

Mid-Atlantic States

Utilization *ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- For Medicare members, please refer to CMS guidelines through Medicare Coverage Database requirements and information as listed below.
- Note: After searching the Medicare Coverage Database, if no NCD/LCD/LCA is found, then use the policy referenced above for coverage guidelines

I. Service or Procedure: Cologuard

II. Specialty: Gastro-Intestinal

III. Description

- A. Cologuard is a non-invasive, multi-target stool DNA colon cancer screening test which use a multi-target fecal DNA (deoxyribonucleic acid, sDNA) to detect molecular markers of altered DNA contained in cells shed by colorectal cancer and pre-malignant colorectal epithelial neoplasia into the lumen of the large bowel. The screening tool incorporates both sDNA and fecal immunochemical test techniques to find elevated levels of DNA and/or hemoglobin in abnormal cells which can be associated with the presence of colorectal cancer and pre-malignant colorectal neoplasia.
- B. The test was approved by the Food and Drug Administration (FDA) in August 2014. Cologuard is not intended to replace diagnostic nor surveillance colonoscopy for high-risk individuals.
- C. A single stool sample is collected by the patient and then sent to Exact Sciences Labs.

IV. Benefit Coverage

A. Commercial

Cologuard is non-covered for VA and DC Commercial, Federal Health Employee Benefit Program (FEHBP), and VA Medicaid members as this test has a lower specificity than a screening fecal immunochemical test (iFOBT) resulting in more false negative results, **(test specificity** is the ability of the **test** to correctly identify those without the disease (true negative rate)). Currently,

1 Effective dates of service on or after October 9, 2014, the Centers for Medicare & Medicaid Services (CMS) will cover Cologuard [™], a multitarget stool DNA test (CPT code 81528) under Medicare Part B, as a colorectal cancer screening test for asymptomatic, average risk beneficiaries, aged 50 to 85 years once every 3 years for Medicare beneficiaries that meet all of the required CMS criteria for the test. National Coverage Determination (NCD) for Screening Colorectal Cancer Using Cologuard[™] - A Multitarget Stool DNA Test. Change Request (CR) 9115. Medicare Learning Network (MLN) Matters ® Number: MM9115.



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coverage is provided for tier one tests as per the U.S. Multi-Society Task Force on Colorectal Cancer.

B. Medicare

CMS has coverage of Cologuard once every three years effective October 9, 2014.1

C. Maryland Commercial and Medicaid members

Cologuard is covered as a screening test once every three years as per Maryland Insurance Agency Life & Health 08-33.

V. Clinical indications for Medicare and Maryland jurisdiction members

- A. Adults 45 years to 75 years who are at average risk for colon cancer; and
- B. 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
- C. At average risk of developing colorectal cancer (no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn's Disease and U Icerative Colitis; no family history of colorectal cancers or adenomatous polyps, familial adenomatous polyposis, or hereditary non-polyposis colorectal cancer); **and**
- D. Do not have a family history of known genetic disorder that predispose them to a high lifetime risk of colorectal cancer

VI. Limitations or Contraindications

- A. The net benefit to screen adults aged 76 to 85 years who were previously screened for colorectal cancer is small to moderate.
- B. Adults who have never been screened for colorectal cancer are more likely to benefit from the test.
- C. The rate of false positive results increases with age. Interpretation of Cologuard results for individuals over age 75 should be made with caution as the benefit of early detection and intervention for colorectal cancer declines after age 75 years.
- D. Cologuard may produce false positive or false negative results.
- E. The test may produce a false positive result though a colonoscopy will not find cancer or precancer. For confirmation of malignancy, a diagnostic colonoscopy should be performed following any positive result.
 - 1. Adherence to a colon cancer screening program with a method appropriate for individual patients should still be followed as the Cologuard may produce a false negative result though a colon cancer or pre-cancer is not detected through colonoscopy.
- F. Stool sample for Cologuard should not be collected in the presence of the following:

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- 1. Diarrhea;
- 2. Blood in urine or stool such as:
 - a. Bleeding hemorrhoids;
 - b. Bleeding cuts or wounds on patient's hands;
 - c. Rectal bleeding; or
 - d. Menstruation

VII. Exclusions

The test is not indicated in the presence of the following conditions:

- A. Personal history of colon cancer, polyps, or other related cancers;
- B. Family history of colon cancer;
- C. Positive result for another colon cancer screening method in the last 6 months;
- D. A clinical diagnosis that would increase the risk for colon cancer. These include but are not limited to the following:
 - 1. Crohn's disease;
 - 2. Chronic ulcerative colitis;
 - 3. Inflammatory bowel disease, or
 - 4. Familial adenomatous polyposis
- E. A hereditary diagnosis of relevant cancer syndrome such as:
 - 1. Familial Hyperplastic Polyposis;
 - 2. Non-polyposis colorectal cancer syndrome;
 - 3. Neurofibromatosis;
 - 4. Cronkhite-Canada syndrome;
 - 5. Juvenile Polyposis;
 - 6. Cowden's syndrome;
 - 7. Turcot's (or Crail's) syndrome;
 - 8. Gardner's syndrome;
 - 9. MYH-Associated Polyposis; or
 - 10. Peutz-Jergens Syndrome

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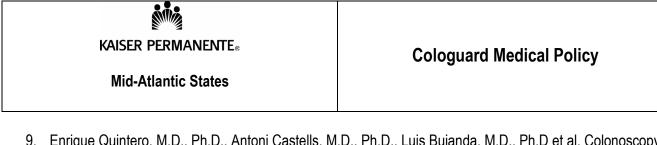
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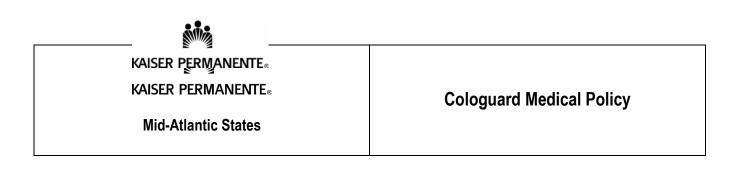
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Approval History

The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Date Approved by RUMC*	Date of Implementation
10/25/2017	10/25/2017
09/26/2018	09/26/2018
09/26/2019	09/26/2019
09/24/2020	09/24/2020
09/27/2021	09/27/2021
08/31/2022	08/31/2022
07/25/2023	07/25/2023
04/25/2024	04/25/2024

Effective June 01, 2016, state filing no longer required per Maryland House Bill <u>HB 798</u> – Health Insurance – Reporting

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Whenever possible, Medical Coverage Policies are evidence-based and may also include expert opinion. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.

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