Colorectal Cancer Screening

MEDICAL POLICY NUMBER: 106

Effective Date: 1/1/2024

Last Review Date: 11/2023

Next Annual Review: 4/2024

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☒ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Notice to Medicaid Policy Readers: For comprehensive rules and guidelines pertaining to this policy, readers are advised to consult the Oregon Health Authority. It is essential to ensure full understanding and compliance with the state's regulations and directives. Please refer to OHA's prioritized list for the following coverage guidelines:

Colorectal Cancer Screening: Guideline Notes: D25, 106

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Notes:

- This policy does not address diagnostic colonoscopies, initial screening colonoscopies, or screening colonoscopies for individuals at high-risk of colorectal cancer.
- Member benefits, which address coverage or non-coverage of colorectal cancer screening, may vary. Member benefit contract language takes precedent over medical policy.

Subsequent Screening Colonoscopies

I. Subsequent screening colonoscopies are considered **medically necessary** when both of the following criteria (A. and B.) are met:

   A. Patient is at average-risk (see Policy Guidelines) of colorectal cancer; **and**
   B. Patient's colonoscopy is being performed in alignment with the screening frequency recommendations as outlined by the U.S. Multi-Society Task Force (MSTF) on Colorectal Cancer guidelines (linked here).

II. Subsequent screening colonoscopies for the routine screening of individuals at average risk

of colorectal cancer are considered **not medically necessary** when criterion I. is not met.

III. Colonoscopies may be considered **medically necessary** as a follow up screening after a positive fecal immunochemical test or fecal DNA test.

Fecal Immunochemical Test (FIT)

IV. Fecal immunochemical test (FIT) is considered **medically necessary** for routine screening for colorectal cancer when **both** the following (A. and B.) criteria are met:

A. Age 45 years or greater; **and**
B. Last test was performed more than 12 months prior to current testing.

V. Fecal immunochemical test (FIT) for routine screening for colorectal cancer is considered **not medically necessary** when criterion IV. is not met.

Fecal DNA Testing (e.g., Cologuard®)

VI. FDA approved fecal DNA testing (e.g., Cologuard®) is **considered medically necessary** for routine screening for colorectal cancer when **all** the following (A.-D.) criteria are met:

A. Age 45 or greater; **and**
B. Typical average-risk for colorectal cancer; **and**
C. No FDA contraindications for fecal DNA testing (see Regulatory Status section); **and**
D. Last fecal DNA test was performed more than 36 months prior to current testing.

VII. Fecal DNA testing (i.e., Cologuard®) for the routine screening for colorectal cancer in considered **not medically necessary** when criterion VI. is not met.

Blood-Based Testing (e.g., Epi proColon®)

VIII. Blood-based biomarker testing (e.g., Epi proColon®) for colorectal cancer screening is considered **not medically necessary**.

Link to Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

Average-Risk[1]

Patient lacks all of the following: inflammatory bowel disease, family history* of colorectal cancer, hereditary syndrome associated with increased risk, serrated polyposis syndrome, personal history of colorectal cancer.

Family history*: single first-degree relative with colorectal cancer or advanced adenoma diagnosed at age < 60 years or two-first degree relatives with CRC or advanced adenomas.
***Individuals with a single first-degree relative with CRC or advanced adenomas diagnosed at age ≥ 60 years can be screened like average-risk persons.

BACKGROUND

Colorectal Cancer (CRC)

According to the American Cancer Society, CRC is the third most common cancer diagnosed in both men and women in the United States.[2] CRC is a cancer that starts as a growth (polyp) on the inner lining of the colon or the rectum. Some types of polyps can change into cancer over time, but not all polyps become cancer. Early detection through regular CRC screening allows for more treatment options and improved outcomes. Additionally, polyps identified early can be removed before becoming cancerous; thereby, preventing CRC. The American Cancer Society recommends that, starting at age 50, men and women at average risk for developing CRC should use one of the following screening tests:

- Tests that find polyps and cancer
    - Colonoscopy every 10 years
    - CT colonography (virtual colonoscopy) every 5 years
    - Flexible sigmoidoscopy every 5 years
    - Double-contrast barium enema every 5 years
- Tests that primarily find cancer
    - Fecal immunochemical test (FIT) every year
    - Guaiac-based fecal occult blood test (gFOBT) every year
    - Stool DNA test every 3 years

Colonoscopy

A colonoscopy refers to the endoscopic examination of the rectum, colon, and a portion of the terminal ileum, wherein a camera on a flexible tube is passed through the anus in order to take tissue samples, and/or remove polyps and abnormal tissues.

Fecal Immunochemical Test (FIT)

FIT looks for occult (hidden) blood in the stool by reacting to part of the human hemoglobin protein found in red blood cells.[2] Blood in the feces can indicate that there is colorectal cancer or a precancerous lesion that is bleeding into the intestines. Small amounts of stool are collected and there

are no drug or dietary restrictions; therefore, patients may find collecting FIT samples to be much easier. However, FIT testing needs to be done every year and if results are positive a colonoscopy is required.

Fecal DNA Testing (i.e., Cologuard®)

Fecal DNA testing (i.e., Cologuard®) "looks for certain abnormal sections of DNA from cancer or polyp cells."[2] DNA mutations in colorectal cancer cells often get into the stool, where fecal DNA testing may be able to detect them. Cologuard® also incorporates FIT by looking for occult blood in the stool. Fecal DNA testing should be done every three years, and if the test is positive a colonoscopy is required.

Blood-Based Biomarker Testing (e.g., Epi proColon®)

In recent years, blood-based biomarker tests have been proposed as another potential non-invasive option for the early detection of colorectal cancer. Currently, the Epi proColon® test (Epigenomics Inc., San Diego, CA) is the only FDA-approved blood-based biomarker test for colorectal cancer screening. The test detects circulating methylated *SEPT9* DNA. The methylation status of the septin9 (*SEPT9*) gene has been shown to distinguish CRC tissue from normal surrounding tissue, which is the basis for research into this target as a plasma biomarker for CRC.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

U.S. Food and Drug Administration (FDA)

The stool DNA-based colorectal cancer screening test (i.e., Cologuard®) received FDA approval in 2014 under the FDA premarket approval (PMA) process (PMA# P130017).[3]

Indications for Use:

Cologuard is intended for the qualitative detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. A positive result may indicate the presence of colorectal cancer (CRC) or advanced adenoma (AA) and should be followed by diagnostic colonoscopy. Cologuard is indicated to screen adults of either sex, 50 years or older, who are at typical average-risk for CRC. Cologuard is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high-risk individuals.

Contraindications:

Cologuard is intended for use with patients, age 45 years and older, at average risk who are typical candidates for CRC screening. Cologuard was not clinically evaluated for the following types of patients:

- Patients with a history of colorectal cancer, adenomas, or other related cancers.
- Patients who have had a positive result from another colorectal cancer screening method within the last 6 months.
- Patients who have been diagnosed with a condition that is associated with high risk for colorectal cancer. These include but are not limited to:
    - Inflammatory Bowel Disease (IBD)
    - Chronic ulcerative colitis (CUC)
    - Crohn's disease
    - Familial adenomatous polyposis (FAP)
    - Family history of colorectal cancer
- Patients who have been diagnosed with a relevant familial (hereditary) cancer syndrome, such as Hereditary non-polyposis colorectal cancer syndrome (HNPCCC or Lynch Syndrome), Peutz-Jeghers Syndrome, MYH-Associated Polyposis (MAP), Gardner's syndrome, Turcot's (or Crail's) syndrome, Cowden's syndrome, Juvenile Polyposis, Cronkhite-Canada syndrome, Neurofibromatosis, or Familial Hyperplastic Polyposis.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

The policy criteria are based on the evidence-based clinical practice guidelines noted below; therefore, a review of evidence was not conducted.

CLINICAL PRACTICE GUIDELINES

National Comprehensive Cancer Network (NCCN)

The NCCN colorectal cancer (CRC) screening guidelines (Version 3.2022) recommend fecal immunochemical-based testing (FIT) or FIT-DNA based testing as an alternative to colonoscopy, high-sensitivity guaiac-based testing, flexible sigmoidoscopy, or CT colonography for those of average risk status.[4] Average risk is defined by NCCN as the following:

- Age ≥45 years
- No history of adenoma or sessile serrated polyp (SSP) or CRC
- No history of inflammatory bowel disease
- Negative family history for CRC or confirmed advanced adenoma (i.e., high-grade dysplasia, ≥1 cm, villous or tubulovillous histology) or an advanced SSP (≥1 cm, any dysplasia)

The guidelines recommended colonoscopy as appropriate for patients presenting with pedunculated or sessile polyp (adenoma) with invasive cancer; colon cancer appropriate for resection (non-metastatic); suspected or proven metastatic synchronous adenocarcinoma (any T, any N, M1); and as part of surveillance following colon cancer surgery.

The NCCN included a footnote stating that, "A blood test that detects circulating methylated SEPT9 DNA has been FDA-approved for CRC screening for those who refuse other screening modalities. Based on current data, the panel concludes that the interval for repeated testing is unknown/unclear. The panel will continue to review this strategy and monitor data as they emerge."

U.S. Multi-Society Task Force (MSTF) on Colorectal Cancer

The 2019 U.S. MSTF evidence-based guideline on colorectal cancer made the following recommendations:[5,6]

- Normal colonoscopy is associated with sustained reduced risk for incident and fatal CRC (*High quality of evidence)*
- Incremental effectiveness of repeat colonoscopy after baseline normal colonoscopy for further reducing CRC incidence and mortality is uncertain (*insufficient evidence)*
- Risk for incident and fatal CRC after baseline adenoma removal is uncertain (*Low quality of evidence).*
- Surveillance colonoscopy after baseline removal of adenoma with high-risk features (e.g. size $\geq$ 10mm) may reduce risk for incident CRC, but impact on fatal CRC is uncertain (*Low quality of evidence)*
- Incremental impact of surveillance colonoscopy after baseline removal of adenoma with low-risk features (such as 1-2 adenomas <10 mm) on risk for incident and fatal CRC is uncertain (*Low quality of evidence)*

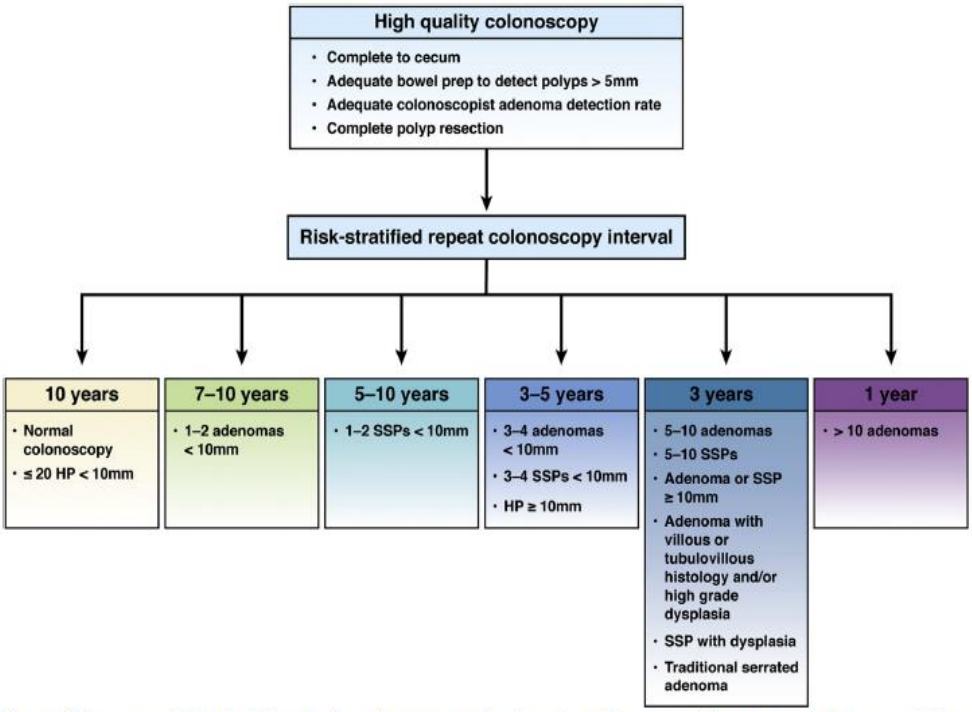

Figure 1. Recommendations for follow-up after colonoscopy and polypectomy. Recommendations for post-colonoscopy follow-up in average risk adults are depicted. After high-quality colonoscopy defined by examination complete to cecum adequate to detect polyps >5 mm, performed by a colonoscopist with adequate ADR with complete polyp resection, risk-stratified repeat colonoscopy intervals are provided. SSP, sessile serrated polyp/sessile serrated adenoma/sessile serrated lesion.

In 2021, the US MSTF updated their recommendations, lowering the age of average risk screening to 45 years old, finding that low level evidence supports screening of 45–49-year-olds who are of average risk.[7]

American Cancer Society (ACS)

In 2018, the American Cancer Society issued a guideline for colorectal cancer screening for average-risk adults.[1] Recommendations were made on the basis of a non-systematic review of evidence, expert opinion and modeling analyses. Investigators issued the following recommendations:

- The ACS recommends that adults aged 45 years and older with an average risk of CRC undergo regular screening with either a high-sensitivity stool-based test or a structural (visual) examination, depending on patient preference and test availability. As a part of the screening process, all positive results on non-colonoscopy screening tests should be followed up with timely colonoscopy.
- The recommendation to begin screening at age 45 years is a *qualified recommendation*.
- The recommendation for regular screening in adults aged 50 years and older is a *strong recommendation*.
- The ACS recommends that average-risk adults in good health with a life expectancy of greater than 10 years continue CRC screening through the age of 75 years (*qualified recommendation*).

- The ACS recommends that clinicians individualize CRC screening decisions for individuals aged 76 through 85 years based on patient preferences, life expectancy, health status, and prior screening history (*qualified recommendation*).
- The ACS recommends that clinicians discourage individuals over age 85 y from continuing CRC screening (*qualified recommendation*)

U.S. Preventive Services Task Force (USPSTF)

The 2021 USPSTF recommendation statement for colorectal cancer screening gives a grade A for CRC screening in adults aged 50 to 75 and a grade and grade B for CRC screening in adults aged 45 to 49 years.[8] For CRC screening in adults aged 76 to 85 years, USPSTF gives a grade C; in adults aged 76 to 85 years, the USPSTF states the decision to screen in this population "should be an individual one, taking into account the patient's overall health and prior screening history."

Regarding screening intervals, the USPSTF recommends the following testing frequencies:

Table 1. Characteristics of Recommended Colorectal Cancer Screening Strategies

Screening Method	**Frequency***	**Evidence of Efficacy**	**Other Considerations**
Stool-Based Tests			
HSgFOBT	Every year	• Evidence from RCTs that gFOBT reduces CRC mortality. • High-sensitivity versions (e.g., Hemoccult SENSA) have superior test performance characteristics than older tests (e.g., Hemoccult II), although there is still uncertainty about the precision of test sensitivity estimates, which means it is likely to detect fewer cases of advanced adenomas and colorectal cancer than other stool-based tests.	• Harms from screening with gFOBT arise from colonoscopy to follow up abnormal gFOBT results. • Requires dietary restrictions and three stool samples. • Requires good adherence over multiple rounds of testing. • Does not require bowel preparation, anesthesia, or transportation to

			and from the screening examination (test is performed at home).
FIT	Every year	• Evidence from one large cohort study that screening with FIT reduces CRC mortality • Certain types of FIT have improved accuracy compared with gFOBT and HSgFOBT.	• Harms from screening with FIT arise from colonoscopy to follow up abnormal FIT results. • Can be done with a single stool sample. • Requires good adherence over multiple rounds of testing. • Does not require bowel preparation, anesthesia, or transportation to and from the screening examination (test is performed at home).
sDNA-FIT	Every 1 or 3 years†	• Improved sensitivity compared with FIT per one time application of screening test. • Specificity is lower than that of FIT, resulting in more false-positive results, more diagnostic colonoscopies, and more associated adverse events per sDNA-FIT	• Harms from screening with sDNA-FIT arise from colonoscopy to follow up abnormal sDNA-FIT results. • Can be done with a single stool sample but involves collecting

		screening test compared to per FIT test. • Modeling suggests that screening every 3 years does not provide a favorable (i.e., efficient) balance of benefits and harms, compared with other stool-based screening options (i.e., annual FIT or annual sDNA-FIT). • There is insufficient evidence about appropriate longitudinal followup of abnormal findings after a negative diagnostic colonoscopy. • There is no direct evidence evaluating effect of sDNA-FIT on CRC mortality.	an entire bowel movement. • Requires good adherence over multiple rounds of testing. • Does not require bowel preparation, anesthesia, or transportation to and from the screening examination (test is performed at home).
Direct Visualization Tests			
Colonoscopy	Every 10 years	• Evidence from cohort studies that colonoscopy reduces CRC mortality. • Harms from colonoscopy include bleeding and perforation, which both increase with age.	• Screening and diagnostic followup of positive results can be performed during the same examination. • Requires less frequent screening. • Requires bowel preparation, anesthesia, and transportation to and from the

			screening examination.
CT Colonography	Every 5 years	• Evidence available that CT colonography has reasonable accuracy to detect CRC and adenomas. • No direct evidence evaluating effect of CT colonography on CRC mortality. • Limited evidence about the potential benefits or harms of possible evaluation and treatment of incidental extracolonic findings, which are common. Extracolonic findings detected in 1.3% to 11.4% of exams; <3% required medical or surgical treatment.	• Additional harms from screening with CT colonography arise from colonoscopy to follow up abnormal CT colonography results. • Requires bowel preparation. • Does not require anesthesia or transportation to and from the screening examination.
Flexible Sigmoidoscopy	Every 5 years	• Evidence from RCTs that flexible sigmoidoscopy reduces CRC mortality. • Risk of bleeding and perforation but less than risk with colonoscopy. • Modeling suggests it provides fewer life-years gained alone than when combined with FIT or in comparison to other strategies.	• Additional harms may arise from colonoscopy to follow up abnormal flexible sigmoidoscopy results. • Test availability has declined in the United States but may be available in some communities where colonoscopy is less available.

Flexible Sigmoidoscopy With FIT	Flexible sigmoidoscopy every 10 years plus FIT every year	• Evidence from RCTs that flexible sigmoidoscopy + FIT reduces CRC mortality. • Modeling suggests combination testing provides similar benefits to colonoscopy with fewer complications. • Risk of bleeding and perforation from flexible sigmoidoscopy but less than risk with colonoscopy.	• Additional potential harms from colonoscopy to follow up abnormal flexible sigmoidoscopy or FIT results. • Flexible sigmoidoscopy availability has declined in the United States but may be available in some communities where colonoscopy is less available. • Screening with FIT requires good adherence over multiple rounds of testing.

* Applies to persons with negative findings (including hyperplastic polyps) and is not intended for persons in surveillance programs. Evidence of efficacy is not informative of screening frequency, with the exception of gFOBT and flexible sigmoidoscopy alone.

† Suggested by manufacturer.

Abbreviations: CRC=colorectal cancer; CT=computed tomography; FIT=fecal immunochemical test; HSgFOBT=high-sensitivity guaiac-based fecal occult blood test; RCT=randomized controlled trial; sDNA-FIT=stool DNA test plus fecal immunochemical test.

American College of Gastroenterology

In 2021, the American College of Gastroenterology published guidelines for colorectal cancer screening. Investigators recommended the following:[9]

	Summary	Recommendation strength	GRADE quality of evidence
1	We recommend colorectal cancer (CRC) screening in average-risk individuals between ages 50 and 75 yr to reduce incidence of advanced adenoma, CRC, and mortality from CRC	Strong	Moderate
2	We suggest CRC screening in average-risk individuals between ages 45 and 49 yr to reduce incidence of advanced adenoma, CRC, and mortality from CRC	Conditional	Very low
3	We suggest that a decision to continue screening beyond age 75 yr be individualized	Conditional	Very low
4	We recommend colonoscopy and fecal immunochemical testing (FIT) as the primary screening modalities for CRC screening	Strong	Low
5	We suggest consideration of the following screening tests for individuals unable or unwilling to undergo a colonoscopy or FIT: flexible sigmoidoscopy, multitarget stool DNA test, CT colonography, or colon capsule	Conditional	Very low
6	We suggest against Septin 9 for CRC screening	Conditional	Very low
7	We recommend that the following intervals should be followed for screening modalities: FIT every 1 yr; colonoscopy every 10 yr	Strong	Low
8	We suggest that the following intervals should be followed for screening modalities: multitarget stool DNA test every 3 yr; flexible sigmoidoscopy every 5–10 yr; CT colonography every 5 yr; colon capsule every 5 yr	Conditional	Very low

EVIDENCE SUMMARY

Subsequent Screening Colonoscopies

There is enough research to show that subsequent screening colonoscopies to detect colorectal cancer (CRC) may improve overall health outcomes in adults ages 45 year or greater. In addition, clinical practice guidelines based on research and the U.S. Preventive Services Task Force (USPSTF) recommend CRC screening in adults ages 45 year or greater including risk-stratified repeat colonoscopy intervals. Therefore**,** subsequent screening colonoscopies may be considered medically necessary.

Fecal Immunochemical Test (FIT), Fecal DNA Testing (i.e., Cologuard®)

There is enough research to show that fecal immunochemical testing (FIT) and fecal DNA testing (i.e., Cologuard®) to detect colorectal cancer (CRC) may improve overall health outcomes for those age 45 year or greater who meet specific patient selection criteria. In addition, clinical practice guidelines based on research recommend FIT and fecal DNA testing (i.e., Cologuard®) as an alternative to standard diagnostic methods (e.g., colonoscopy). Therefore, FIT and fecal DNA testing (i.e., Cologuard®) may be considered medically necessary.

Blood-Based Testing (e.g., Epi proColon®)

There is not enough research to show whether or not blood-based biomarker testing for colorectal cancer screening, including but not limited to Epi proColon®, improves overall health outcomes. Clinical practice guidelines based on research state that it is unknown or unclear when to use this type of testing

and that data are still being monitored. Therefore, blood-based biomarker testing (including but not limited to Epi proColon®) is considered not medically necessary.

BILLING GUIDELINES AND CODING

- Fecal immunochemical testing (82274 or G0328) is limited to once per year. Fecal DNA testing (81528) is limited to once every 3 years.
- CPT 82274 should be billed once regardless of the number of specimens required to complete the test. The test should be reported with one date of service reflecting the date the test was completed, even if specimens are collected on different dates.
- CPT codes 44388 and 45378 require a diagnosis code of Z12.11 for screening colonoscopy in order to be considered screening.
- Any colonoscopy code billed with modifier PT or 33 is considered a screening.

CODES*		
Screening Colonoscopy		
HCPCS/CPT	G0121	Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk
	44388	Colonoscopy through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
	45378	Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
Fecal Immunochemical Testing (FIT)		
	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
Fecal DNA Testing (Cologuard®)		
	0421U	Oncology (colorectal) screening, quantitative real-time target and signal amplification of 8 RNA markers (GAPDH, SMAD4, ACY1, AREG, CDH1, KRAS, TNFRSF10B, EGLN2) and fecal hemoglobin, algorithm reported as a positive or negative for colorectal cancer 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

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.

- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Wolf AMD, Fontham ETH, Church TR, et al. Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. *CA: a cancer journal for clinicians.* 2018.
2. American Cancer Society | About Colorectal Cancer | Key Statistics for Colorectal Cancer. https://www.cancer.org/cancer/colon-rectal-cancer/about/key-statistics. Accessed 3/7/2023.
3. Food & Drug Administration. Premarket approval. ColoGuard. 8/11/2014. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130017. Accessed 3/7/2023.
4. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology. Colorectal Cancer Screening. Version 3.2022. 9/30/2022. https://www.nccn.org/professionals/physician_gls/pdf/colorectal_screening.pdf. Accessed 3/6/2023.
5. Gupta S, Lieberman D, Anderson JC, et al. Recommendations for follow-up after colonoscopy and polypectomy: a consensus update by the US Multi-Society Task Force on Colorectal Cancer. *Gastrointestinal Endoscopy.* 2020;91(3):463-485. e465.
6. 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. *The American journal of gastroenterology.* 2017;112(7):1016-1030.
7. Patel SG, May FP, Anderson JC, et al. Updates on age to start and stop colorectal cancer screening: recommendations from the U.S. Multi-Society Task Force on Colorectal Cancer. *Gastrointestinal Endoscopy.* 2022;95(1):1-15. https://doi.org/10.1016/j.gie.2021.06.012
8. US Preventive Services Task Force. Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. *JAMA.* 2021;325(19):1965-1977. https://doi.org/10.1001/jama.2021.6238
9. Shaukat A, Kahi CJ, Burke CA, Rabeneck L, Sauer BG, Rex DK. ACG Clinical Guidelines: Colorectal Cancer Screening 2021. *Official journal of the American College of Gastroenterology | ACG.* 2021;116(3). https://journals.lww.com/ajg/Fulltext/2021/03000/ACG_Clinical_Guidelines__Colorectal_Cancer.14.aspx

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
7/2023	Annual update. Change denial language to not medically necessary
8/2023	Interim update. Billing Guidelines updated.
1/1/2024	Interim update. Q1 2024 code set update. Updated criteria language to reflect FDA approval for testing.