Colorectal Cancer Screening Options for Your Highmark Patients

The HEDIS® Colorectal Cancer Screening measure identifies the percentage of members 50-75 years of age who had one of the following screenings for colorectal cancer:

1. Fecal occult blood test (FOBT Value Set) during the measurement year. For administrative data, assume the required number of samples were returned, regardless of FOBT type.

2. Colonoscopy (Colonoscopy Value Set) during the measurement year or the nine years prior to the measurement year.

3. Flexible Sigmoidoscopy (Flexible Sigmoidoscopy Value Set) during the measurement year or the four years prior to the measurement year.

4. CT Colonography (CT Colonography Value Set) during the measurement year or the four years prior to the measurement year.

5. FIT-DNA Test (FIT-DNA Value Set) during the measurement year or the two years prior to the measurement year.

Fecal Occult Blood Test (FOBT), also referred to as Fecal Immunochemical Test (FIT)

- FIT is a high-sensitivity, fecal immunochemical test method that can be completed in the comfort of a member's home.
- Depending on the FIT manufacturer, one or two samples from bowel movements are collected and placed in a supplied containment device and sent to the testing laboratory or to a patient's physician's office for processing.
- The FIT method for colorectal cancer screening confronts many barriers associated with colonoscopy, including time constraints, inconvenience and discomfort associated with the bowel preparation, and fear of invasive procedures.
- Member Cost Sharing:
    - A FIT is on the commercial and Medicare Advantage preventive health schedule.
    - Members should always check with Highmark Member Services regarding their benefits and any out-of-pocket expenses.

Healthcare providers may choose to institute one of the following options in order to promote the importance of colorectal cancer screening, address member barriers and meet quality and performance metrics.

Option 1: FIT – Utilizing Laboratory Testing Services

(No cost to the provider)

Some laboratories and vendors will provide physician practices with a limited supply of FIT kits to keep in-office for distribution to patients. With this option, the kits are to be processed by a laboratory. If a large number of kits are requested, the laboratory testing service may charge the provider a small fee for the kits in an effort to offset costs of kits that may not be returned for processing. Healthcare providers should contact their medical supply vendor and/or local laboratory testing services representatives to determine the feasibility of and procedure for obtaining FIT kits.

Healthcare providers will identify patients to receive the FIT kits. Practices may choose to target patients based on the HEDIS® Colorectal Cancer Screening measure specifications; or the practice may choose to target a select patient population, such as Medicare Advantage patients.

Dependent upon the test kit manufacturer specifications, the patient may be required to take the kit home to complete the stool specimen collection. When complete, he/she returns the stool specimen to the appropriate laboratory. Some test kits include postage-paid return envelopes for the specimens. The laboratory processes the stool sample and provides the results to the member's healthcare provider, who is responsible to notify the member of the result and to follow up with the member for additional testing in the event of abnormal test results. The patient's health plan is billed by the testing laboratory for processing of the FIT kit.

Option 2: In-office/Point of Care (POC) Testing

(Minimal cost to provider)

Providers may check with their medical supply vendors to determine the type of FIT available for order for in-office/POC testing. The InSure® FIT™ kit, manufactured by Enterix, is an example of one such FIT kit that can be used at minimal expense for in-office POC testing.

Certain FIT kits have been granted waived status under the Clinical Laboratory Improvement Amendments (CLIA). CLIA requires all entities that perform even one test, including waived tests, on "materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings" to meet certain federal requirements. If an entity performs tests for these purposes, it is considered under CLIA to be a laboratory and must register with the CLIA program.

If a provider is performing other POC testing in-office, there is likely no other action needed to be able to process a FIT kit. If a practice is not performing any type of in-office POC testing, it would need to complete a CMS 116 form to obtain a CLIA Certificate. That form and instructions for its completion can be downloaded from: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA Certificate_International_Laboratories.html.

The price of FIT kits varies with medical supply distributors and contracts. The provider assumes the cost of the FIT kits and may bill for the in-office POC processing of the kits.

Dependent upon the test kit manufacturer specifications, the patient may be required to take the kit home to complete the stool specimen collection. The practice can choose a preferred method of return once the patient completes specimen collection:

- The provider may provide a self-addressed stamped envelope for the member to return the kit. The amount of postage required for return varies with kit selection and can be as low as that of one first class postage stamp.
- The provider may ask that the patient assume the return-mail cost.
- The provider may ask that the patient hand-deliver the test card to the office upon completion.

Once returned, the test card can then be processed in-office by the practice staff. A sample in-office tracking form is attached at the end of this document.

The provider's office will notify the patient of test results and coordinate follow-up if needed. The provider may bill the patient's health plan for the processing of the FIT. The rate of reimbursement is dependent on the member's health plan.

Billing Information

When immunoassay-based FOBT (iFOBT) was FDA-approved and CLIA-waived in 2004, new CPT codes were assigned to distinguish this methodology from guaiac testing. Since the reimbursement for FIT is significantly higher than that of guaiac testing, it is important that healthcare providers bill insurers correctly to receive the full benefit of this increase.

Procedure / Test	**HEDIS® approved Procedure Codes (CPT)**
FOBT	G0328, 82270, 82274

Diagnostic Fecal Occult Blood Tests are covered by a National Coverage Determination (NCD) for the following indications:

1) To evaluate known or suspected alimentary tract conditions that might cause bleeding into the intestinal tract.
2) To evaluate unexpected anemia.
3) To evaluate abnormal signs, symptoms, or complaints that might be associated with loss of blood.
4) To evaluate patient complaints of black or red-tinged stools.

FOBTs may be performed with or without evidence of iron deficiency anemia, which may be related to gastrointestinal blood loss. The range of causes for blood loss include inflammatory causes, including acid-peptic disease, non-steroidal anti-inflammatory drug use, hiatal hernia, Crohn's disease, ulcerative colitis, gastroenteritis, strongyloides, ascariasis, tuberculosis, and enteroamebiasis. Vascular causes include angiodysplasia, hemangiomas, varices, blue rubber bleb nevus syndrome, and watermelon stomach. Tumors and neoplastic causes include lymphoma, leiomyosarcoma, lipomas, adenocarcinoma and primary and secondary metastases to the GI tract. Drugs such as nonsteroidal anti-inflammatory drugs also cause bleeding. There are extra gastrointestinal causes such as hemoptysis, epistaxis, and oropharyngeal bleeding. Artifactual causes include hematuria and menstrual bleeding. In addition, there may be other causes such as coagulopathies, gastrostomy tubes or other appliances, factitial causes, and long distance running.

The proper approach to billing iFOBTs is to use the same rules that are used in billing guaiac-based FOBTs. Simply substitute the new iFOBT CPT codes for the old ones.

IMPORTANT Always use the "QW" modifier when billing iFOBT to designate it as CLIA-waived.

The **G0328QW** (screening) code is primarily used for Medicare. Medicare covers one FOBT annually for beneficiaries 50 and older. A written order from the beneficiary's attending physician is required. Medicare will pay for an iFOBT as an alternative to the guaiac-based FOBT, **but will only pay for one FOBT**, not both, per year. Beneficiaries do not have to pay coinsurance for the FOBT and do not have to meet the annual Medicare Part B deductible.

Note: Some commercial insurers (and Railroad Insurance) also use the **GO328QW** code. They do so in order to simplify the processing of Medicare and Non-Medicare billing. It may also be used if Medicare is secondary to the primary insurer. **GO328QW** is an annual screen for fecal occult blood in patients over 50 years of age. It can only be used once a calendar year with an appropriate screening diagnosis code, such as Z12.11 (Screening for malignant neoplasms of the colon). The code, Z00.00 (annual physical exam), should not be used since Medicare does not pay for routine annual exams. As a rule, screening CPT codes require a screening diagnosis code.

Non-Medicare patient screening uses the code **82274QW** with a screening diagnosis code (screening procedures require a screening code). This would apply to annual physical exams billed to third party payers. CPT code **82274** represents; blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1-3 simultaneous determinations. The code is reported once for 1, 2 or 3 specimens. The date of service is the date the laboratory receives the specimen from the patient.

When using CPT **82274QW** for diagnostic purposes, the same ICD-10 codes should be used as is indicated when billing with the guaiac-based diagnostic CPT code 82270. CPT **82274QW** (diagnostic) can be used multiple times annually, has few limitations, and is dictated by the patient's medical symptoms. The **82274QW** CPT does not use a screening diagnosis code when used for diagnostic testing; instead it would require a diagnostic ICD-10, such as 280.0 (iron deficiency anemia), or diarrhea, abdominal pain, etc., and/or have an advance beneficiary notice (ABN) for frequency.

Note: Payment at the routine preventive level is ultimately determined by the benefits of the member's plan. As with any insurance plan, members are eligible for services only as long as they are active members and the services are covered benefits of the plan.

If you have further questions or concerns related to billing for the FOBT kits, please contact your assigned Highmark Clinical Transformation Consultant.

Colonoscopy

- A test that allows the physician to look at the inner lining of the large intestine (rectum and entire colon) with the aid of a thin flexible tube called a colonoscope. A colonoscopy helps find ulcers, colon polyps, tumors and inflammation of the lining of the intestines. Tissue samples can be collected at the time of the procedure and sent for testing to detect cancer or precancerous growths.
- Requires colon prep of 1-2 days including liquid diet and colon cleansing.
- Colonoscopy usually requires a sedative or anesthesia. Driving restrictions for 24 hours after testing.
- Colonoscopy is a more expensive procedure than a stool test or sigmoidoscopy but it can be done less often if results are normal.
- Procedure:
    - Lie on table, physician inserts colonoscope into rectum and slowly advances throughout the entire colon.
    - The scope pumps air into the intestines for better visualization of the colon.
    - The camera sends pictures of the intestinal lining to a monitor allowing the physician to examine the tissue lining the entire colon and rectum.
    - Cramping and bloating of the abdomen can occur shortly after the procedure.
- Member Cost Sharing:
    - A colonoscopy is on the commercial and Medicare Advantage preventive health schedule.
    - Members should always check with Highmark Member Services regarding their benefits and any out-of-pocket expenses.

Procedure / Test	**HEDIS® approved Procedure Codes (CPT)**
Colonoscopy	44388, 44389, 44390, 44391, 44392, 44393, 44394, 44397, 44401, 44402, 44403, 44404, 44405, 44406, 44407, 44408, 45355, 45378, 45379, 45380, 45381, 45382, 45383, 45384, 45385, 45386, 45387, 45388, 45389, 45390, 45391, 45392, 45393, 45398

Flexible Sigmoidoscopy

- A procedure that uses a flexible narrow tube, called a sigmoidoscope, with a light and tiny camera on one end to look inside the rectum and lower colon (sigmoid colon and descending colon). It can show irritated or swollen tissue, ulcers, polyps and cancer in the rectum and lower colon. A colonoscopy can look at the entire colon. If abnormal tissue or polyps are found on a flexible sigmoidoscopy, a colonoscopy would be recommended to remove the tissue or polyps.
- Flexible sigmoidoscopy may not require sedatives or anesthesia and the procedure takes about 20 minutes.
- Bowel prep and clear liquid diet are required for the test.
- Procedure:
    - Lie on table, physician inserts sigmoidoscope into rectum and slowly advances it into the sigmoid colon. The scope does not enter the transverse colon.
    - The scope pumps air into the intestines for better visualization of the colon.
    - The camera sends pictures of the intestinal lining to a monitor allowing the physician to examine the tissue lining the sigmoid colon and rectum.
    - Cramping and bloating of the abdomen can occur shortly after the procedure.
- Member Cost Sharing:
    - A flexible sigmoidoscopy is on the commercial and Medicare Advantage preventive health schedule.
    - Members should always check with Highmark Member Services regarding their benefits and any out-of-pocket expenses.

Procedure / Test	**HEDIS® approved Procedure Codes (CPT)**
Flexible Sigmoidoscopy	45330, 45331, 45332, 45333, 45334, 45335, 45337, 45338, 45339, 45340, 45341, 45342, 45345, 45346, 45347, 45349, 45350, G0104

CT Colonography

- CT Colonography (VT-Virtual Colonoscopy) is different from a regular colonoscopy. A regular colonoscopy uses a colonoscope that is inserted into the rectum and large intestines. A CT Colonography is a medical imaging procedure which uses low dose X-rays and computers to obtain interior images of the colon (large intestines) from the rectum to the lower end of the small intestines. CT Colonography is not able to detect polyps smaller than 10 mm where a regular colonoscopy can detect all sizes.
- CT Colonography can view the colon from different angles where a regular colonoscopy is more limited in viewing.
- CT Colonography does not require sedation.
- CT Colonography does not allow the physician to remove polyps if found and would require a follow up colonoscopy to remove them.
- Test Prep includes:
    - Bowel cleansing with enemas, 1-3 days of clear liquid diet prior to exam, laxatives
    - Stop medications such as Iron pills, Aspirin, Ibuprofen, Naproxen, and other blood thinning medications several days prior to exam.
- Test Procedure:
    - X-rays are painless
    - Lay on narrow table with knees drawn toward chest
    - A small tube is inserted into the rectum; air is pumped through the tube to inflate the colon for easier viewing. Pumping air into the colon may cause cramping or gas pains, bloating or mild abdominal cramping.
    - Return to normal activities post test
- Member Cost Sharing:
    - A CT Colonography is on the commercial and Medicare Advantage preventive health schedule.
    - Members should always check with Highmark Member Services regarding their benefits and any out-of-pocket expenses.

Procedure / Test	**HEDIS® approved Procedure Codes (CPT)**
CT Colonography	74261, 74262, 74263

FIT-DNA Test

Cologuard®-is a noninvasive colorectal cancer screening test for both men and women over the age of 50. It uses a stool DNA test manufactured by Exact Sciences® to identify precancerous and cancer cells. Cologuard is the only DNA test that is approved for use in the United States. Cologuard detects 92% of colon cancers. You can read more about Exact Sciences and Cologuard at http://www.exactsciences.com/ and http://www.cologuardtest.com/.

- Easy to use. It allows you to collect the specimen in your own home, and does not require a special diet or medication adjustments
- Cannot be purchased over the counter, your health care provider must prescribe it
- Collection kits are sent directly to the home for easy use
- Exact Sciences Laboratories is currently the only facility distributing testing kits and processing samples. They send the results directly to the provider. They have a toll-free Customer Support Center number for questions.
- Member Cost Sharing:
    - A FIT-DNA is on the commercial and Medicare Advantage preventive health schedule
    - Members should always check with Highmark Member Services regarding their benefits and any out-of-pocket expenses.

Procedure / Test	**HEDIS® approved Procedure Codes (CPT)**
FIT-DNA	81528, G0464

FOBT In-Office Tracking Form

Your office may choose to utilize this tool, or create your own, to track the distribution, return, processing, and follow up for FOBT testing.

To increase the possibility of return, we suggest a follow-up reminder call or mailing within two weeks of patient receipt of the kit.

Date *(Kit provided to patient – mailed or given in office)*	**Kit ID #** *(Your office may choose to record the lot # or assign a unique numbering system)*	**Patient Name**	**Reminder Call/Mailing** *(Your office may choose to follow up on kits not returned with a phone call or mailed reminder)*	**POC Processing Date** *(Date specimen received and processed in-office, staff that completed processing)*	**Results**	**Date Patient Notified**
EX: 2/29/17 In-office	063459 #2	Mary Ann Doe	NA	3/4/17 TS	+	3/4/17
EX: 3/4/17 Mailed	063459 #3	John Amos	3/18/17 JM			

FOBT In-Office Tracking Form

Your office may choose to utilize this tool, or create your own, to track the distribution, return, processing, and follow up for FOBT testing.

To increase the possibility of return, we suggest a follow-up reminder call or mailing within two weeks of patient receipt of the kit.

Date *(Kit provided to patient – mailed or given in office)*	**Kit ID #** *(Your office may choose to record the lot # or assign a unique numbering system)*	**Patient Name**	**Reminder Call/Mailing** *(Your office may choose to follow up on kits not returned with a phone call or mailed reminder)*	**POC Processing Date** *(Date specimen received and processed in-office, staff that completed processing)*	**Results**	**Date Patient Notified**