

Clinical Policy: DNA Analysis of Stool to Screen for Colorectal Cancer

Reference Number: PA.CP.MP.125

Effective Date: 09/18

Last Review Date: 09/18

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Description

Cologuard is a noninvasive screening test for colon cancer. This test comprises a multi-target screen for several aberrant DNA markers of colon cancer, as well as a hemoglobin immunoassay. This policy describes the medical necessity requirements for DNA analysis of stool with Cologuard.

Policy/Criteria

- I. It is the policy of PA Health & Wellness® (PHW) that screening for colorectal cancer by DNA analysis of stool (i.e., Cologuard) is **medically necessary** every three years when meeting the following:
 - A. Age 50-85 years;
 - B. Asymptomatic and at average risk for colon cancer;
 - C. Is not within the standard interval of another screening test for colon cancer.
- II. It is the policy of PHW that DNA analysis of stool (i.e., Cologuard) is **experimental/investigational** for any circumstances other than those specified above.

Background

Colorectal cancer has become the second leading cause of cancer-related deaths in the United States, according to the latest statistics.³ Multi-target stool testing for colorectal cancer is a noninvasive DNA test that screens for multiple lesions, including those related to *Kras* mutations, *NDRG4* and *BMP3* methylations, *β-actin*, and hemoglobin immunoassay.¹ The FDA approved Cologuard (Exact Sciences) based on this multi-target stool testing.² The sensitivity for detecting colorectal cancer from the multi-target DNA testing was 92.3% (60 of 65) and 73.8% (48 of 65) with fecal immunohistochemical tests (FIT), which look for intact human hemoglobin. Multi-target DNA testing is not a replacement for diagnostic colonoscopy testing in patients at high risk for colorectal cancer.

The United States Preventative Services Task Force recommends screening for colorectal cancer starting at age 50 years and continuing until age 75 years. According to this recommendation, the specificity of FIT-DNA is lower than that of FIT alone, and has a higher number of false-positive results, as well as a higher likelihood of follow-up colonoscopy and associated adverse events per screening test.³ While no longitudinal follow-up data exists, with an abnormal FIT-DNA test result followed by a negative colonoscopy, there is potential for overly intensive surveillance due to clinician and patient concerns about the implications of the genetic component of the test.³

Coding Implications

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CPT® Codes	Description
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

HCPCS Codes	Description

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
Z12.11	Encounter for screening for malignant neoplasm of colon

Reviews, Revisions, and Approvals	Date	Approval Date
Policy Developed	09/18	

References

1. Imperiale TF, Ransohoff DF, Itzkowitz SH, Levin TR, Lavin P, Lidgard GP, Ahlquist DA, Berger BM. Multitarget stool DNA testing for colorectal-cancer screening. *N Engl J Med* 2014;370:1287-97.
2. Abramowicz, Mark, Gianna Zuccotti, and Jean-Marie Pflomm. A stool DNA test (Cologuard) for colorectal cancer screening. *JAMA*. 2014;312(23).
3. US Preventive Services Task Force. Final Recommendation Statement: Screening for Colorectal Cancer. Announcement detail. June 2016. Accessed July 6, 2018. <https://www.uspreventiveservicestaskforce.org/Announcements/News/Item/final-recommendation-statement-screening-for-colorectal-cancer>
4. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: Colorectal cancer screening. Version 1.2018. Accessed July 6, 2018.

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5. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Colorectal Cancer Screening Tests (210.3). CMS.gov. Effective October 9, 2014. Accessed July 6, 2018.
6. American Cancer Society. American Cancer Society Guideline for Colorectal Cancer Screening: A Summary for Clinicians. American Cancer Society. 2018. Accessed July 7, 2018.
7. Siegel RL, Fedewa SA, Anderson WF, et al. Colorectal Cancer Incidence Patterns in the United States, 1974–2013. J Natl Cancer Inst. 2017 Aug 1;109(8). doi: 10.1093/jnci/djw322.
8. Rex DK, Boland CR, Dominitz JA, et al. Colorectal Cancer Screening: Recommendations for Physicians and Patients from the U.S. Multi-Society Task Force on Colorectal Cancer. Am J Gastroenterol. 2017;112(7):1016. Epub 2017 Jun 6.