



National Coverage Determination (NCD) 210.3 - Screening for Colorectal Cancer (CRC) - Blood-Based Biomarker Tests

MLN Matters Number: MM12280

Related Change Request (CR) Number: 12280

Related CR Release Date: May 20, 2021

Effective Date: January 19, 2021

Related CR Transmittal Number: R10818CP and R10818NCD

Implementation Date: October 4, 2021

Provider Types Affected

This MLN Matters® Article is for physicians and providers who bill Medicare Administrative Contractors (MACs) for colorectal cancer (CRC) screening tests provided to Medicare patients.

Provider Types Affected

This Article tells you that CMS determined, effective January 19, 2021, the blood-based biomarker test is an appropriate CRC screening test based on specific criteria.

Background

[Sections 1861\(s\)\(2\)\(R\) and 1861\(pp\) of the Social Security Act](#) (the Act) and regulations at [42 Code of Federal Regulations \(CFR\) 410.37](#) authorize Medicare coverage for CRC screening tests under Medicare Part B. The statute and regulations authorize the HHS Secretary to add other tests and procedures (and modifications to such tests and procedures for CRC screening) as the Secretary determines in consultation with appropriate organizations.

Over the last several years, blood-based biomarker tests have emerged as another potential non-invasive option for the early detection of CRC. The blood-based biomarker measured in a person's blood can be an indicator of a process, such as CRC disease risk or progression.

For services you perform on or after January 19, 2021, the blood-based biomarker test is an appropriate CRC screening test once every 3 years for Medicare patients when performed in a Clinical Laboratory Improvement Act (CLIA)-certified laboratory, ordered by a treating physician, and when the following requirements are met.

The patient is:

- Aged 50-85 years

- 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 CRC (no personal history of adenomatous polyps, or inflammatory bowel disease, including Crohn's Disease and ulcerative colitis; no family history of CRCs or adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis CRC).

The blood-based biomarker screening test must have:

- FDA market authorization with an indication for CRC 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 CRC compared to the recognized standard (accepted as colonoscopy at this time), based on the pivotal studies included in the FDA labeling.

Effective for claims with dates of service on or after January 19, 2021, report at least 1 of the following diagnosis codes when submitting claims for the Blood-based Biomarker test HCPCS code G0327 (Colorectal cancer screening; blood-based biomarker):

- Z12.11 Encounter for screening for malignant neoplasm of colon
- Z12.12 Encounter for screening for malignant neoplasm of rectum

Effective for claims with dates of service on and after January 19, 2021, deductible and coinsurance don't apply to the Blood-based biomarker test (HCPCS G0327)

Your MAC won't search for prior claims containing HCPCS G0327 with dates of service on or after January 19, 2021. They will adjust such claims you bring to their attention.

More Information

We issued CR 12280 to your MAC as the official instruction via 2 transmittals. The first [transmittal](#) updates the Medicare Claims Processing Manual. The second [transmittal](#) updates the NCD Manual. The manual revisions are part of the transmittals.

For more information, contact your [MAC](#).

Document History

Date of Change	Description
May 26, 2021	Initial article released.

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