

MLN Matters Number: MM6145

Related Change Request (CR) #: 6145

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Effective Date: April 28, 2008

Related CR Transmittal #: R93BP and R92NCD Implementation Date: August 25, 2008

Screening DNA Stool Test for Colorectal Cancer

Note: This article was revised on January 26, 2018, to update Web addresses. All other information remains the same.

Provider Types Affected

Physicians, providers, and suppliers submitting claims to Medicare contractors (carriers, DME Medicare Administrative Contractors (DME MACs), Fiscal Intermediaries (FIs), and/or A/B MACs) for services provided to Medicare beneficiaries.

Provider Action Needed



STOP – Impact to You

This article is based on Change Request (CR) 6145 which announces the Centers for Medicare & Medicaid Services (CMS) decision regarding a request for reconsideration of the current national coverage determination (NCD) for colorectal cancer screening.



CAUTION – What You Need to Know

CMS will not expand the colorectal cancer screening benefit to include coverage of PreGen-Plus™, a commercially available screening DNA stool test; because the Food and Drug Administration (FDA) determines that this test requires pre-market review and approval. A subsequent request for reconsideration will be considered once FDA approval is obtained.

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GO – What You Need to Do

See the Background and Additional Information Sections of this article for further details regarding these changes.

Background

Congress specifically authorized coverage of certain screening tests under Part B of the Medicare program and made necessary conforming changes in order to ensure that payments are made. As a result, CMS currently covers colorectal cancer screening for average-risk individuals ages 50 years and older using fecal occult blood testing, sigmoidoscopy, colonoscopy, and barium enema.

Neither the law nor regulations identify screening DNA stool tests as a possible coverage option under the colorectal cancer screening benefit. However, under the Code of Federal Regulations (42 CFR 410.37(a)(1)(v)) at http://www.access.gpo.gov/nara/cfr/waisidx_02/42cfr410_02.html and the Social Security Act (section 1861(pp)(1)(D)) http://www.ssa.gov/OP_Home/ssact/title18/1861.htm on the internet), CMS is allowed to use the NCD process to determine coverage of other types of colorectal cancer screening tests not specifically identified in the law or regulations as it determines to be appropriate, and in consultation with appropriate organizations.

Following a request for reconsideration of the current NCD at Section 210.3 of the Medicare NCD Manual for colorectal cancer screening, CMS will not expand the colorectal cancer screening benefit to include coverage of PreGen-Plus™, a commercially available screening DNA stool test, as an alternative to a screening colonoscopy or a screening flexible sigmoidoscopy.

The FDA determined that this test is a medical device that requires pre-market review and approval prior to marketing, which, to date, has not been obtained. In the absence of an FDA determination, CMS believes that there may be unresolved questions regarding the safety and effectiveness of the stool DNA test. Therefore, CMS does not believe that identification of stool DNA mutations is an appropriate colorectal cancer screening test at this time.

Additional Information

The official instruction, CR 6145, issued to your carrier, FI, A/B MAC, and DME MAC regarding this change, is reflected in two transmittals, one for the Medicare Benefit Policy Manual and one for the National Coverage Determinations Manual. These two transmittals are at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R93BP.pdf> and <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R92NCD.pdf>, respectively, on the CMS website.

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If you have any questions, please contact your carrier, FI, A/B MAC, or DME MAC at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html>.

Document History

Date of Change	Description
January 26, 2018	This article was revised to update Web addresses.
August 11, 2008	This article was revised on to reflect changes made to CR6145. The transmittal number, release date, and Web address for accessing the NCD portion of CR6145 were revised.
July 28, 2008	Initial article released

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