



Colon Cancer Screening - Updates/Cologuard Testing

The Maryland Department of Health (MDH), Fee-for-Service Program, provides coverage for the following screening tests of **average risk*** for colon cancer in patients between 45 and 85 years of age:

- Stool-Based Test Frequency Fecal Occult Blood Test (FOBT) - once a year
- Highly sensitive fecal immunochemical test (FIT) - once a year
- Fecal Immunochemical Test (FIT-DNA) **Cologuard** - testing option every three years
- Visualization Tests Colonoscopy - every 10 years or Flexible Sigmoidoscopy - once every five years
- Imaging Tests: CT colonography (virtual colonoscopy) - once every five years

* **Definition of Average Risk:** 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.

Colon Cancer Screening - Coverage Updates:

1. **Age:** Coverage, will now include patients **starting at age 45 until age 85**. The decision to screen between ages 76 to 85 years should remain individualized and include a discussion on the risks and benefits based on comorbidity status and estimated life expectancy.
2. **Cologuard Testing Option:**
Cologuard can now be considered, without prior authorization, as a screening tool for patients of **average risk** of colon cancer who meet the following criteria:
 - 2.1. Clinical Criteria:
 - 2.1.1. Cologuard is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high risk individuals.
 - 2.1.2. The recipient is between the ages of 45 and 85. The decision to screen between ages 76 to 85 years should be individualized and include a discussion on the risks and benefits based on comorbidity status and estimated life expectancy.
 - 2.1.3. Eligibility for testing is once every three years.
 - 2.1.4. The recipient must be 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 or fecal immunochemical test).

- 2.1.5. The recipient must be 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).
- 2.1.6. The recipient must not have had a positive result from another colorectal cancer screening method within the last 6 months.

2.2. Coverage Limitations and Exclusions:

Cologuard must be administered according to the guidelines outlined above in Section 2.1 - *Clinical Criteria*. All other screening stool DNA tests not otherwise specified above, remain not covered.

2.3. Updated - Billing Code/Information:

CPT Code: 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.

Supporting Criteria and Organizational References:

- American Cancer Society:
<https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/acs-recommendations.html>
- U.S. Preventive Services Task Force (USPSTF):
<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening>
- The American Society of Colon and Rectal Surgeons:
<https://fascrs.org/patients/diseases-and-conditions/a-z/screening-and-surveillance-for-colorectal-cancer>
- Center for Disease Control (CDC):
https://www.cdc.gov/cancer/colorectal/basic_info/screening/index.htm

Prior authorization of benefits is not the practice of medicine nor the substitute for the independent medical judgment of a treating medical provider. The materials provided are a component used to assist in making coverage decisions and administering benefits. Prior authorization does not constitute a contract or guarantee regarding member eligibility or

payment. Prior authorization criteria are established based on a collaborative effort using input from the current medical literature and based on evidence available at the time.

Approved by MDH Clinical Criteria Committee: 8/31/2021
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