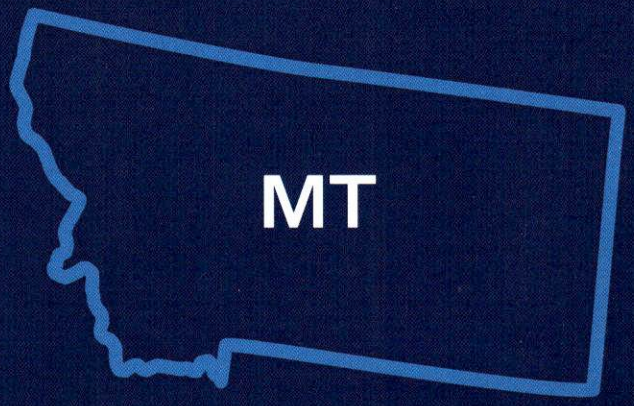
Cologuard®

Coverage & Access For All

in Montana

For members 45-75 years old, who are asymptomatic, at average risk of developing colorectal cancer (CRC) and eligible for screening.



Cologuard is covered by Medicare, Medicaid, Medicare Advantage & most major insurers. Learn more at Cologuard.com/access

95%

Patients who have no out-of-pocket costs for Cologuard screening in Montana*

Currently, 93% of Montana Cologuard patients aged 45-49 have no out-of-pocket cost for screening.*

Top 5 In-Network Insurers†**

- BlueCross BlueShield of Montana
- Cigna Corporation
- Mountain Health CO-OP
- PacificSource Health Plans
- Centene Corporation

Cologuard Patient Assistance Program

Patients facing challenges with insurance coverage can call our Customer Care Center at: 1-844-870-8870.

*Exact Sciences estimate based on historical patient billing as of February 28, 2023. Rate of coverage varies by state and region. Exceptions for coverage may apply; only your patients' insurers can confirm how Cologuard would be covered.

**In-network means Exact Sciences Laboratories has contracted with the insurer to be part of their network, and the insurer will cover the test if eligible patients meet certain clinical criteria. Coverage and benefit plan type can change over time. This is not a comprehensive list of in-network insurers. Exceptions for coverage may apply; only an insurer can confirm how Cologuard would be covered.

† Colorectal Cancer screening policy updated to reflect the 2021 USPSTF recommendations for screening average-risk patients beginning at age 45 (Grade B). Exceptions for coverage may apply; only an insurer can confirm how Cologuard would be covered.

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Cologuard is included in major CRC screening guidelines and quality measures[1-8]

Ages 45+

USPSTF and ACS CRC screening recommendations[1,2*†]

3 year screening interval

USPSTF and ACS recommendations following a negative Cologuard result[1,2‡]

3 years of credit

Healthcare Effectiveness Data and Information Set (HEDIS®)[3§]

Cologuard is part of the standard of care for CRC screening

- U.S. Preventive Services Task Force (USPSTF)[1]
- American Cancer Society (ACS)[2]
- American College of Obstetricians and Gynecologists (ACOG)[4]
- Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)[5]
- Medicare Advantage Star Rating Program[6]
- Electronic Clinical Quality Measure (eCQM)[7]
- Health Resources and Services Administration Uniform Data Set (UDS)[8]

*The USPSTF found adequate evidence that screening patients aged 45 to 49 years provides a moderate benefit in reducing CRC deaths and increasing life-years gained. USPSTF-recommended screening modalities include stool-based tests or direct visualization tests.[1]

†The ACS makes a qualified recommendation for screening in patients aged 45 to 49 years, indicating clear evidence of benefit of screening but less certainty about the balance of benefits, harms, and patient preferences. ACS-recommended screening modalities include high-sensitivity stool-based tests or structural (visual) examinations.[2]

‡The USPSTF-recommended screening frequency for sDNA-FIT is every 1 to 3 years. The ACS-recommended screening interval for mt-sDNA is every 3 years.[1,2]

§DNA (ie, Cologuard) is one of the methods permitted for patients at average risk aged 45 to 75 years as part of the National Committee for Quality Assurance's (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS®) quality measures for colon cancer screening. Third-party guidelines and quality measures do not specifically "endorse" commercial products, and inclusion in same does not imply otherwise. HEDIS® is a registered trademark of the National Committee for Quality Assurance (NCQA).[3]

References: 1. 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. **2.** 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. **3.** Healthcare Effectiveness Data and Information Set (HEDIS® Measurement Year 2022 Volume 2: Technical Update. National Committee for Quality Assurance. Accessed November 14, 2022. https://www.ncqa.org/wp-content/ uploads/2022/03/MY-2022-Vol-2-Technical-Updatepdf. ACOG endorsed. **4.** The American College of Obstetricians and Gynecologists. Accessed November 14, 2022. https:// www.acog.org/clinical/clinical-guidance/acog-endorsed. **5.** Quality measure specifications. Quality ID#113 (NQF 0034): colorectal cancer screening. Centers for Medicare & Medicaid Services. Accessed November 14, 2022. https://qpp.cms.gov/docs/QPP_quality_measure_specifications/ Claims-Registry-Measures/2020_Measure_II3_MedicarePartBClaims.pdf. **6.** Announcement of Calendar Year (CY) 2020 Medicare Advantage capitation rates and Medicare Advantage and Part D payment policies and final call letter. Centers for Medicare & Medicaid Services Center. Accessed November 14, 2022. https://www.cms.gov/Medicare/Health-Plans/ MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf. **7.** Colorectal cancer screening. eCQM for 2021 performance period. Electronic Clinical Quality Improvement Resource. Accessed November 14, 2022. https://ecqi.healthit.gov/sites/default/files/ecqm/measures/CMS130v9.html. **8.** 2021 uniform data system (UDS) program assistance letter (PAL): uniform data system changes for calendar year 2021; October 21, 2020. US Health Resources and Services Administration (HRS) Health Center Program. Accessed November 14, 2022. https://bphc.hrsa.gov/datareporting/reporting/udspals/2020-07.

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.

EXACT SCIENCES CORPORATION | 5505 Endeavor Lane, Madison, WI 53719
Exactsciences.com | Exactlabs.com | 1-844-870-8870

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