



News Flash - The Office of the Inspector General in the Department of Health and Human Services has issued a policy statement that assures Medicare providers, practitioners, and suppliers affected by retroactive increases in payment rates under the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 that they will not be subject to OIG administrative sanctions if they waive retroactive beneficiary cost-sharing amounts attributable to those increased payment rates, subject to the conditions noted in the policy statement. To view the document, go to http://oig.hhs.gov/fraud/docs/alertsandbulletins/2008/MIPPA_Policy_Statement.PDF on the Internet.

MLN Matters Number: MM6145 **Revised**

Related Change Request (CR) #: 6145

Related CR Release Date: July 25, 2008

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 August 11, 2008, to reflect changes made to CR6145. The transmittal number, release date, and Web address for accessing the NCD portion of CR6145 were revised. 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

Disclaimer

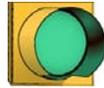
This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

**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.

**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.

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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.hhs.gov/Transmittals/downloads/R93BP.pdf> and <http://www.cms.hhs.gov/Transmittals/downloads/R92NCD.pdf>, respectively, on the CMS website.

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.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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