GI TO PROVIDER COMMUNICATION TEMPLATE

Cologuard® Health System Letter From GI

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

Many people are surprised to learn that colorectal cancer (CRC) remains the most preventable, yet least prevented, cancer.[1] However, regular screening for CRC may help to reduce mortality rates and has the potential to save lives.[2] And with an estimated 53,000 people expected to die from CRC in 2022,[3] [our health system] has a tremendous opportunity to improve outcomes today and help lower health care costs tomorrow.

Overcoming barriers to CRC screening is an important initiative for us. These barriers can impact multiple stakeholders, including the patient, the provider, and the system itself.[4,5] We believe that offering choice to our patients and sharing in the decision-making process with them are two ways we can work to overcome these barriers together. In fact, the American Cancer Society highlights the importance of choice-based shared decision-making in screening conversations with patients.[5]

One option you can offer your patients is Cologuard®. Cologuard is a noninvasive, multitarget stool DNA (mt-sDNA) CRC screening choice for average-risk patients who are 45 years of age or older.[6] In a clinical study, Cologuard demonstrated superior sensitivity versus fecal immunochemical test (FIT)* in detecting CRC and advanced adenomas.[6,7†] In a separate study, Cologuard patients had nearly double the adherence rates to follow-up colonoscopy versus FIT within six months.[8]

It is important to note that Cologuard is not for patients at an increased risk for 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]

Together we are going to do our best to flip the statistics on this most preventable, yet least prevented, cancer[1]; [our health system] will work to improve both screening rates and outcomes. Can we count on you to join this important initiative?

Please feel free to contact us 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. Itzkowitz SH. Incremental advances in excremental cancer detection tests. *J Natl Cancer Inst.* 2009;101(18):1225-1227. **2.** Davidson KW, Barry MJ, Mangione CM, et al. Screening for colorectal cancer: US Preventive Services Task Force recommendation statement. *JAMA.* 2021:325(19):1965-1977. **3.** Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer statistics, 2022. *CA Cancer J Clin.* 2022;72(1):7-33. **4.** Wang H, Qiu F, Gregg A, et al. Barriers and facilitators of colorectal cancer screening for patients of rural accountable care organization clinics: a multilevel analysis. *J Rural Health.* 2018;34(2):202-212. **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. **8.** Finney Rutten LJ, Jacobson DJ, Jenkins GD, et al. Colorectal cancer screening completion: an examination of differences by screening modality. *Prev Med Rep.* 2020.

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