

CMS May Cover Stool Test for Colorectal Cancer

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

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 sig-

moidoscopy, 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 compa-

ny 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 Improve-

ment Amendments. PreGen-Plus has been on the market since 2003, 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, he said.

—Ingrid Mezo

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

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Please see brief summary of full Prescribing Information on the following page.

References: 1. Castell D. Review of immediate-release omeprazole for the treatment of gastric acid-related disorders. *Expert Opin Pharmacother*. 2005;6:2501-2510. 2. ZEGERID Prescribing Information. Santarus, Inc. February 2006. 3. Katz PO, Koch FK, Ballard ED, et al. Comparison of the effects of immediate-release omeprazole oral suspension, delayed-release lansoprazole capsules and delayed-release esomeprazole capsules on nocturnal gastric acidity after bedtime dosing in patients with night-time GERD symptoms. *Aliment Pharmacol Ther*. 2007;25:197-205. 4. Castell D, Bagin R, Goldlust B, Major J, Hepburn B. Comparison of the effects of immediate-release omeprazole powder for oral suspension and pantoprazole delayed-release tablets on nocturnal acid breakthrough in patients with symptomatic gastro-oesophageal reflux disease. *Aliment Pharmacol Ther*. 2005;21:1467-1474.

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