

FDA approves first DNA-based test for colon cancer (Update)

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The Food and Drug Administration on Monday approved the first screening test for colon cancer that uses patients' DNA to help spot potentially deadly tumors and growths.

The Cologuard test from Exact Sciences detects irregular mutations in stool samples that can be an early warning sign of cancer. Patients who test positive for the mutations should undergo a colonoscopy to confirm the results.

Doctors have long used stool tests to look for hidden blood that can be a warning sign of tumors and precancerous polyps.

But company studies of Cologuard showed that it was more accurate at detecting cancerous tumors and worrisome polyps than traditional stool blood tests. Cologuard detected 92 percent of colon cancers and 42 percent of advanced polyps in a study of 10,000 patients, while traditional blood screening only detected 74 percent of cancers and 24 percent of advanced polyps.

The new test was not superior on all counts though. Cologuard was less accurate than older blood tests at correctly ruling out cancer, reporting more growths when none were actually present.

The approval has the potential to reshuffle current medical practice, though FDA officials stressed Monday that DNA-based stool screening has not been endorsed by federal medical advisers who set screening

guidelines. A spokeswoman for Exact Sciences, which is based in Madison, Wisconsin, said the new test would cost \$599 per patient. That compares to about \$25 for a traditional stool blood test.

Current federal guidelines recommend traditional stool tests every year and a colonoscopy every 10 years for patients between ages 50 and 75. Colonoscopy is the most accurate method for spotting colon cancer but many adults are reluctant to undergo the invasive procedure, which requires sedation as doctors probe the colon with a camera-fitted endoscope.

Colorectal cancer is the second leading cause of cancer death in the U.S., with over 50,000 deaths expected this year, according to the American Cancer Society. Deaths from the disease have been declining for more than two decades, a development attributed to increased screening. Still, only about 60 percent of people between ages 50 to 75 have had the recommended tests.

Officials at the Centers for Medicare and Medicaid Services—which runs the federal health programs for seniors and the poor—said they plan to cover the new test once every three years for people ages 50 to 85 who have a normal risk of developing colon cancer. The agency will take comments on its coverage proposal before making it final.

Shares of Exact Sciences Corp. rose 51 cents, or 3 percent, to \$17.60 in afterhours trading after closing up 2.5 percent to \$17.09 in regular-session trading.

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