National Coverage Determination (NCD) Update

Benefit: Blood biomarker testing as a colorectal cancer screening test

Effective Date: January 19, 2021

On January 19, 2021, the Centers for Medicare and Medicaid Services (CMS) announced its determination that the evidence is sufficient to cover a blood biomarker test as an appropriate colorectal cancer screening once every three years for Medicare beneficiaries, when performed by a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory, when ordered by an attending physician, and when all the following requirements are met:

1. Patient:
    a. Is age 50-85, and
    b. Is asymptomatic (no signs or symptoms of colorectal disease, including lower gastrointestinal pain, blood in the stool, positive guaiac test for occult blood in the stool, or a fecal immunochemical test, and
    c. Has an 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 cancer or adenomatous polyps, familiar adenomatous polyposis, or hereditary colorectal cancer without polyposis).
2. The blood biomarker screening must have all of the following:

    a. Food and Drug Administration (FDA) approval, with an indication for colorectal cancer detection, and
    b. Proven test performance characteristics for a blood-based screening with sensitivity greater than or equal to 74%, and specifically greater than or equal to 90% in colorectal cancer detection, compared with the recognized standard (accepted as a colonoscopy at this time), based on the studies included in the FDA approval.

To access the memo containing the CMS decision, go to: https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=299.

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