



Stop Cancer Before It Starts!

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August 15, 2014

Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group
Center for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Re: Proposed Decision Memorandum for Screening for Colorectal Cancer Using
Cologuard™—A Multitarget Stool DNA Test

Dear Ms. Syrek Jensen:

As the only national nonprofit organization in the United States dedicated solely to the prevention and early detection of cancer, the Prevent Cancer Foundation appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the national coverage determination for Cologuard™. This multitarget stool DNA (sDNA) test for colorectal cancer screening is an innovative, noninvasive product that is an important tool to detect this cancer. Having demonstrated the safety, effectiveness, and risk benefit profile, the U.S. Food and Drug Administration (FDA) approved Cologuard™ on August 11, 2014. As such, we strongly support coverage for Cologuard™ tests once every three years for Medicare beneficiaries who meet the CMS-outlined criteria.

Cologuard™ has demonstrated dramatic improvements in the detection of early-stage colorectal cancer and precancerous lesions with high-grade dysplasia. Compared to a commonly used, automated immunochemical test for fecal hemoglobin, Cologuard™ detected significantly more colorectal cancers overall. Cologuard™ offers a non-invasive screening alternative for individuals who are unwilling or unable to be screened by colonoscopy. This is a particular challenge in areas of the country that are underserved and lack robust screening resources and coverage. Currently, one in three Americans between the ages of 50 and 75 (about 23 million people) is not getting any of the recommended tests.ⁱ People of color, rural populations, men, those 50 to 64, and those with lower education and income are the least likely to get tested.ⁱⁱ

There are nearly 150,000 new cases of colorectal cancer each year in the United States at a cost of \$14 billion. This disease is the second leading cause of cancer-related deaths in the nation, taking over 50,000 lives this year.ⁱⁱⁱ However, screening asymptomatic people can greatly reduce these numbers, particularly in older Americans who are at higher risk for the disease.

Ms. Syrek Jensen
August 15, 2014
Page Two

Approximately 90 percent of people live five or more years when their colorectal cancer is found early.^{iv} Medicare beneficiaries deserve access to this test. As evidenced by the Affordable Care Act and the U.S. Preventive Services Task Force (USPSTF), preventive services such as recommended cancer screenings must be affordable and accessible to all.

Again, we appreciate the opportunity to comment on this national coverage determination for Cologuard™. If we can provide further information, please feel free to contact me at Carolyn.Aldige@preventcancer.org or at 703.519.2114.

Sincerely,

Carolyn Aldigé

Carolyn Aldigé
President and Founder

ⁱ National Colorectal Cancer Roundtable. (n.d.). *80% by 2018 fact sheet*. Retrieved from http://nc crt.org/wp-content/uploads/80-by-2018-FACT-SHEET.FINAL_.pdf.

ⁱⁱ American Cancer Society. (2014). *New studies may help reduce colon cancer screening disparities*. Retrieved from <http://www.cancer.org/research/acresearchupdates/coloncancer/new-studies-may-help-reduce-colon-cancer-screening-disparities>.

ⁱⁱⁱ American Cancer Society. (n.d.). *What are the key statistics about colorectal cancer?* Retrieved from <http://www.cancer.org/cancer/colonandrectumcancer/detailedguide/colorectal-cancer-key-statistics>.

^{iv} Centers for Disease Control and Prevention. (n.d.). *Colorectal cancer tests save lives*. Retrieved from <http://www.cdc.gov/vitalsigns/colorectalcancerscreening/>.