

January 8, 2025

Exact Sciences (EXAS): Cologuard Plus Coverage Questions

A Jan. 1 update to CMS's colorectal cancer (CRC) screening [guide](#) appears to support our [view](#) that Medicare coverage of **EXAS'** Cologuard Plus (0464U: \$592) and its 16% rate premium over the legacy version (81528: \$509) risks delay until YE25 or 1H26. In short, we have been waiting for an explicit indication that code 0464U is covered under the established [National Coverage Determination \(NCD\)](#), and though the updated screening guide now includes CT colonography code 74263 (\$700), the Cologuard Plus code remains omitted. In the absence of an explicit directive to Medicare Administrative Contractors (MACs), it is unclear whether / how Cologuard Plus claims can be processed, and we suspect a full NCD reconsideration may be required.

Note: With the JP Morgan Healthcare Conference coming up next week, please see our recently-published [CPP Conference Policy Prep Pack](#) for key questions on this and other issues that we would like to see management address.

Colorectal Cancer Screening Tests [National Coverage Determination 210.3](#)

Print

HCPCS & CPT Codes

- 00812** — Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; screening colonoscopy
- 74263** — Computed tomographic (CT) colonography, screening, including image postprocessing
- 81528** — Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result
- 82270** — Blood, occult, by peroxidase activity (eg, guaiac), qualitative; feces, consecutive collected specimens with single determination, for colorectal neoplasm screening (ie, patient was provided 3 cards or single triple card for consecutive collection)
- G0104** — Colorectal cancer screening; flexible sigmoidoscopy
- G0105** — Colorectal cancer screening; colonoscopy on individual at high risk
- G0121** — Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk
- G0327** — Colorectal cancer screening; blood-based biomarker
- G0328** — Colorectal cancer screening; fecal occult blood test, immunoassay, 1-3 simultaneous

What's Changed?

- Expanded coverage to include computed tomography (CT) colonography (74263), effective January 1, 2025
- Removed coverage for barium enema procedures (G0106 and G0120), effective January 1, 2025
- Removed ICD-10 code Z86.010, effective September 30, 2024
- Added ICD-10 codes Z83.72, Z86.0100, Z86.0101, Z86.0102, and Z86.0109, effective October 1, 2024

Source: Medicare Preventive Services Tool

To be clear, the above CRC screening guide is *not* the final word on which codes are covered under a given NCD, which is instead derived from transmittal / change requests (CRs) sent from CMS to the local MACs responsible for claims administration. These are posted at the bottom of each NCD [\[see here for CRC\]](#), with the [most recent \(zip\)](#) for CRC screening updated on Oct. 24.

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Price:	\$56.79
52-Week High:	\$79.62
52-Week Low:	\$40.62

TRANSMITTAL #12904 / CHANGE REQUEST #13828 – OCT. 24, 2024

Effective 10/9/14, shall allow **Cologuard™ test G0464**, and effective 1/19/21, allow **blood-based biomarker tests using generic G0327 unless a more specific code becomes available (G0327 effective 7/1/21).327 effective 7/1/21).327 effective 7/1/21).**

Effective for claims with **date of service on and after 1/1/16, G0464 shall be replaced with 81528.**

Source: CMS Transmittal #12904 (Oct. 24, 2024)

We should note that these coding instructions from Oct. 24 also do not include the Jan. 1, 2025, update highlighted in the CRC screening guide indicating coverage for CT colonography code 74263, which was finalized as part of the CY25 Physician Fee Schedule (PFS) [published](#) on Nov. 1. This suggests that a formal NCD coding update will be released in the near future, if only to formalize the status of CT colonography, which in our view allows for two possible interpretations:

- **Glass Half Full:** If coverage of Cologuard Plus code 0464U is self-evident under the existing NCD, we would expect it to be included in updated instructions, or at the very least a directive that the MACs may use their own discretion to cover additional multi-target stool DNA tests beyond the legacy “Cologuard™” test billed under CPT 81528.
- **Glass Half Empty:** The fact that this screening guide update seems to be preceding a formal NCD coding revision, Cologuard Plus code 0464U would likely remain absent as well, indicating that CMS views the current NCD language – which refers only to “Cologuard™” – as limiting its ability to cover “Cologuard Plus™” absent a full reconsideration.

Effective for dates of service on or after October 9, 2014. The **Cologuard™** test is covered once every three years for Medicare beneficiaries that meet all of the following criteria:

- Age 50 to 85 years, and,
- 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 (gFOBT) or fecal immunochemical test (iFOBT)), and,
- 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).

Effective January 1, 2023, the minimum age for sDNA is reduced to 45 years and older.

Source: CMS National Coverage Determination 210.3

Between these options we increasingly take the half empty view, particularly with CMS already signaling its intention to reopen the CRC NCD for reconsideration via its inclusion on the published [wait list](#) of accepted requests that will be addressed once there is sufficient staff capacity. Unfortunately, NCD reconsiderations typically take ~9 months to complete once they are formally opened, suggesting that even an announcement from CMS *today* would imply an implementation date in 4Q25.

NCD Wait List

Topic
Diaphragm Pacemakers for Neuromuscular Disease (request for non-coverage)
Colorectal Cancer Screening
Hepatitis C Screening
Hyperbaric Oxygen (HBO) Therapy for Radiation Proctitis and Radiation Enteritis
Infusion Pumps - Continuous subcutaneous insulin infusion (CSII)
Latent Tuberculosis Infection (LTBI) Screening
Power Standing Systems
Screening for Cervical Cancer with Human Papillomavirus (HPV) Testing

Source: CMS NCD Wait List, Published Nov. 15, 2024

This is particularly the case when one considers the cadence of recent events for the Cologuard Plus code that would seem to allow ample time for NCD inclusion, with an update applicable to 1Q25 at the very latest:

- **Apr. 1, 2024:** Code 0464U is created for Cologuard Plus™
- **July 1, 2024:** Code 0464U takes effect
- **Sept. 1, 2024:** Code 0464U is published in the CPT code book
- **Oct. 3, 2024:** Cologuard Plus™ is approved by FDA
- **Nov. 1, 2024:** CMS finalizes coverage of CT colonography (CPT 74263) in CY25 PFS
- **Nov. 25, 2024:** CMS finalizes CY25 payment rate for Cologuard Plus™ code 0464U
- **Jan. 1, 2025: (A)** Cologuard Plus™ payment rate takes effect; **(B)** CMS updates CRC screening guide to include coverage of CT colonography code 74263 but makes no reference of Cologuard Plus™ code 0464U

For code 0464U to be covered under the current NCD, in the absence of any directive to that effect, the assumption would like have to be that: (A) CMS is merely disregarding the direct language of the NCD itself, as well as the fact that there are two different tests described under two distinct billing codes; (B) decisions on which tests are to be covered under the NCD will be left up to each individual MAC; and / or (C) the agency believes this is self-evident, and does not require any explicit clarification.

Under option (A) we would still expect CMS to include the billing code itself in some manner of NCD coding directive, given that reliance on their own discretion strikes us as improbable given the [statutory](#) prohibition against coverage of CRC screening tests outside of those “established by a national coverage determination.”

§ 410.37 Colorectal cancer screening tests: Conditions for and limitations on coverage.

(a) **Definitions.** As used in this section, the following definitions apply:

- (1) **Colorectal cancer screening tests** means any of the following procedures furnished to an individual for the purpose of early detection of colorectal cancer:
 - (i) Screening fecal-occult blood tests.
 - (ii) Screening flexible sigmoidoscopies.
 - (iii) Screening colonoscopies, including anesthesia furnished in conjunction with the service.
 - (iv) Screening computed tomography colonography.
 - (v) **Other tests or procedures established by a national coverage determination, and modifications to tests under this paragraph, with such frequency and payment limits as CMS determines appropriate, in consultation with appropriate organizations**

Source: 42 CFR §410.37

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