



National Coverage Determination 210.3: Colorectal Cancer Screening Tests – Non-Invasive Biomarker Testing

Related Change Request (CR) Information	
Number: 14581	Release Date: August 27, 2026
Effective Date: June 8, 2026	Implementation Date: January 4, 2027
Transmittal Numbers: R13921CP & R13921NCD	
Title: NCD 210.3 Screening for Colorectal Cancer-Non-Invasive Biomarker Tests	

Affected Providers

- Laboratories
- Physicians
- Other providers billing Medicare Administrative Contractors (MACs) for services

Action Needed

Make sure your billing staff knows that CMS determined non-invasive biomarker screening tests are appropriate for colorectal cancer (CRC) screening based on specific criteria, effective June 8, 2026.

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Key Updates

Non-invasive biomarker CRC screening tests detect molecular markers from CRC and pre-malignant colorectal epithelial neoplasia in blood, bodily secretions, or the intestinal lumen. The tests use amplification and enrichment techniques to detect small marker amounts that may identify CRC or pre-malignant colorectal neoplasia.

We cover non-invasive biomarker CRC screening tests once every 3 years based on meeting all relevant criteria.

Before ordering the test and using the results for patient management:

- Confirm the patient is:
 - Aged 45–85
 - Asymptomatic
 - At average risk
- Explain how the test performs and why a follow-up colonoscopy is important if the test result is positive

The test must:

- Be FDA market-authorized and indicated for CRC screening
- Meet FDA-required post-approval study requirements in the Safety and Effectiveness Data to continue coverage
- Be processed by a Clinical Laboratory Improvement Amendments-certified laboratory
- Demonstrate performance characteristics in detecting CRC compared to the recognized standard (currently accepted as colonoscopy) that meet either of the test performance criteria in the table

Test Performance Guidelines

Performance Characteristic	Test Performance Criteria 1	Test Performance Criteria 2
Sensitivity for CRC	≥ 90%	≥ 79%
Specificity for CRC	≥ 87%	≥ 90%

MACs will accept and pay for the CRC screening test (ColoSense™) using CPT code 0421U as a covered service. MACs waive patient coinsurance and deductible for 0421U. Use type of bills 13X, 14X, or 85X.

Note: MACs won't search for claims containing CPT code 0421U with dates of service on or after June 8, 2026, but may adjust claims you bring to their attention.

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Background

Sections 1861(s)(2)(R) and 1861(pp) of the [Social Security Act](#) and regulations at [42 CFR 410.37](#) authorize us to cover CRC screening tests under Medicare Part B. They also authorize the HHS Secretary to add other CRC tests and procedures (and modifications to CRC tests and procedures when appropriate) based on consultation with appropriate organizations.

Refer to the [Medicare National Coverage Determinations Manual, Chapter 1, Part 4](#), section 210.3 for more information about CRC coverage policy. Refer to the [Medicare Claims Processing Manual, Chapter 18](#), section 60 for updated claims processing instructions.

More Information

We issued transmittals R13921CP and R13921NCD to your MAC as the official instructions for this change. For more information, find your [MAC's website](#).

Document History

Date of Change	Description
September 2, 2026	Initial article released.

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