Colorectal Cancer Screening (CRC) Tests (82270, G0328, 81528, G0327) – NCD 210.3

Indications:

1. Fecal Occult Blood Tests (guaiac-based 82270 and immunoassay-based G0328): **Screening** tests are appropriate when the patient is asymptomatic (no signs or symptoms of colorectal disease including but not limited to lower gastrointestinal pain, blood in stool)
2. The Cologuard – Multi-target Stool DNA (sDNA) Test (81528):
   - Screening stool or fecal DNA (deoxyribonucleic acid, sDNA) testing 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.
   - Using selective enrichment and amplification techniques, sDNA tests are designed to detect very small amounts of DNA markers to identify colorectal cancer or pre-malignant colorectal neoplasia.
   - The Cologuard™ – multi-target sDNA test is a proprietary in vitro diagnostic device that incorporates both sDNA and fecal immunochemical test techniques and is designed to analyze patients' stool samples for markers associated with the presence of colorectal cancer and pre-malignant colorectal neoplasia.
3. Blood-based Biomarker Tests (G0327):
   - Blood-based DNA testing detects molecular markers of altered DNA that are contained in the cells shed into the blood by colorectal cancer and pre-malignant colorectal epithelial neoplasia.

Limitations:

1. Fecal Occult Blood Tests (FOBT):

Medicare covers **one screening FOBT per annum** for the early detection of colorectal cancer. This means that Medicare will cover one gFOBT or one iFOBT at a frequency of every 12 months; i.e., at least 11 months have passed following the month in which the last covered screening FOBT was performed, for beneficiaries aged **45** years and older. The beneficiary completes the existing gFOBT by taking samples from two different sites of three consecutive stools; the beneficiary completes the iFOBT by taking the appropriate number of stool samples according to the specific manufacturer's instructions. This screening requires a written order from the beneficiary's attending physician. ("Attending physician" means a doctor of medicine or osteopathy (as defined in §1861(r)(1) of the Act) who is fully knowledgeable about the beneficiary's medical condition, and who would be responsible for using the results of any examination performed in the overall management of the beneficiary's specific medical problem.)

2. The Cologuard – Multi-target Stool DNA (sDNA) Test:

Effective for dates of service on or after October 9, 2014, The Cologuard™ test is covered **once every three years** for Medicare beneficiaries that meet all of the following criteria:

- Age **45** to 85 years, and,
- Asymptomatic (no signs or symptoms of colorectal disease including but not limited to lower gastrointestinal pain, blood in stool, positive guaiac fecal occult blood test (gFOBT) or fecal immunochemical test (iFOBT)), and,
- At average risk of developing colorectal cancer (no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn's Disease

and ulcerative colitis; no family history of colorectal cancers or adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer).

3. Blood-based Biomarker Tests:

Effective for dates of service on or after January 19, 2021, a blood-based biomarker test is covered as an appropriate colorectal cancer screening test **once every 3 years** for Medicare beneficiaries when performed in a Clinical Laboratory Improvement Act (CLIA)-certified laboratory, when ordered by a treating physician and when all of the following requirements are met:

The patient is:

- age **45**-85 years, and,
- asymptomatic (no signs or symptoms of colorectal disease including but not limited to lower gastrointestinal pain, blood in stool, positive guaiac fecal occult blood test or fecal immunochemical test), and,
- at average risk of developing colorectal cancer (no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn's Disease and ulcerative colitis; no family history of colorectal cancers or adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer).

The blood-based biomarker screening test must have all of the following:

- Food and Drug Administration (FDA) market authorization with an indication for colorectal cancer screening; and,
- proven test performance characteristics for a blood-based screening test with both sensitivity greater than or equal to 74% and specificity greater than or equal to 90% in the detection of colorectal cancer compared to the recognized standard (accepted as colonoscopy at this time), as minimal threshold levels, based on the pivotal studies included in the FDA labeling.

Required diagnosis (only 1 dx required) *	
Z12.11	Encounter for screening for malignant neoplasm of colon
Z12.12	Encounter for screening for malignant neoplasm of rectum

Note: The regulatory definition of a colorectal cancer screening test has been expanded to include follow-on **screening** colonoscopy after a Medicare covered non-invasive stool-based test returns a positive result (without a frequency limitation or beneficiary cost sharing). This policy change is meant to remove barriers and encourage the patient to proceed to the colonoscopy procedure soon after the positive result from the stool-based test.

*For the complete coverage guidelines for NCD 210.3, see the Medicare Coverage Database:
NCD 210.3 Colorectal Cancer Screening Tests

The above CMS and WPS-GHA guidelines are current as of: 07/01/2025.