Not Applicable for:

Kentucky Medicaid

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 Date(s): N/A

BACKGROUND

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 U.S. Preventive Services Task Force (USPSTF) has found convincing evidence that screening for colorectal cancer in adults ages 50 to 75 years reduces colorectal cancer mortality. The Task Force reports, with high certainty, that the net benefit (i.e., the benefit minus the harm) of screening for colorectal cancer in adults ages 50 to 75 years is substantial. The USPSTF reports with moderate certainty that the net benefit of screening for colorectal cancer in adults ages76 to 85 years who have been previously screened is small. Adults who have never been screened for colorectal cancer are more likely to benefit.

POSITION STATEMENT

One CologuardTM test every three years is a covered benefit for Medicare and Medicaid beneficiaries who meet all of the following criteria:

- Age 50 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)); and
- 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.

CODING & BILLING

ICD-10: Z12.11 and Z12.12
CPT Code: 81528

REFERENCES

1. https://www.cms.gov/medicare-coverage-database/(S(v0cxhe45alguxjupvjx24zai))/details/ncd-details.aspx?NCDId=281&ncdver=5&CALId=97&ver=5&CalName=Prothrombin+Time+and+Fecal+Occult+Blood+(Revision+of+ICD-9-CM+Codes+for+Injury+to+Gastrointestinal+Tract)&bc=gAgAAAAAgAIAAA%3D%3D&

2. https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/colorectal-cancer-screening2#tab

IMPORTANT INFORMATION ABOUT THIS DOCUMENT

Claims and Payment Policies (CPPs) are policies regarding claims 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 and Payment Committee (RPPC) Approvals

Date	Action
07/06/2018	• Approved by RPPC