

Fecal DNA Testing for Colorectal Cancer - Cologuard™

Policy Number: **M20161122035**
Effective Date: **1/1/2017**
Sponsoring Department: **Health Care Services**
Impacted Department(s): **Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐ Confidential ☐ Restricted ☒ Public

Applies to (Line of Business):

- ☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒ MediSource; ☒ MediSource Connect; ☐ Child Health Plus ☒ Essential Plan
☒ Medicare, if yes, which plan(s): ☒ MAPD; ☐ PDP; ☒ ISNP; ☒ CSNP
☒ Commercial, if yes, which type: ☒ Large Group; ☒ Small Group; ☒ Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No ☒

Purpose and Applicability:

To set forth the medical necessity criteria for fecal DNA testing for **colorectal cancer (CRC)** utilizing **Cologuard™**.

Policy:

Commercial and Self-Funded:

The Cologuard™ test is covered once every one to three years for members who meet all of the following criteria:

- Age 45 to 75 years; and
- Documentation presented to support patient is 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
- At average risk of developing CRC (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).

Medicare Advantage:

Medicare Advantage covers fecal DNA testing once every 3 years following the Medicare Preventive Service guidelines:

- Aged 50–85 years
- Asymptomatic
- At average colorectal cancer risk

MediSource, MediSource Connect and Essential Plan:

Per New York State Department of Health criteria, MediSource, MediSource Connect and Essential Plan cover Cologuard™. All men and women between the ages of 45-75 years at average risk for colorectal cancer should be screened with one of the recommended screening tests. Screening of individuals at high risk for colorectal cancer should begin earlier than age 45.

Table 1: Colorectal Cancer Screening Methods for Patients Considered to be of Average Risk

Method	Recommended Frequency
Fecal Immunochemical Test (FIT) or High Sensitivity Fecal Occult Blood Testing (FOBT)	once annually
FIT-DNA*(e.g., Cologuard)	once every three years
Computed Tomography Colonography (CTC)	once every five years
Flexible Sigmoidoscopy (SIG)	once every five years
Colonoscopy	once every ten years
SIG with FIT	once every ten years (SIG), plus once every year (FIT)

*DNA - deoxyribonucleic acid, in this case based from stool and any blood shed therein.

Reminders:

- The colorectal cancer screening methods included in Table 1 may be used for individuals considered to be at high risk. In general, however, screening with colonoscopy is the preferred method for most individuals at high risk for colorectal cancer.
- More frequent colorectal cancer screening methods may be considered medically necessary for individuals considered to be at high risk of developing colorectal cancer.
- It is important to discuss with patients that positive results from the screening methods outlined in Table 1, other than colonoscopy, may result in the need for diagnostic colonoscopies.
- Colorectal cancers should be considered possible diagnoses in patients (regardless of age) presenting with blood in their bowel movements, changes in bowel habits, abdominal pains, weight losses, or unexplained anemias. In such situations, the USPSTF and the American Cancer Society (ACS) recommend clinical decision making to determine whether diagnostic colonoscopies should be performed.
- NYS Medicaid considers colorectal cancer screening by any method not listed above experimental and investigational at this time.

Background:

Several genetic biomarkers have been associated with CRC. Cologuard™ uses stool DNA samples to test multiple biomarkers known to be associated with CRC and premalignant colorectal adenomas as well as fecal hemoglobin immunoassay. According to Hayes, Inc., Cologuard's other names are include multitarget stool DNA, mt-sDNA, MT-sDNA, fecal DNA, FIT-DNA, FIT and stool DNA test, FIT plus sDNA, and sDNA-FIT. Individuals collect a full stool sample which is submitted in a collection kit to the laboratory for testing. A positive Cologuard™ test result indicates that abnormal gene methylation, sequence variants, and/or elevated hemoglobin were detected, while a negative result indicates that none of these were identified in the patient's stool. Cologuard™ is not appropriate for patients with a history of CRC or colorectal adenomas, patients with a hereditary cancer predisposition syndrome associated with CRC, or patients with other chronic colorectal disorders such as inflammatory bowel disease or Crohn's disease. Cologuard™ has been approved by the US Food and Drug Administration (FDA) in August 2014 as a screening test for colorectal carcinoma to be followed, when abnormal, by diagnostic colonoscopy. The United States Preventive Services Task Force in their 2021 guidelines state "that beginning screening at age 45 years and continuing to the age of 75 years, for the following screening strategies, yielded a reasonable balance of benefits (life-years gained) and burdens or harms (number of colonoscopies): annual FIT, sDNA-FIT every 1 to 3 years, CT colonography or flexible sigmoidoscopy every 5 years, colonoscopy every 10 years, or flexible sigmoidoscopy every 10 years with annual FIT."

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☐ No ☒

Pre-authorization is not required at the present time. Criteria above will be utilized upon retro-review.

Definitions

Cologuard is an at-home stool sample collection kit that is to be returned to the laboratory to test for biomarkers associated with colorectal cancer or advanced adenomas from shed neoplasia cells. Biomarkers include increased methylation of NDRG4 and BMP3 and point mutations in KRAS using quantitative allele-specific real-time target and signal amplification (QuARTS) technology with β -actin as a control.

Colorectal Cancer (CRC) is the second leading cause of cancer death, and accounts for approximately 9 percent of cancer deaths and 3 percent of total deaths. Approximately one in three people diagnosed with CRC die of this disease in the five years after diagnosis. Removal of premalignant adenomas can prevent the cancer and removal of localized cancer may prevent CRC-related death.

References

Related Policies, Processes and Other Documents

N/A

Non-Regulatory references

Doubeni, C. Tests for screening for colorectal cancer. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on June 10, 2024.)

Hayes, Inc. Molecular Test Assessment Cologuard (Exact Sciences Corp. for Colorectal Cancer Screening in Average-Risk Adults). Lansdale, PA: March 2023.

National Comprehensive Cancer Network (NCCN) [web site]. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Colorectal Cancer Screening Version 1.2024, February 27, 2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/colorectal_screening.pdf Accessed June 10, 2024.

Shaukat A, Kahi CJ, Burke CA, et al. ACG Clinical Guidelines: Colorectal Cancer Screening 2021. Am J Gastroenterol. 2021 Mar 1;116(3):458-479.

U.S. Preventative Services Task Force (USPSTF) [web site]. Colorectal Cancer: Screening. May 18, 2021. Available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening> Accessed June 10, 2024.

Regulatory References

Centers for Medicare and Medicaid (CMS) Medicare Learning Network [web site]. Medicare Preventive Services; Colorectal Cancer. May 2024. Available at: https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html#COLO_CAN Accessed June 10, 2024.

Centers for Medicare and Medicaid (CMS) [web site]. National Coverage Determination (NCD) for Colorectal Cancer Screening Tests (210.3). Available at: <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=281> Accessed June 10, 2024.

New York State Department of Health Medicaid Update [web site] New York State Medicaid Expansion of Coverage for Colorectal Cancer Screening. June 2017. Volume 33 Number 6, pp. 10-11. Available at: https://www.health.ny.gov/health_care/medicaid/program/update/2017/jun17_mu.pdf Accessed June 10, 2024.

New York State Department of Health Medicaid Update [web site]. New York State Medicaid Expansion of Coverage for Colorectal Cancer Screening. June 2021. Volume 37 Number 8, cover page. Available at: https://health.ny.gov/health_care/medicaid/program/update/2021/no08_2021-06.htm#colorectal . Accessed June 10, 2024.

U.S Food and Drug Administration (FDA) [web site]. Premarket Approval (PMA) Cologuard P130017. Available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p130017> Accessed June 10, 2024.

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No ☐

Revision Date	Owner	Notes
8/1/2024	Health Care Services	Revised
1/1/2024	Health Care Services	Revised
8/1/2023	Health Care Services	Revised
8/1/2022	Health Care Services	Revised
9/1/2021	Health Care Services	Revised
6/1/2021	Health Care Services	Reviewed
6/1/2020	Health Care Services	Reviewed
7/1/2019	Medical Management	Revised
8/1/2018	Medical Management	Revised
9/1/2017	Medical Management	Revised
6/1/2017	Medical Management	Revised
2/1/2017	Medical Management	Revised