



## Screening DNA Stool Test for Colorectal Cancer – JA6145

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Implementation Date: August 25, 2008

**Key Words**

MM6145, CR6145, R93BP, R92NCD, DNA, Stool, Screening, Colorectal, Cancer

- Medicare Carriers

**Contractors Affected**

- Durable Medical Equipment Medicare Administrative Contractors (DME MACs)
- Fiscal Intermediaries (FIs)
- Part A/B Medicare Administrative Contractors (A/B MACs)

**Provider Types Affected**

Physicians, providers, and suppliers submitting claims to Medicare Carriers, DME MACs, FIs, and/or A/B MACs for services provided to Medicare beneficiaries



- The Centers for Medicare & Medicaid Services (CMS) will not expand the colorectal cancer screening benefit to include coverage of PreGen-Plus™.
- The Food and Drug Administration (FDA) has determined that this test requires pre-market review and approval. A subsequent request for reconsideration will be considered once FDA approval is obtained.

**Provider Needs to Know...**

- Following a request for reconsideration of the current National Coverage Determination (NCD) at Section 210.3 of the *Medicare NCD Manual* for colorectal cancer screening ([http://www.cms.hhs.gov/manuals/downloads/ncd103c1\\_Part4.pdf](http://www.cms.hhs.gov/manuals/downloads/ncd103c1_Part4.pdf)), 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 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.

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](http://www.access.gpo.gov/nara/cfr/waisidx_02/42cfr410_02.html) and the Social Security Act (Section 1861(pp)(1)(D)) at [http://www.ssa.gov/OP\\_Home/ssact/title18/1861.htm](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.

Operational Impact

All current claims processing and billing requirements remain in effect.

Reference Materials

The related MLN Matters article can be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6145.pdf> on the CMS website.

The official instruction (CR6145) issued 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.

For additional information, providers can review the *Medicare Benefit Policy Manual*, Chapter 15, Section 280 at <http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf> and the *Medicare Claims Processing Manual*, Chapter 18, Section 60 at <http://www.cms.hhs.gov/manuals/downloads/clm104c18.pdf> on the CMS website.