GI TO PROVIDER COMMUNICATION TEMPLATE

Cologuard® GI Alignment Letter

Entities using this material are responsible for, and should pay close attention to, the accuracy of the information about the specific circumstances in which they distribute these materials. This template is provided to any appropriately requesting entity, regardless of the manner in which they recommend or participate in the ordering of Cologuard, and is not intended to interfere with the individualized care decision made between the provider and patient.

Dear [PRIMARY CARE NAME]:

As healthcare providers, we know how important early detection is in the fight against colorectal cancer (CRC), which remains the most preventable, yet least prevented, cancer.[1-3] Through our efforts, getting the estimated 44 million eligible unscreened average-risk patients screened for CRC can become a top priority.[4] **Together, we can close this screening gap.**

There are a few specific ways we can work together to address this gap. One way, as recommended by the American Cancer Society, is to take a shared decision-making approach in which we offer choices for CRC screening methods.[5] Another way to address patient barriers to screening is to offer noninvasives.

For patients at average risk for CRC who are 45 years or older, the noninvasive screening option I recommend is Cologuard®.[6] Cologuard is a convenient, at-home multitarget stool DNA (mt-sDNA) test; it demonstrated superior sensitivity over fecal immunochemical test (FIT)* in detecting CRC and advanced adenomas.[6,7†] Cologuard also has a built-in patient navigation program that is instrumental in guiding patients to complete the screening test.[6]

Cologuard is not for patients at increased risk of CRC due to family history of CRC, personal history of CRC or adenoma, IBD, or certain hereditary syndromes. Cologuard is also not a replacement for diagnostic or surveillance colonoscopy. With Cologuard, there is a chance for false positives and false negatives.[6]

Let's work together to close the screening gap. I've committed to a shared decision-making approach between my patients and me. Will you join me in this initiative?

Please feel free to contact me if you have any questions.

[Sign off]
[GI contact information]

*OC FIT-CHEK, Polymedco, Inc.[7]
†Results from a prospective, head-to-head, point-in-time, 90-site, pivotal study of 10,000 patients aged 50-84 years at average risk for CRC.[7]

Indications and Important Risk Information

Cologuard is intended for the qualitative detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. A positive result may indicate the presence of colorectal cancer (CRC) or advanced adenoma (AA) and should be followed by colonoscopy. Cologuard is indicated to screen adults of either sex, 45 years or older, who are at typical average risk for CRC. Cologuard is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high-risk individuals.

Cologuard is not for high-risk individuals, including patients with a personal history of colorectal cancer and adenomas; have had a positive result from another colorectal cancer screening method within the last 6 months; have been diagnosed with a condition associated with high risk for colorectal cancer such as IBD, chronic ulcerative colitis, Crohn's disease; or have a family history of colorectal cancer, or certain hereditary syndromes.

Positive Cologuard results should be referred to colonoscopy. A negative Cologuard test result does not guarantee absence of cancer or advanced adenoma. Following a negative result, patients should continue participating in a screening program at an interval and with a method appropriate for the individual patient.

False positives and false negatives do occur. In a clinical study, 13% of patients without colorectal cancer or advanced adenomas received a positive result (false positive) and 8% of patients with cancer received a negative result (false negative). The clinical validation study was conducted in patients 50 years of age and older. Cologuard performance in patients ages 45 to 49 years was estimated by sub-group analysis of near-age groups.

Cologuard performance when used for repeat testing has not been evaluated or established. Rx only.

References: 1. Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer statistics, 2022. *CA Cancer J Clin.* 2022;72(1):7-33. **2.** American Cancer Society survival rates for colorectal cancer. American Cancer Society. Accessed August 17, 2022. https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/survival-rates.html. **3.** Itzkowitz SH. Incremental advances in excremental cancer detection tests. *J Natl Cancer Inst.* 2009;101(18):1225-1227. **4.** Piscitello A, Edwards DK 5th. Estimating the screening-eligible population size, ages 45-74, at average risk to develop colorectal cancer in the United States. *Cancer Prev Res*. 2020;13(5):443-448. **5.** Wolf AMD, Fontham ETH, Church TR, et al. Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. *CA Cancer J Clin.* 2018;68(4):250-281. **6.** Cologuard® Clinician Brochure. Madison, WI: Exact Sciences Corporation. **7.** Imperiale TF, Ransohoff DF, Itzkowitz SH, et al. Multitarget stool DNA testing for colorectal-cancer screening. *N Engl J Med.* 2014;370(14):1287-1297.

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