Priority Health

MEDICAL POLICY
No. 91547-R8

COLORECTAL CANCER SCREENING

Effective Date: June 1, 2025	**Review Date: 4/08, 4/09, 4/10, 4/11, 12/11, 12/12, 12/13, 2/15, 2/16, 2/17, 2/18, 2/19, 2/20, 2/21, 11/21, 11/22, 11/23, 11/24, 05/25**
Date Of Origin: April 16, 2008	**Status: Current**

Summary of Changes

Additions:

- Added link to Priority Health's utilization management delegate EviCore where applicable.
- The **Cologuard Plus™ (Exact Sciences Corp.)** qualitative in vitro diagnostic test (approved by the U.S. Food and Drug Administration (FDA) in October 2024) is managed by Priority Health's utilization management delegate EviCore.
- The **Shield™ (Guardant Health, Inc.)** blood test for colorectal cancer (CRC) screening (approved by the U.S. Food and Drug Administration (FDA) in July 2024) is managed by Priority Health's utilization management delegate EviCore (effective July 1, 2025).
- Computer or artificial intelligence assisted reading tools intended to help endoscopists detect polyps and adenomas during colonoscopy (e.g., GI Genius Intelligent Endoscopy Module) may be used to support clinicians' standard methods of detection. However, such use will be not separately payable.
- Discussion: Added brief discussion addressing water immersion (WI) and water exchange (WE) colonoscopy as well as underwater endoscopic mucosal resection (UEMR).

Clarifications:

- I A.: Clarified and reorganized this section to better align with how information is presented in the Priority Health Preventive Health Care Guidelines.

I. POLICY/CRITERIA

A. General Preventive Screening for average risk population:

Average risk is defined as no **personal** history adenomatous polyps, colorectal cancer, or inflammatory bowel disease (Crohn's Disease and Ulcerative Colitis); no **family** history of colorectal cancer or adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer.

Beginning at age 45, both men and women at average risk for developing colorectal cancer should begin screening as discussed in the Priority Health Preventive Health Care Guidelines.

Preventive testing modalities include:

1. Colonoscopy

    a. Age 45-75 ears
    b. Performed once every 10 years

2. Flexible sigmoidoscopy

   a. Age 45-75 years
   b. Performed once every 5 years

3. Computed tomography colonography (CTC):

   Prior authorization through EviCore is required. CTC may be medically necessary when EviCore criteria are met (see *Abdomen Imaging Guidelines*).

   To access EviCore clinical guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

4. Fecal DNA or FI-DNA – Quantitative real-time target and signal amplification of DNA markers plus fecal hemoglobin:

   a. **Cologuard® (Exact Sciences Corp.)**: Fecal DNA testing using Cologuard is considered medically necessary for members who meet all the following criteria:

      i. Age 45-75
      ii. Once every 3 years
      iii. Those patients who show no signs or symptoms of colorectal disease including and not limited to lower gastrointestinal pain, blood in stool, positive fecal occult blood test or fecal immunochemical test
      iv. No prior history of abnormal fecal DNA test
      v. Those patients who are at average risk for developing colorectal cancer
      vi. No personal history adenomatous polyps colorectal cancer, or inflammatory bowel disease (Crohn's Disease and Ulcerative Colitis)
      vii. No family history of colorectal cancer or adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer

   b. **Cologuard Plus™** (Exact Sciences Corp.): **Managed by EviCore.**

      To access EviCore clinical guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

5. Fecal occult blood test (FOBT) using guaiac-based FOBT (gFOBT) or immunochemical-based FOBT (iFOBT)/fecal immunochemical test (FIT)

a. Age 45-75 years
b. Annually

6. **Shield™ (Guardant Health Inc.)** analysis of cell-free DNA (cfDNA) for epigenomic patterns from blood sample as screening test for colorectal cancer (CRC): **Managed by EviCore**.

   To access EviCore clinical guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

7. **Computer or artificial intelligence aided colonoscopy:** Computer or artificial intelligence assisted reading tools intended to help endoscopists detect polyps and adenomas during colonoscopy (e.g., GI Genius Intelligent Endoscopy Module) may be used to support clinicians' standard methods of detection. However, such use will be not separately payable.

B. General Non-covered colorectal cancer screening tests:

1. **Magnetic resonance imaging (MRI) colonography** is considered experimental and investigational for the screening or diagnosis of colorectal cancer, inflammatory bowel disease, or other indications because its value for these indications has not been established.
2. **Wireless Capsule Endoscopy (WCE)** (i.e. PillCam) is accomplished by encasing video, illumination and transmission modules inside a capsule the size of a large vitamin pill**.** WCE is not a covered benefit for general screening.

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

To access EviCore clinical guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

❖ **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***

- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

IV. BACKGROUND

Colorectal cancer is the third leading cause of cancer death for both men and women. Widespread screening for colorectal cancer (CRC) could prevent many of these deaths since prognosis improves dramatically with early detection and treatment. Colon cancer prevention should be the primary goal of CRC screening. Tests that are designed to detect both early cancer and adenomatous polyps should be encouraged if resources are available and patients are willing to undergo an invasive test. Existing screening methods include both invasive and non-invasive tests with varying sensitivities and specificities. Commonly used tests include the fecal occult blood test (FOBT), flexible sigmoidoscopy, traditional colonoscopy and virtual colonoscopy.

Colonoscopy is a procedure in which a colonoscope or scope is used to look inside the rectum and colon. Colonoscopy can show irritated and swollen tissue, ulcers, polyps, and cancer. It is the most complete screening procedure and is considered the gold standard of the screening modalities.

Computed Tomographic Colonography (CTC) or virtual colonoscopy is an non-invasive x-ray test that does not require anesthesia. However, with CTC the entire length of the colon is not viewed and CTC may not find certain polyps as easily as a colonoscopy.

Flexible sigmoidoscopy is a procedure in which a flexible, narrow tube with a light and tiny camera on one end, called a sigmoidoscope or scope, is used to look

inside the rectum and lower colon. Flexible sigmoidoscopy can show irritated or swollen tissue, ulcers, polyps, and cancer.

Currently available stool-based tests include guaiac fecal occult blood test (gFOBT), fecal immunochemical test (FIT), and stool DNA with a FIT (sDNA-FIT). Fecal occult blood tests (FOBTs) are generally divided into two types: immunoassay and guaiac types. Immunoassay (or immunochemical) fecal occult blood tests (iFOBT or FIT) measures hemoglobin, a protein in red blood cells. Guaiac fecal occult blood tests (gFOBT) use a peroxidase reaction to indicate presence of the heme portion of hemoglobin. The Cologuard, a multi-target sDNA test, incorporates both sDNA and fecal immunochemical test techniques. It detects molecular markers of altered DNA that are contained in the cells shed by colorectal cancer and pre-malignant colorectal epithelial neoplasia into the lumen of the large bowel.

The Cologuard Plus™ test is a qualitative in vitro diagnostic test intended for the detection of colorectal neoplasia-associated DNA markers and for the presence of occult hemoglobin in human stool. The Cologuard Plus test is performed on samples collected using the Cologuard Plus Collection Kit. A positive result may indicate the presence of colorectal cancer (CRC) or advanced precancerous lesions (APL) and should be followed by colonoscopy. The Cologuard Plus test is indicated to screen adults 45 years or older, who are at average risk for CRC. The Cologuard Plus test is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high-risk individuals.

The Cologuard Plus™ test is performed at Exact Sciences, Madison, WI.

Shield™ is intended as a noninvasive screening test for colorectal cancer (CRC). It is indicated for individuals 45 years at average risk for genomic alterations and epigenomic modifications in cell-free DNA (cfDNA) from a blood sample. Test results are reported as positive or negative, where positive indicates that the individuals may have CRC or advanced adenoma and should be evaluated by colonoscopy. The laboratory notes a limited ability to detect stage I cancer and advanced adenomas.

Computer-assisted reading tools have been created to help endoscopists detect polyps and adenomas during standard white-light endoscopy examinations for screening and surveillance. One such tool is the GI Genius intelligent endoscopy module (Medtronic). The GI Genius reads images in real time and is intended to support, rather than to replace, clinicians' standard methods of adenoma detection (Hayes, Inc., 2024).

In **water immersion colonoscopy (WI, also known as water infusion or water instillation colonoscopy)**, water is infused to facilitate scope progression and cecal intubation; gas insufflation (room air or carbon dioxide) may be used as

needed during insertion; most infused water is aspirated during withdrawal. **Water exchange colonoscopy (WE)** is a standardized insertion technique in which infused water is removed mainly during insertion to allow progression in clear water, without any gas insufflation, and removing all residual gas pockets trying to achieve the best possible degree of colon cleanliness. The cecal intubation rate can be higher using WI or WE than gas insufflation, however the overall intubation time is generally slightly longer. Use of WI or WE during insertion is associated with less patient discomfort when compared with gas insufflation colonoscopy. Available evidence suggests that complications of colorectal underwater polypectomy and **underwater endoscopic mucosal resection (UEMR)** are comparable with conventional **endoscopic mucosal resection (EMR)** techniques (Cadoni et al, 2021)

Recommendations for follow-up after colonoscopy and polypectomy are provided by the US Multi-Society Task Force on Colorectal Cancer (Gupta et al., 2020).

V. CODING INFORMATION

ICD-10 Codes that support payment of the following CPT/HCPCS procedures as a preventive benefit (not subject to deductible):

Z12.11	Encounter for screening for malignant neoplasm of colon
Z12.12	Encounter for screening for malignant neoplasm of rectum
Z80.0	Family history of malignant neoplasm of digestive organs
Z83.710	Family history of colonic polyps
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.01	Personal history of malignant neoplasm of esophagus
Z85.020	Personal history of malignant carcinoid tumor of stomach
Z85.028	Personal history of other malignant neoplasm of stomach
Z85.030	Personal history of malignant carcinoid tumor of large intestine
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.040	Personal history of malignant carcinoid tumor of rectum
Z85.048	Personal history of other malignant neoplasm of rectum, rectosigmoid junction, and anus
Z85.810	Personal history of malignant neoplasm of tongue
Z85.818	Personal history of malignant neoplasm of other sites of lip, oral cavity, and pharynx
Z85.819	Personal history of malignant neoplasm of unspecified site of lip, oral cavity, and pharynx
Z86.010	Personal history of colonic polyps

CPT/HCPCS Procedure Codes

**These codes billed with modifier 33 - Preventive Services or modifier PT - Colorectal cancer screening test; converted to diagnostic test or other procedure will process as a preventive benefit regardless of diagnosis.*

45330* Sigmoidoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
45331* Sigmoidoscopy, flexible; with biopsy, single or multiple
45333* Sigmoidoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps
45334* Sigmoidoscopy, flexible; with control of bleeding, any method
45335* Sigmoidoscopy, flexible; with directed submucosal injection(s), any substance
45338* Sigmoidoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique
45346* Sigmoidoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)

45378* Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
45380* Colonoscopy, flexible; with biopsy, single or multiple

45381* Colonoscopy, flexible; with directed submucosal injection(s), any substance
45382* Colonoscopy, flexible; with control of bleeding, any method
45384* Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps
45385* Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique
45388* Colonoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)
45390* Colonoscopy, flexible; with endoscopic mucosal resection
G0104 Colorectal cancer screening; flexible sigmoidoscopy
G0105 Colorectal cancer screening; colonoscopy on individual at high risk
G0121 Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk
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 ***[Cologuard (Exact Sciences)]***

ICD-10 codes that support payment of the following CPT/HCPCS procedures as a preventive benefit in addition to the codes above:
Z00.00 Encounter for general adult medical examination without abnormal findings
Z00.01 Encounter for general adult medical examination with abnormal findings

CPT/HCPCS procedure codes:
82270 Blood, occult, by peroxidase activity (e.g., guaiac), qualitative; feces, consecutive collected specimens with single determination, for colorectal neoplasm screening (i.e., patient was provided 3 cards or single triple card for consecutive collection)

82274	Blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1-3 simultaneous determinations
G0328	Colorectal cancer screening; fecal occult blood test, immunoassay, 1-3 simultaneous determinations
S0285	Colonoscopy consultation performed prior to a screening colonoscopy procedure *(not covered for Medicare or Medicaid)*
G0327	Colorectal cancer screening; blood-based biomarker (Medicare only)

Pre-authorization required:

Note: EviCore provides prior authorization medical necessity review services on behalf of Priority Health for participating providers. Prior authorization for out-of- network providers must be requested through Priority Health.

To access EviCore clinical guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

Computed Tomography Colonography (CTC) may be considered medically necessary and therefore covered when EviCore criteria are met (see Abdomen Imaging Guidelines):

74263	Computed tomographic (CT) colonography, screening, including image post processing *(Covered as preventive for Medicare as of 1/1/25) this code only qualifies for the preventive benefit for plans that cover this service.*

The Cologuard Plus™ (Exact Sciences) colorectal cancer screening test is managed by EviCore (see Lab Management Guidelines – Experimental, Investigational, or Unproven Laboratory Testing):

0464U	Oncology (colorectal) screening, quantitative real-time target and signal amplification, methylated DNA markers, including LASS4, LRRC4 and PPP2R5C, a reference marker ZDHHC1, and a protein marker (fecal hemoglobin), utilizing stool, algorithm reported as a positive or negative result ***[Cologuard Plus™ (Exact Sciences Corp.); code effective July 1, 2024]***

Effective July 1, 2025, The Shield™ (Guardant Health, Inc.) blood test for colorectal cancer (CRC) screening is managed by EviCore (see Lab management Guidelines – Experimental, Investigational, or Unproven Laboratory Testing):

0537U	Oncology (colorectal cancer), analysis of cell-free DNA (cfDNA) for epigenomic patterns, next-generation sequencing, >2500 differentially methylated regions (DMRs), plasma, algorithm reported as positive or negative ***[Shield™ (Guardant Health, Inc.); code effective April 1, 2025]***

GoCheckTM (Blood-Based Colorectal Cancer Test), Milagen, Inc, Milagen, Inc is not covered

0558U Oncology (colorectal), quantitative enzyme-linked immunosorbent assay (ELISA) for secreted colorectal cancer protein marker (BF7 antigen), using serum, result reported as indicative of response/no response to therapy or disease progression/regression

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