Medicare May Cover DNA Stool Screening Test

The Centers for Medicare and Medicaid Services is considering whether to add DNA stool testing as an alternative method of colorectal cancer screening, the agency announced in August.

Exact Sciences holds the patent for the stool DNA analysis technology behind the PreGen-Plus test. The company has requested that the CMS cover a DNA stool test every 5 years as an alternative to a screening colonoscopy, which is covered every 10 years, or as an alternative to sigmoidoscopy, which is covered every 4 years.

Currently, Medicare covers fecal occult blood testing, sigmoidoscopy, colonoscopy, and barium enema for average-risk beneficiaries aged 50 years and older.

The PreGen-Plus test, marketed by the Laboratory Corporation of America (LabCorp), costs about half as much as colonoscopy and is less invasive and uncomfortable, which might support better patient adherence to screening guidelines, according to Exact Sciences. The company recommends that a follow-up colonoscopy be done for patients who test positive with PreGen-Plus.

However, an August 2006 BlueCross BlueShield Technology Evaluation Center assessment concluded that "several questions remain before fecal DNA screening can be widely recommended."

PreGen-Plus currently is not approved by the Food and Drug Administration, but is offered as a "home-brew" diagnostic under the Clinical Laboratory Improvement Amendments.

PreGen-Plus has been on the market since 2003, and more than 300 private payers have paid for the test thus far, according to Exact Sciences president Jeff Luber.

The companies are waiting for the American Cancer Society to formally recommend stool DNA testing in its colorectal cancer guidelines before they "seek an FDA approval on a test kit of some kind," he said.

This step will mandate coverage by private insurers in 19 states, Mr. Luber explained, adding that his company expects revised guidelines soon. "That's when the private payers start to look more closely at coverage."

The CMS expects to propose a decision by Feb. 2, 2008, and complete its analysis by May 1, 2008.

—Ingrid Mezo

Ingrid Mezo is a staff writer for Elsevier's "The Gray Sheet."

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