GI TO PROVIDER COMMUNICATION TEMPLATE

Unsuccessful Scheduling Attempt From GI

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.

To: [Office Name]
Attn: [Provider Name]

According to our records, your patient, [Patient Name – (DOB xx/xx/xxxx)], was referred to our practice on [Date xx/xx/xxxx] for colorectal cancer (CRC) screening via colonoscopy. After several attempts to reach this patient, we have been unsuccessful in scheduling their procedure.

[GI Group Name or Individual Provider Name] believes that, with all we can do to help patients today, improving screening rates has never been more important. That is why we are informing you of [Patient Name]'s screening status. I encourage you to follow up with them to gain a clearer understanding of the barriers preventing them from being screened for CRC, and perhaps to offer them alternative options.

If colonoscopy is not an option for this patient, and if they are at average risk for CRC, I recommend offering Cologuard® as an alternative choice. Cologuard is a noninvasive multitarget stool DNA (mt-sDNA) CRC screening choice for average-risk patients aged 45 years or older.[1] It showed superior sensitivity compared with fecal immunochemical test (FIT)* in detecting CRC and advanced adenomas.[1,2†] As a convenience to you and your patient, Cologuard has a patient navigation program backed by an expert Customer Care Team that offers support at every step of the screening process.

Cologuard is not for patients at increased CRC risk due to a family history of CRC, a personal history of CRC or adenoma, inflammatory bowel disease (IBD), or certain hereditary syndromes.[1] Cologuard is also not a replacement for diagnostic or surveillance colonoscopy.[1] With Cologuard, there is a chance for false positives and false negatives.[1] However, if this patient is eligible for Cologuard, it might be just the option they need to get screened.

The American Cancer Society highlights the importance of choice-based shared decision-making in screening conversations with patients.[3] In one study, for participants who were offered more than one choice for CRC screening, adherence rates almost doubled.[4] Cologuard could be a powerful tool in implementing this approach and improving screening rates.

I know we share the goal of improving screening rates for CRC. Combining our efforts to knock down the barriers to screening is crucial because of the benefits of early detection. Can I count on your commitment to this initiative?

Please update your records based on the information shared above, and feel free to contact our offices with any questions.

[Sign off]
[GI contact information]

*OC FIT-CHECK, Polymedco, Inc.[2]
†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.[2]

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. Cologuard® Clinician Brochure. Madison, WI: Exact Sciences Corporation. **2.** 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. **3.** 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. **4.** Inadomi JM, Vijan S, Janz NK, et al. Adherence to colorectal cancer screening: a randomized clinical trial of competing strategies. *Arch Intern Med*. 2012:172(7):575-582.

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