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

I. Fecal immunochemical test (FIT) is considered medically necessary and covered for routine screening for colorectal cancer when all the following (A.-B.) criteria are met:

A. Age 50 or greater; and
B. Last test was performed more than 12 months prior to current testing.

II. 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 50 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.

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/HCPCS CODES

<table>
<thead>
<tr>
<th>All Lines of Business</th>
<th>No Prior Authorization Required</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fecal Immunochemical Testing (FIT):</strong></td>
<td></td>
</tr>
<tr>
<td>82274</td>
<td>Blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1-3 simultaneous determinations</td>
</tr>
<tr>
<td>G0328</td>
<td>Colorectal cancer screening; fecal occult blood test, immunoassay, 1-3 simultaneous</td>
</tr>
<tr>
<td><strong>Fecal DNA Testing (Cologuard®):</strong></td>
<td></td>
</tr>
<tr>
<td>81528</td>
<td>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</td>
</tr>
</tbody>
</table>

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. 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
MEDICAL POLICY

Colorectal Cancer Screening: Fecal Immunochemical Testing and Fecal DNA Testing

- Fecal immunochemical test (FIT) every year
- Guaiac-based fecal occult blood test (gFOBT) every year
- Stool DNA test every 3 years

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. 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.” 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 2018 NCCN colorectal cancer (CRC) screening guideline gave a category 2A recommendation for 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 in the following patient population:

- Average risk
- Age ≥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, ≥1 cm, villous or tubulovillous histology)

U.S. Multi-Society Task Force (MSTF) on Colorectal Cancer
The 2017 U.S. MSTF evidence-based guideline on colorectal cancer gave the following rankings of currently available colorectal cancer screening tests:

- **Tier 1:**
  - Colonoscopy every 10 years
  - Annual fecal immunochemical test (FIT)

- **Tier 2:**
  - CT colonography every 5 years
  - FIT-fecal DNA every 3 years
  - Flexible sigmoidoscopy every 10 years (or every 5 years)

- **Tier 3:**
  - Capsule colonoscopy every 5 years

- **Available tests not currently recommended:**
  - Septin 9

**U.S. Preventive Services Task Force (USPSTF)**

The 2016 USPSTF recommendation for colorectal cancer screening gives a grade A for CRC screening in adults aged 50 to 75 and a grade C for CRC screening in adults aged 76 to 85 years. 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>
<thead>
<tr>
<th>Screening Method</th>
<th>Frequency</th>
<th>Evidence of Efficacy</th>
<th>Other Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stool-Based Tests</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>gFOBT</td>
<td>Every year</td>
<td>RCTs with mortality endpoints: High-sensitivity versions (eg, Hemoccult SENSA)</td>
<td>Does not require bowel preparation, anesth, or transportation to and from the screening examination (test is performed at home)</td>
</tr>
<tr>
<td>FIT</td>
<td>Every year</td>
<td>Test characteristic studies: Improved accuracy compared with gFOBT Can be done with a single specimen</td>
<td>Does not require bowel preparation, anesth, or transportation to and from the screening examination (test is performed at home)</td>
</tr>
<tr>
<td>FIT-DNA</td>
<td>Every 1 or 3 y</td>
<td>Test characteristic studies: Improved sensitivity compared with FIT per single screening test</td>
<td>There is insufficient evidence about appropriate longitudinal follow-up of abnormal findings after a negative diagnostic colonoscopy; may potentially lead to overly intensive surveillance due to provider and patient concerns over the genetic component of the test</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Direct Visualization Tests</th>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Colonoscopy</td>
<td>Every 10 y</td>
<td>Prospective cohort study with mortality and point</td>
<td>Requires less frequent screening</td>
</tr>
<tr>
<td>CT colonography</td>
<td>Every 5 y</td>
<td>Test characteristic studies</td>
<td>There is insufficient evidence about the potential harms of associated extracolonic findings, which are common</td>
</tr>
<tr>
<td>Flexible sigmoidoscopy</td>
<td>Every 5 y</td>
<td>RCTs with mortality endpoints: Modeling suggests it provides less benefit than when combined with FIT or compared with other strategies</td>
<td>Test availability has declined in the United States</td>
</tr>
<tr>
<td>Flexible sigmoidoscopy with FIT</td>
<td>Every 10 y plus FIT every year</td>
<td>RCT with mortality end point (subgroup analysis)</td>
<td>Test availability has declined in the United States</td>
</tr>
</tbody>
</table>

Abbreviations: FIT, fecal immunochemical test; FIT-DNA, multtargeted stool DNA test; gFOBT, guaiac-based fecal occult blood test; RCT, randomized clinical trial.

Although a serology test to detect methylated SEPT9 DNA was included in the systematic evidence review, this screening method currently has limited evidence evaluating its use (a single published test characteristic study met inclusion criteria, which found it had sensitivity to detect colorectal cancer of “<90%”); it is therefore not included in this table.

Strategy yields comparable life-years gained (i.e., the life-years gained with the noncolonoscopy strategies were within 90% of those gained with the colonoscopy strategy) and an efficient balance of benefits and harms in GINSNET modeling.

* Suggested by manufacturer.

* Strategy yields comparable life-years gained (i.e., the life-years gained with the noncolonoscopy strategies were within 90% of those gained with the colonoscopy strategy).
CENTER FOR MEDICARE & MEDICAID

On May 22, 2018, an advanced search of the Medicare Coverage Database identified a National Coverage Determination for Colorectal Cancer Screening Tests (210.3). The CMS criteria for fecal immunochemical testing (FIT) and fecal DNA testing (i.e., Cologuard®) 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 recommends colorectal cancer (CRC) screening in adults aged 50 years or older who are at an average risk for CRC. 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®) received FDA approval in 2014 under the FDA premarket approval (PMA) process (PMA# P130017).6

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.

REFERENCES

1. American Cancer Society: Colorectal Cancer Screening Tests.  
2. National Comprehensive Cancer Network: Colorectal Cancer Screening 2018;  
4. U.S. Preventive Services Task Force Recommendations for Primary Care Practice: Colorectal Cancer Screening. 2016;
MEDICAL POLICY

Colorectal Cancer Screening: Fecal Immunochemical Testing and Fecal DNA Testing

