

# MedStar Health, Inc.

## POLICY AND PROCEDURE MANUAL

Policy Number: MP.150.MH

Last Review Date: \*NEW\*

Effective Date: 01/01/2019

### MP.150.MH – Cologuard/Colonic Fecal DNA Testing

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar CareFirst PPO

MedStar Health considers the **Cologuard Test** medically necessary for the following indications:

- Age 45 years and older, AND
- Asymptomatic
  - o 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
- At average risk of developing colorectal cancer, meaning:
  - o No personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn's Disease and ulcerative colitis
  - o No family history of colorectal cancers or adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer).

For all other indications, MedStar Health considers Cologuard to be ***experimental and investigational***.

MedStar Health does not provide coverage for experimental or investigational services and procedures.

#### Limitations

For those members with Medicare Part B, the Cologuard test will be covered once every three years. Reference NCD 210.3 for Colorectal Cancer Screening Tests.

All other screening stool DNA tests not otherwise specified above remain nationally non-covered.

#### Background

CMS reports that colorectal cancer is the fourth most common cancer and the second leading cause of cancer deaths in the United States. Early detection through screening has been shown to improve mortality. Multi-target stool DNA test, Cologuard, detects small amounts of DNA markers that identify colorectal cancer or pre-malignant colorectal neoplasia.

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### Codes:

Covered CPT Codes/ HCPCS Codes/ ICD-10 Codes	
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

### References

1. Centers for Medicare and Medicaid Services (CMS). Decision Memo for Screening for Colorectal Cancer – Stool DNA Testing (CAG-00440N). October 9, 2014. <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=277>
2. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Colorectal Cancer Screening Tests (201.3). Effective Date: 10/9/2014. <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=281&ncdver=5&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=colorectal&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABAAAAAAAA%3d%3d&>
3. Hayes. GTE Report: Cologuard. Publication Date: October 16, 2014. Annual Review: October 7, 2015.
4. National Cancer Institute. SEER Stat Fact Sheets: Colon and Rectum Cancer. <http://seer.cancer.gov/statfacts/html/colorect.html>
5. U.S. Preventive Services Task Force. Colorectal Cancer: Screening. June 2016. <http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/colorectal-cancer-screening2>

### Disclaimer:

MedStar Health medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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