coverage Determination (NCD), one Cologuard™ test every three years is a covered benefit for beneficiaries who meet all of the following criteria:

- Age 45 to 85 years
- Asymptomatic (no signs or symptoms of colorectal disease including, but not limited to, lower gastrointestinal pain, blood in stool, positive guaiac fecal occult blood test (gFOBT) or fecal immunochemical test (iFOBT))
- At average risk of developing colorectal cancer (no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn's Disease and ulcerative colitis; no family history of colorectal cancers or adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer).

All screening stool DNA tests not otherwise specified above are not covered benefits.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this payment policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this payment policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs should be reviewed prior to applying the criteria set forth in this payment policy. Refer to the CMS website at http://www.cms.gov for additional information.

CODING & BILLING

ICD-10 Codes

Z12.11	Encounter for screening for malignant neoplasm of colon
Z12.12	Encounter for screening for malignant neoplasm of rectum

CPT Codes

81528	Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result

DEFINITIONS

Colorectal cancer	Cancer that begins in the last part of the digestive tract-colon.
DNA genetic markers	A genetic marker is a gene or DNA sequence with a known location on a chromosome that can be used to identify individuals or species. It can be described as a variation (which may arise due to mutation or alteration in the genomic loci) that can be observed.

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Epithelial neoplasia	Abnormal cell growth that is found within epithelial cells but has not yet spread to neighboring, underlying, or distant tissues. Intraepithelial neoplasia is thought to be an early marker of some cancers.
Immunochemical test techniques	Immunochemistry is an advanced area of immunology. It deals with the chemical components and chemistry (chemical reactions) of immunological phenomena that is of antibody and antigen. Immunochemical methods are processes utilizing the highly specific affinity of an antibody for its antigen. The methods used for the immunochemical analysis are called Immunochemical techniques; they are highly important in diagnostic and clinical context, as now even normal cell with many proteins are altered in diseased state (in cancer).

REFERENCES

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IMPORTANT INFORMATION ABOUT THIS DOCUMENT

Claims and Payment Policies (CPPs) are policies regarding claims or claim line processing and/or reimbursement related to the administration of health plan benefits. They are not recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for diagnosing, treating, and making clinical recommendations to the member. CPPs are subject to, but not limited to, the following:

- State and federal laws and regulations;
- Policies and procedures promulgated by the Centers for Medicare and Medicaid Services, including National Coverage Determinations and Local Coverage Determinations;
- The health plan's contract with Medicare and/or a state's Medicaid agency, as applicable;
- Other CPPs and clinical policies as applicable including, but not limited to, *Pre-Payment and Post-Payment Review.*
- The provisions of the contract between the provider and the health plan; and
- The terms of a member's particular benefit plan, including those terms outlined in the member's Evidence of Coverage, Certificate of Coverage, and other policy documents.

In the event of a conflict between a CPP and a member's policy documents, the terms of a member's benefit plan will always supersede the CPP.

The use of this policy is neither a guarantee of payment, nor a prediction of how a specific claim will be adjudicated. Any coding information is for informational purposes only. No inference should be made regarding coverage or provider reimbursement as a result of the inclusion, or omission, in a CPP of a CPT, HCPCS, or ICD-10 code. Always consult the member's benefits that are in place at time of service to determine coverage or non-coverage. Claims processing is subject to a number of factors, including the member's eligibility and benefit coverage on the date of service, coordination of benefits, referral/authorization requirements, utilization management protocols, and the health plan's policies. Services must be medically necessary in order to be covered.

References to other sources and links provided are for general informational purposes only, and were accurate at the time of publication. CPPs are reviewed annually but may change at any time and without notice, including the lines of business for which they apply. CPPs are available at www.wellcare.com. Select the "Provider" tab, then "Tools" and then "Payment Guidelines".

RULES, PRICING & PAYMENT COMMITTEE HISTORY AND REVISIONS

Date	Action
N/A	• Approved by RGC

Original Effective Date: 08/21/2018- Revised:02/18/2020
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