



KAISER PERMANENTE®

Mid-Atlantic States

## Cologuard Medical Coverage Policy

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### 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

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### 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.<sup>1</sup>

### 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 Ulcerative 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 pre-cancer. 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:

<sup>1</sup> 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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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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## References

1. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Screening Colorectal Cancer Using Cologuard™ – a Multi-target Stool DNA Test. MLN Matters<sup>®</sup> Number: MM9115\_ (2014, October 9). accessed 10/3/2017. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM9115.pdf>.
2. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Colorectal Cancer Screening Tests. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=281&ncdver=7&keyword=colorectal&keywordType=starts&areald=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>. Accessed 1/29/2024
3. Centers for Medicare and Medicaid Services (CMS). National Coverage Analysis (NCA) Tracking Sheet for Screening for Colorectal Cancer - Stool DNA Testing (CAG-00440N).” (2014 October 9). accessed 10/3/2017. <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=277>
4. U.S. Preventive Services Task Force. Final Recommendation Statement: Colorectal Screening. *JAMA*. 2016;315(23):2564-2575. doi:10.1001/jama.2016.5989. accessed 10/3/2017 <http://jamanetwork.com/journals/jama/fullarticle/2529486> and <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/colorectal-cancer-screening2>.
5. Justin L. Sovich, Zachary Sartor, and Subhasis Misra. Developments in Screening Tests and Strategies for Colorectal Cancer. *Biomed Res Int*. 2015; 2015: 326728. Published online 2015 Oct 4. doi: 10.1155/2015/326728 PMID: PMC4609363. accessed 10/3/2017
6. Rex DK, Boland CR, Dominitz JA, Giardiello FM, Johnson DA, Kaltenbach T, Levin TR, Lieberman D, Robertson DJ. Colorectal Cancer Screening: Recommendations for Physicians and Patients From the U.S. Multi-Society Task Force on Colorectal Cancer. *Gastroenterology*. 2017 Jul;153(1):307-323. doi: 10.1053/j.gastro.2017.05.013. Epub 2017 Jun 9 accessed 10/3/2017.
7. Thomas F. Imperiale, David F. Ransohoff, Steven H. Itzkowitz, Theodore R. Levin, Philip Lavin, Graham P. Lidgard, David A. Ahlquist, and Barry M. Berger. Multitarget stool DNA testing for colorectal-cancer screening. *The New England Journal of Medicine*. 2014;370:1287.
8. Kisiel JB, et al. Stool DNA testing for the detection of colorectal neoplasia in patients with inflammatory bowel disease. *Alimentary Pharmacology & Therapeutics*. 2013;37:546.

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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9. Enrique Quintero, M.D., Ph.D., Antoni Castells, M.D., Ph.D., Luis Bujanda, M.D., Ph.D et al. Colonoscopy versus Fecal Immunochemical Testing in Colorectal-Cancer Screening *N Engl J Med* 2012; 366:697-706. February 23, 2012. DOI: 10.1056/NEJMoa1108895
10. Centers for Disease Control. Screening for Colorectal Cancer. accessed 10/3/2017 [https://www.cdc.gov/cancer/.../crc\\_screening\\_optimizing\\_quality\\_primary\\_care2.pdf](https://www.cdc.gov/cancer/.../crc_screening_optimizing_quality_primary_care2.pdf).
11. American Cancer Society: Colorectal Cancer Screening Guidelines updated March 30, 2018 <https://www.cancer.org/health-care-professionals/american-cancer-society-prevention-early-detection-guidelines/colorectal-cancer-screening-guidelines.html> accessed 9/6/2018.
12. Onieva-García, M.Á.; Llanos-Méndez, A.; Baños-Álvarez, E.; Isabel-Gómez, R. A systematic review of the clinical validity of the Cologuard™ genetic test for screening colorectal cancer / Validez clínica de la prueba genética Cologuard™ para el cribado de cáncer colorrectal: revisión sistemática (Spanish; Castilian) *Revista Clínica Española (English Edition)*. December 2015 215(9):527-536 Language: English. DOI: 10.1016/j.rceng.2015.08.006, Database: ScienceDirect
13. John M. Carethers. Fecal DNA Testing for Colorectal Cancer Screening. *Annual Review of Medicine* Vol. 71:59-69 (Volume publication date January 2020). First published as a Review in Advance on August 26, 2019. Accessed 05/03/2020. <https://doi.org/10.1146/annurev-med-103018-123125> <https://www.annualreviews.org/doi/abs/10.1146/annurev-med-103018-123125>
14. Naber SK, Knudsen AB, Zauber AG, Rutter CM, Fischer SE, et al. (2019) Cost-effectiveness of a multitarget stool DNA test for colorectal cancer screening of Medicare beneficiaries. *PLOS ONE* 14(9): <https://doi.org/10.1371/journal.pone.0220234> <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0220234>
15. IARC Working Group on the Evaluation of Cancer-Preventive Interventions. Colorectal cancer screening. Lyon (FR): International Agency for Research on Cancer; 2019. Accessed 05/03/2020 [https://www.ncbi.nlm.nih.gov/books/NBK553200/pdf/Bookshelf\\_NBK553200.pdf](https://www.ncbi.nlm.nih.gov/books/NBK553200/pdf/Bookshelf_NBK553200.pdf)
16. Center for Medicare and Medicaid Services. Decision Memo for Screening for Colorectal Cancer – Stool DNA Testing (CAG-00440N). Accessed 05/05/20. <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=277>
17. Ebner, D. W., & Kisiel, J. B. (2020). Stool-Based Tests for Colorectal Cancer Screening: Performance Benchmarks Lead to High Expected Efficacy. *Current gastroenterology reports*, 22(7), 32. <https://doi.org/10.1007/s11894-020-00770-6>
18. Kleinschmidt, T. K., Clements, A., Parker, M. A., & Scarcliff, S. D. (2021). Retrospective Review of Multitarget Stool DNA as a Screening Test for Colorectal Cancer. *The American surgeon*, 31348211031844. Advance online publication. <https://doi.org/10.1177/00031348211031844>
19. Lin, J. S., Perdue, L. A., Henrikson, N. B., Bean, S. I., & Blasi, P. R. (2021). *Screening for Colorectal Cancer: An Evidence Update for the U.S. Preventive Services Task Force*. Agency for Healthcare Research and Quality (US). <https://pubmed.ncbi.nlm.nih.gov/34097369/>
20. Jayasinghe, M., Prathiraja, O., Caldera, D., Jena, R., Coffie-Pierre, J. A., Silva, M. S., & Siddiqui, O. S.

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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- (2023). Colon Cancer Screening Methods: 2023 Update. *Cureus*, 15(4), e37509. <https://doi.org/10.7759/cureus.37509>
21. Shen, Yuguang; Wang, Dongyang; Yuan, Tianli; Fang, Hongsheng; Chen, Zhu; et al. Novel DNA methylation biomarkers in stool and blood for early detection of colorectal cancer and precancerous lesions. *Clinical Epigenetics*, London Vol. 15, (2023): 1-13. DOI:10.1186/s13148-023-01443-7
  22. Rao, PK et al. Comprehensive Cost Implications of Commercially Available Non-invasive Colorectal Cancer Screening Modalities: Results of A Large National Insurer Claims Database Analysis, Scientific Forum, American College of Surgeons Clinical Congress 2022. <https://www.facs.org/for-medical-professionals/news-publications/news-and-articles/press-releases/2022/study-finds-less-expensive-noninvasive-test-is-an-effective-alternative-to-a-more-costly-test-for-colorectal-cancer-screening/>
  23. Allen, Casey J MD1; Bloom, Nathan BS2; Rothka, Michael BS2; Rao, Pavan MD1; Wagner, Patrick L MD FACS; Bartlett, David L MD FACS; Farah, Katie MD4; Chalikonda, Sricharan MD FACS. Comprehensive Cost Implications of Commercially Available Non-invasive Colorectal Cancer Screening Modalities. *Journal of the American College of Surgeons* ();10.1097/XCS.0000000000000768, May 23, 2023. | DOI: 10.1097/XCS.0000000000000768
  24. Anand, S., & Liang, P. S. (2022). A Practical Overview of the Stool DNA Test for Colorectal Cancer Screening. *Clinical and translational gastroenterology*, 13(4), e00464. <https://doi.org/10.14309/ctg.0000000000000464>
  25. MCG 28<sup>th</sup> edition. Copyright 2024 MCG Health, LLC. Fecal DNA Testing ACG:A-0388 (AC). Accessed 01/25/2024.
  26. Soin, S., Akanbi, O., Ahmed, A. *et al.* Use and abuse of fecal occult blood tests: a community hospital experience. *BMC Gastroenterol* 19, 161 (2019). <https://doi.org/10.1186/s12876-019-1079-9>
  27. Barry, H. C. (2020a, December 1). Fecal occult blood testing is inaccurate as part of diagnostic workup. *American Family Physician*. <https://www.aafp.org/pubs/afp/issues/2020/1201/p692.html>
  28. Lu, M., Luo, X., Li, N., Chen, H., & Dai, M. (2019). Diagnostic Accuracy Of Fecal Occult Blood Tests For Detecting Proximal Versus Distal Colorectal Neoplasia: A Systematic Review And Meta-Analysis. *Clinical epidemiology*, 11, 943–954. <https://doi.org/10.2147/CLEP.S213677>
  29. Lin JS, Perdue LA, Henrikson NB, et al. Screening for Colorectal Cancer: An Evidence Update for the U.S. Preventive Services Task Force [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2021 May. (Evidence Synthesis, No. 202.) <https://www.ncbi.nlm.nih.gov/books/NBK570913/>
  30. American Cancer Society. Colorectal Cancer Causes, Risk Factors, and Prevention. (2024, January 17). Accessed 01/26/2024. <https://www.cancer.org/content/dam/CRC/PDF/Public/8605.00.pdf>
  31. US Preventive Services Taskforce. (2021, May 18). Colorectal cancer: Screening. Recommendation: [Colorectal Cancer: Screening | United States Preventive Services Taskforce. Accessed 01/26/2024. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening#bootstrap-panel--12](https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening#bootstrap-panel--12)



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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 [HB 798](#) – 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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