

<b>MEDICAL POLICY</b>		<b>Colorectal Cancer Screening</b>	
<b>Effective Date: 2/1/2021</b>		Section: MED	Policy No: 187
 <div style="text-align: right;">2/1/2021</div>		Technology Assessment Committee Approved Date: 11/14	
		Medical Policy Committee Approved Date: 2/15; 1/16; 3/16; 8/17; 7/18; 8/19; 03/2020; 6/2020; 12/2020	
Medical Officer	Date		

**See Policy CPT/HCPCS CODE section below for any prior authorization requirements**

**SCOPE:**

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

**APPLIES TO:**

All lines of business

**BENEFIT APPLICATION**

Medicaid 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.

**POLICY CRITERIA**

**Note:** This policy does not address diagnostic colonoscopies, initial screening colonoscopies, or screening colonoscopies for individuals at high-risk of colorectal cancer.

**Subsequent Screening Colonoscopies**

- I. Subsequent screening colonoscopies are considered **medically necessary and covered** when both of the following criteria (A.-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 and not covered** when criterion I. is not met.

#### Fecal Immunochemical Test (FIT)

- III. Fecal immunochemical test (FIT) is considered **medically necessary and covered** for routine screening for colorectal cancer when both the following (A.-B.) criteria are met:
- A. Age 45 years or greater; **and**
  - B. Last test was performed more than 12 months prior to current testing.
- IV. Fecal immunochemical test (FIT) for routine screening for colorectal cancer is considered **not medically necessary and not covered** when criterion III. is not met.

#### Fecal DNA Testing (i.e., Cologuard®)

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

Link to [Policy Summary](#)

## POLICY GUIDELINES

### Average-Risk

*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.<sup>1</sup>

\**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  $\geq$  60 years can be screened like average-risk persons.<sup>1</sup>

**BILLING GUIDELINES**

- Fecal immunochemical testing (82274 or G0328) is limited to once per year. Fecal DNA testing (81528) is limited to once every 3 years.
- 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.

**CPT/HCPCS CODES**

All Lines of Business	
No Prior Authorization Required	
<b>Screening Colonoscopy</b>	
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)
<b>Fecal Immunochemical Testing (FIT):</b>	
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
<b>Fecal DNA Testing (Cologuard®):</b>	
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

**DESCRIPTION**

**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.<sup>1</sup> 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.<sup>1</sup> 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.”<sup>1</sup> 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.

## REVIEW OF EVIDENCE

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 (v.2.2020) 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.<sup>2</sup> Average risk is defined by NCCN as the following:

- Age  $\geq 50$  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,  $\geq 1$  cm, villous or tubulovillous histology) or an advanced SSP ( $\geq 1$  cm, any dysplasia)

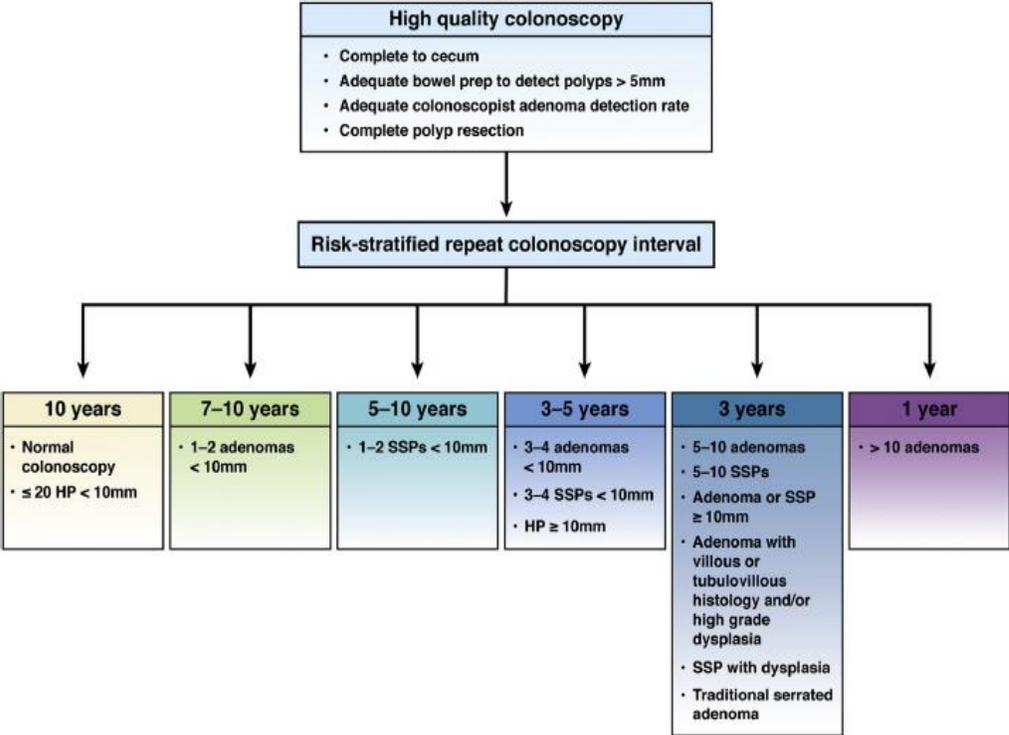
The guidelines recommended colonoscopy as appropriate for patients presenting with pedunculated or sessile polyp (adenoma) with invasive cancer; colon cancer appropriate for resection (non-metastatic); suspected or proven metastatic synchronous adenocarcinoma (any T, any N, M1); and as part of surveillance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

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:<sup>3,4</sup>

- 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*)

MSTF authors made the following recommendations for follow-up after colonoscopy and polypectomy in average risk adults:



**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.

American Cancer Society (ACS)

In 2018, the American Cancer Society issued a guideline for colorectal cancer screening for average-risk adults.<sup>5</sup> 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 2020 USPSTF draft 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.<sup>6</sup> 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
<b>Stool-Based Tests</b>			
HSgFOBT	Every year	<ul style="list-style-type: none"> <li>• Evidence from RCTs that gFOBT reduces CRC mortality.</li> <li>• High-sensitivity versions (e.g., Hemoccult SENSА) have superior test performance characteristics than older</li> </ul>	<ul style="list-style-type: none"> <li>• Harms from screening with gFOBT arise from colonoscopy to follow up abnormal gFOBT results.</li> </ul>

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		<p>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.</p>	<ul style="list-style-type: none"> <li>• Requires dietary restrictions and three stool samples.</li> <li>• Requires good adherence over multiple rounds of testing.</li> <li>• Does not require bowel preparation, anesthesia, or transportation to and from the screening examination (test is performed at home).</li> </ul>
FIT	Every year	<ul style="list-style-type: none"> <li>• Evidence from one large cohort study that screening with FIT reduces CRC mortality</li> <li>• Certain types of FIT have improved accuracy compared with gFOBT and HSgFOBT.</li> </ul>	<ul style="list-style-type: none"> <li>• Harms from screening with FIT arise from colonoscopy to follow up abnormal FIT results.</li> <li>• Can be done with a single stool sample.</li> <li>• Requires good adherence over multiple rounds of testing.</li> <li>• Does not require bowel preparation, anesthesia, or transportation to and from the screening examination (test is performed at home).</li> </ul>
sDNA-FIT	Every 1 or 3 years†	<ul style="list-style-type: none"> <li>• Improved sensitivity compared with FIT per one time application of screening test.</li> <li>• Specificity is lower than that of FIT, resulting in more false-positive results, more diagnostic colonoscopies, and</li> </ul>	<ul style="list-style-type: none"> <li>• Harms from screening with sDNA-FIT arise from colonoscopy to follow up abnormal sDNA-FIT results.</li> <li>• Can be done with a single stool sample</li> </ul>

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		<p>more associated adverse events per sDNA-FIT screening test compared to per FIT test.</p> <ul style="list-style-type: none"> <li>• 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).</li> <li>• There is insufficient evidence about appropriate longitudinal followup of abnormal findings after a negative diagnostic colonoscopy.</li> <li>• There is no direct evidence evaluating effect of sDNA-FIT on CRC mortality.</li> </ul>	<p>but involves collecting an entire bowel movement.</p> <ul style="list-style-type: none"> <li>• Requires good adherence over multiple rounds of testing.</li> <li>• Does not require bowel preparation, anesthesia, or transportation to and from the screening examination (test is performed at home).</li> </ul>
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**Direct Visualization Tests**

Colonoscopy	Every 10 years	<ul style="list-style-type: none"> <li>• Evidence from cohort studies that colonoscopy reduces CRC mortality.</li> <li>• Harms from colonoscopy include bleeding and perforation, which both increase with age.</li> </ul>	<ul style="list-style-type: none"> <li>• Screening and diagnostic followup of positive results can be performed during the same examination.</li> <li>• Requires less frequent screening.</li> <li>• Requires bowel preparation, anesthesia, and transportation to and from the screening examination.</li> </ul>
CT Colonography	Every 5 years	<ul style="list-style-type: none"> <li>• Evidence available that CT colonography has reasonable accuracy to detect CRC and adenomas.</li> </ul>	<ul style="list-style-type: none"> <li>• Additional harms from screening with CT colonography arise from</li> </ul>

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		<ul style="list-style-type: none"> <li>• No direct evidence evaluating effect of CT colonography on CRC mortality.</li> <li>• 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; &lt;3% required medical or surgical treatment.</li> </ul>	<p>colonoscopy to follow up abnormal CT colonography results.</p> <ul style="list-style-type: none"> <li>• Requires bowel preparation.</li> <li>• Does not require anesthesia or transportation to and from the screening examination.</li> </ul>
Flexible Sigmoidoscopy	Every 5 years	<ul style="list-style-type: none"> <li>• Evidence from RCTs that flexible sigmoidoscopy reduces CRC mortality.</li> <li>• Risk of bleeding and perforation but less than risk with colonoscopy.</li> <li>• Modeling suggests it provides fewer life-years gained alone than when combined with FIT or in comparison to other strategies.</li> </ul>	<ul style="list-style-type: none"> <li>• Additional harms may arise from colonoscopy to follow up abnormal flexible sigmoidoscopy results.</li> <li>• Test availability has declined in the United States but may be available in some communities where colonoscopy is less available.</li> </ul>
Flexible Sigmoidoscopy With FIT	Flexible sigmoidoscopy every 10 years plus FIT every year	<ul style="list-style-type: none"> <li>• Evidence from RCTs that flexible sigmoidoscopy + FIT reduces CRC mortality.</li> <li>• Modeling suggests combination testing provides similar benefits to colonoscopy with fewer complications.</li> <li>• Risk of bleeding and perforation from flexible sigmoidoscopy but less than risk with colonoscopy.</li> </ul>	<ul style="list-style-type: none"> <li>• Additional potential harms from colonoscopy to follow up abnormal flexible sigmoidoscopy or FIT results.</li> <li>• Flexible sigmoidoscopy availability has declined in the United States but may be available in some communities where colonoscopy is less available.</li> </ul>

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			<ul style="list-style-type: none"> <li>• Screening with FIT requires good adherence over multiple rounds of testing.</li> </ul>
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\* 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 2008, the American College of Gastroenterology published guidelines for colorectal cancer screening based on a non-systematic review of evidence.<sup>7</sup> Investigators recommended that colonoscopy be performed every 10 years, beginning at age 50, and at age 45 in African-Americans. For patients with a family history of CRC but evaluation of hereditary non-polyposis colorectal cancer, colonoscopy is recommended every 5 years beginning at age 40 years or 10 years younger than age at diagnosis of the youngest affected relative.

**CENTERS FOR MEDICARE & MEDICAID**

As of February 2020, a search of the Medicare Coverage Database identified National Coverage Determination for Colorectal Cancer Screening Tests (210.3)<sup>8</sup> and Medicare Claims Processing Manual – Chapter 18 – Preventive and Screening Services.<sup>9</sup> The CMS criteria for fecal immunochemical testing (FIT), fecal DNA testing (i.e., Cologuard®) and colonoscopy screenings of average risk individuals are in-line with the policy criteria noted above; therefore, this policy applies to all lines of business.

**POLICY SUMMARY**

The U.S. Preventive Services Task Force (USPSTF) recommends colorectal cancer (CRC) screening in adults age 45 years and older. The 2019 U.S. Multi-Society Task Force on colorectal cancer recommends risk-stratified repeat colonoscopy intervals. Both the National Comprehensive Cancer Network and U.S. Multi-Society Task Force consider fecal immunochemical testing (FIT) or fecal DNA testing (i.e., Cologuard®) an alternative to standard diagnostic methods (e.g., colonoscopy).

**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 Companies reserve the right to

determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

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.

## REGULATORY STATUS

### U.S. Food and Drug Administration (FDA)

The stool DNA-based colorectal cancer screening test (i.e., Cologuard<sup>®</sup>) received FDA approval in 2014 under the FDA premarket approval (PMA) process (PMA# P130017).<sup>10</sup>

#### *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 50 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.

Mental Health Parity Statement

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.

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