ORDERING Provider:

Provider Name Address

City, State, Zip

NPI #:

Date: / /

ATTN: Medical Management, Medical Director

RE: **Authorization Request**: Medical Necessity for colorectal cancer screening using a multitarget stool DNA test called Cologuard® from Exact Sciences Laboratories (COMMERCIAL PLAN MEMBER):

|  |  |
| --- | --- |
| **Patient:** | **Date range for service:**  **TO** |
| **Birth date:** | **Insurance ID#:** |

Contact person: Phone #: Fax #:

I am requesting authorization based on medical necessity for the above-mentioned patient to use Exact Sciences Laboratories noninvasive multitarget stool DNA colorectal cancer screening test called Cologuard.

ENTER ICD-10 CODES and SPECIFIC REASON FOR ORDERING COLOGUARD FOR THIS PATIENT HERE

This patient meets all of the indications for the Cologuard test, which are the following:

* Age 45 and older
* Asymptomatic (no signs or symptoms of colorectal disease, including but not limited to lower gastrointestinal pain, blood in stool, positive guaiac fecal occult blood test, or fecal immunochemical test)
* At average risk of developing colorectal cancer (no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn’s disease and ulcerative colitis; no family history of colorectal cancers or adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer)

**Procedure Code:** Laboratory Services (Exact Sciences NPI: 1629407069; Tax ID: 46-3095174):

**81528** Administrative Codes for Multianalyte Assays with Algorithmic Analyses (MAAA)

**About Cologuard for colorectal cancer screening:**

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 diagnostic 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. Rx only.

* Cologuard was FDA approved on August 11, 20141
* CMS/Medicare issued a National Coverage Decision for Cologuard on October 9, 20142
* The American Cancer Society included Cologuard in recommendations for screening for colorectal cancer beginning at age 45 for men and women at average risk in 20183
* National Comprehensive Cancer Network® included Cologuard in NCCN Guidelines® Version 2.2020 Colorectal Cancer Screening in 20204
* The U.S. Preventive Services Task Force included Cologuard in recommendations for screening for colorectal cancer beginning at age 45 for men and women at average risk in 20215

Sincerely, Date

**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 diagnostic 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 diagnostic 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.** FDA summary of safety and effectiveness data: PMA P130017. Food and Drug Administration. Accessed March 2, 2022. [http://www.accessdata.fda.gov/cdrh\_docs/pdf13/P130017b.pdf.](http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130017b.pdf) **2.** Decision memo for screening for colorectal cancer—stool DNA testing (CAG-0044ON). Centers for Medicare & Medicaid Services. Accessed March 2, 2022. https://cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=277. **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. doi:10.3322/caac.21457. **4.** NCCN clinical practice guidelines in oncology (NCCN Guidelines®) colorectal cancer screening version 2.2021—April 13, 2021. National Comprehensive Cancer Network®. Accessed March 2, 2022. https://[www.nccn.org/professionals/physician\_gls/pdf/colorectal\_screening.pdf.](http://www.nccn.org/professionals/physician_gls/pdf/colorectal_screening.pdf) **5.** 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. doi:10.1001/jama.2021.6238.

Cologuard is a registered trademark of Exact Sciences Corporation in the U.S. and other countries.

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