



Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

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|---|---|
| Plan: PA Health & Wellness | Submission Date: 01/01/2021 1/1/2020 |
| Policy Number: PA.CP.MP.125 | Effective Date: 09/01/18 Revision Date: 12/22/2021 10/2020 |
| Policy Name: DNA Analysis of stool for Colorectal Cancer | |
| Type of Submission – Check all that apply: <input type="checkbox"/> New Policy <input type="checkbox"/> Revised Policy* <input checked="" type="checkbox"/> Retiring Policy – This option indicates the retirement of an active policy. If there is no indicated replacement, then “NONE” will be listed as the New/Replacement Policy. <input type="checkbox"/> Annual Review – No Revisions <input type="checkbox"/> Statewide PDL - Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL. | |
| *All revisions to the policy <u>must</u> be highlighted using track changes throughout the document. Please provide any changes or clarifying information for the policy below: <p>Policy being retired effective 1/1/2022 with no replacement indicated.</p> | |
| Name of Authorized Individual (Please type or print): Carla Huitt, MD MPH | Signature of Authorized Individual: |

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

Reference Number: PA.CP.MP.125

Effective Date: 09/18

~~Last Review~~ Retirement Effective Date:
01/01/2022-10/2020

[Coding Implications](#)

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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 45-85 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.

American Cancer Society

2018 Guidelines by the ACS give a qualified recommendation for screening for colorectal cancer starting at age 45. A qualified recommendation “indicates there is clear evidence of benefit of screening but less certainty about the balance of benefits and harms, or about patients’ values and preferences, which could lead to different decisions about screening.” The ACS gives a strong recommendation that colorectal cancer screening be performed in adults aged 50-75, and a qualified recommendation for adults aged 76-85.

United States Preventative Services Task Force (USPSTF)

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The USPSTF 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 CLINICAL POLICY DNA Analysis of Stool Page 2 of 5 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

National Comprehensive Cancer Network (NCCN)

NCCN states that “the data in an average-risk individual indicate that stool DNA performs well,” noting also that there are “no or limited data in high-risk individuals and the use of stool DNA should be individualized.” NCCN recommends colorectal cancer screening for average-risk individuals 50-75 years of age, and on an individualized basis for those 76-85 years of age.

Multi-Society Task Force for Colorectal Cancer

The American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy issued a joint statement recommending FIT-fecal DNA tests every 3 years, as a second-tier screening tool for colorectal cancer. They offer a strong recommendation, based on high-quality evidence, for colorectal cancer screening beginning at age 50. Based on limited evidence and the high incidence of colorectal cancer in African-Americans, they recommend screening for this population starting at age 45.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2020, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| 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 |
|-------------|-------------|
| N/A | |

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

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| ICD-10-CM Code | Description |
|----------------|--|
| Z12.11 | Encounter for screening for malignant neoplasm of colon |
| Z12.12 | Encounter for screening for malignant neoplasm of rectum |

| Reviews, Revisions, and Approvals | Date | Approval Date |
|---|-------------------|---------------|
| Policy Developed | 09/18 | 10/18 |
| Added that request is not within the standard interval of another normal screen for colon cancer. | 09/18 | |
| Removed parenthetical example of appropriate intervals for colon cancer screening in I.C. | 09/18 | |
| References reviewed and updated. Background updated. References reviewed and updated. HCPCs code G0464 removed from the policy as the code is deleted in 2018. | 10/19 | |
| Changed age supporting medical necessity from 50-85 to 45-85. Updated background with no impact on criteria. Added ICD-10 code Z12.12. References reviewed and updated. Specialist reviewed. | 10/2020 | |
| <u>Policy being retired effective 1/1/2022 with no replacement indicated.</u> | <u>12/22/2021</u> | |

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References

1. Imperiale TF, Ransohoff DF, Itzkowitz SH, et al. 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 May 29, 2019. <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening>
4. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: Colorectal cancer screening. Version 2.2020. Accessed June 11, 2020.
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 June 11, 2020.
6. American Cancer Society. American Cancer Society Guideline for Colorectal Cancer Screening: A Summary for Clinicians. American Cancer Society. 2018. Accessed June 11, 2020.
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.

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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.
9. Doubeni C. Screening for colorectal cancer: Strategies in patients at average risk. In: UpToDate. Lamont JT, Elmore JG (Eds). UpToDate, Waltham, MA. Accessed June 11, 2020
10. Doubeni C. Tests for screening for colorectal cancer In: UpToDate. Lamont JT, Elmore JG (Eds). March 18, 2020. Accessed June 11, 2020
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