

**DRAFT Medical Coverage Policy | Serologic
Genetic and Molecular Screening for Colorectal
Cancer**



EFFECTIVE DATE: 01 | 01 | 2022

POLICY LAST UPDATED: 11 | 01 | 2021

OVERVIEW

It is well established that early detection of colorectal cancer (CRC) reduces disease-related mortality. For patients at average risk for CRC, organizations such as the U.S. Preventive Services Task Force have recommended several options for colon cancer screening. Currently accepted screening options for CRC include colonoscopy or sigmoidoscopy, fecal occult blood testing, and fecal immunochemical testing. However, many individuals do not undergo recommended screening with fecal tests or colonoscopy. A simpler screening blood test for genetic alterations associated with non-familial CRC may have the potential to encourage screening and decrease mortality if associated with increased screening compliance. Genetic testing is also being investigated to guide therapy.

MEDICAL CRITERIA

Medicare Advantage Plans

BeScreened™–CRC test may be considered medically necessary when the Medicare Advantage Plans medical necessity criteria is used for review, found in the Medical Necessity policy. Please see Related Policies section.

Commercial Products

Not applicable.

PRIOR AUTHORIZATION

Medicare Advantage Plans

Prior authorization is required for the following test(s):

- BeScreened™–CRC test

Commercial Products

Not applicable.

POLICY STATEMENT

Medicare Advantage Plans

The following test(s) may be considered medically necessary when the medical criteria in the Medical Necessity policy are met:

- BeScreened™–CRC test

The following test(s) are covered without an authorization requirement:

- SEPT9 methylated DNA testing (eg, ColoVantage®, Epi proColon®)
- Blood-based Biomarker Tests

Commercial Products

The following test(s) are not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcomes:

- SEPT9 methylated DNA testing (eg, ColoVantage®, Epi proColon®)
- Gene expression profiling (eg, ColonSentry®)
- BeScreened™–CRC test

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND

Colorectal Cancer

For patients at average risk for colorectal cancer (CRC), organizations such as the U.S. Preventive Services Task Force have recommended several options for colon cancer screening. The diagnostic performance characteristics of the currently accepted screening options (ie, colonoscopy, sigmoidoscopy, fecal tests) have been established using colonoscopy as the criterion standard. Modeling studies and clinical trial evidence on some of the screening modalities have allowed some confidence in the effectiveness of several cancer screening modalities. The efficacy of these tests is supported by numerous studies evaluating the diagnostic characteristics of the test for detecting cancer and cancer precursors along with a well-developed body of knowledge on the natural history of the progression of cancer precursors to cancer. Early detection of CRC reduces disease-related mortality, yet many individuals do not undergo recommended screening with fecal occult blood test or colonoscopy. A simpler screening blood test may have the potential to encourage screening and decrease mortality if associated with increased screening compliance.

SEPT9 Methylated DNA

ColoVantage (various manufacturers) blood tests for serum Septin9 (*SEPT9*) methylated DNA are offered by several laboratories (ARUP Laboratories, Quest Diagnostics, Clinical Genomics). Epi proColon (Epigenomics) received U.S. Food and Drug Administration (FDA) approval in April 2016. Epigenomics has licensed its Septin 9 DNA biomarker technology to Polymedco and LabCorp. ColoVantage and Epi proColon are both polymerase chain reaction (PCR) assays; however, performance characteristics vary across tests, presumably due to differences in methodology (eg, DNA preparation, PCR primers, probes).

Gene Expression Profiling

ColonSentry (Stage Zero Life Sciences) is a PCR assay that uses a blood sample to detect the expression of 7 genes found to be differentially expressed in CRC patients compared with controls: *ANXA3*, *CLEC4D*, *TNFAIP6*, *LMNB1*, *PRRG4*, *VNN1*, and *IL2RB*. The test is intended to stratify average-risk adults who are non-compliant with colonoscopy and/or fecal occult blood testing. Because of its narrow focus, the test is not expected to alter clinical practice for patients who comply with recommended screening schedules.

BeScreened-CRC (Beacon Biomedical) is a PCR assay that uses a blood sample to detect the expression of 3 protein biomarkers: teratocarcinoma derived growth factor-1 (TDGF-1, Cripto-1); carcinoembryonic antigen, a well-established biomarker associated with CRC; and an extracellular matrix protein involved in early stage tumor stroma changes.

CODING

The following code(s) are covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

81327 SEPT9 (Septin9) (eg, colorectal cancer) promoter methylation analysis

G0327 Colorectal cancer screening; blood-based biomarker

The following CPT code(s) is covered for Medicare Advantage Plans when medical criteria found in the Medical Necessity policy are met and is not medically necessary for Commercial Products.

This code can be used for BeScreened™-CRC test

0163U Oncology (colorectal) screening, biochemical enzyme-linked immunosorbent assay (ELISA) of 3 plasma or serum proteins (teratocarcinoma derived growth factor-1 [TDGF-1, Cripto-1], carcinoembryonic antigen [CEA], extracellular matrix protein [ECM]), with demographic data (age, gender, CRC-screening compliance) using a proprietary algorithm and reported as likelihood of CRC or advanced adenomas

RELATED POLICIES

Colorectal Screening Mandate
Genetic Testing Services Policy
Medical Necessity Policy
Medicare Advantage Plans National and Local Coverage Determinations
Preventive Services for Commercial Products
Preventive Services for Medicare Advantage Plans
Proprietary Laboratory Analyses (PLA)

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