FDA Approves Blood Test for Colon Cancer

Guardant Health's Shield blood test may help improve screening rates—but it doesn't replace colonoscopies.

July 31, 2024 By Laura Schmidt

This week, the Food and Drug Administration (FDA) approved a new blood test to screen for colon cancer, according to an FDA announcement.

Guardant Health's Shield is not a replacement for colonoscopies but has potential to improve the low screening rates for colon cancer, the second leading cause of cancer-related death in the United States (lung cancer tops that list by far).

FDA approval for Shield means that the screening tool is more likely to be covered by Medicare and private insurance companies, boosting accessibility. Before the FDA approval, Shield cost nearly $900 out of pocket, according to NBC.

Discounting skin cancers, colon cancer is the third most common cancer diagnosed in the United States, according to the American Cancer Society (ACS). Although effective methods can detect colorectal cancer early and increase the likelihood of long-term survival, screening rates remain low; indeed, less than 60% of eligible people get screened. Some experts attribute low screening rates to the discomfort associated with colonoscopies.

The ACS estimates that 53,000 people will die of colorectal cancer this year. What's more, it reports that 2024 will likely see about 106,590 new cases of colon cancer and 46,220 new cases of rectal cancer.

The Shield blood test, also known as a liquid biopsy, detects DNA that cancerous tumors release into the bloodstream. A study published in The New England Journal of Medicine found that Shield was about 83% effective in detecting colorectal cancers. It is most effective, however, in finding later-stage cancers, when tumors release more cancerous DNA. In fact, the blood test detected

only about 13% of early-stage polyps, according to the study.

Shield “has limited detection (55% to 65%) of Stage I colorectal cancer and does not detect 87% of precancerous lesions,” notes the FDA. “The test is used for [colorectal] screening in individuals at average risk for the disease who are 45 years of age or older. Patients with positive test results should have a colonoscopy, since the test is not a replacement for diagnostic colonoscopy or for surveillance colonoscopy in high-risk individuals.”

Shield would be used every three years, starting at age 45, the age at which experts recommend people begin colorectal screening.

A positive blood test indicates that cancer is present, but a colonoscopy would still be required to locate tumors and determine how far they have progressed.

“People have to understand that a positive Shield test requires a colonoscopy to confirm that you have an advanced lesion or colorectal cancer or that the results were false,” Robert Smith, PhD, of ACS, told NBC News. “A test like this is not complete if it’s positive and you have not had a colonoscopy.”

Shield is the second blood test to screen for colon cancer after Epigenomics’ Epi proColon, which was approved in 2016 but is rarely used, according to Smith, who said people are concerned about its accuracy and the fact that it is not covered by Medicare or private insurance.

Older age is the biggest risk factor for colon cancer. This is because colon and rectal tumors can take a long time to form. Sometimes benign (noncancerous) tumors in the colon can take 10 to 20 years to progress to cancer.

New colon cancer cases and deaths among older adults have been decreasing overall in recent years, likely due to more screening, but the rates are increasing among people younger than 50.

Colon cancer can cause many symptoms, including:

- Changes in bowel habits such as diarrhea or constipation;
- Blood in the stool;

- Feeling the need to have a bowel movement even after doing so;
- Persistent abdominal pain or cramps;
- Unexplained weight loss;
- Iron deficiency (anemia).

Many people with colon cancer do not develop symptoms until its late stages, when it is harder to treat. For this reason, routine screening is important for prevention and early treatment.

To read more, click #Colon Cancer or #Early Detection. There, you'll find headlines such as "New Tests May Beat FIT for Detecting Colon Cancer," "Blood Test Accurately Detects Early-Stage Pancreatic Cancer," and "New Blood Test to Detect Aggressive Form of Prostate Cancer."

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