



Colorectal Cancer Control Program

Funded by the Centers for Disease Control and Prevention

Colorectal Cancer Control Program (CRCCP) Policies and Procedures

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Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion
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Program Overview

The purpose of the Colorectal Cancer Control Program (CRCCP) is to establish and integrate evidence-based colorectal cancer (CRC) screening programs with existing CRC screening programs and/or chronic disease programs, in order to increase high quality population-based CRC screening among average-risk, uninsured and insured persons 50 years of age and older. (See **PC.1.b.** for definition of average risk.)

The overarching focus of the program is to increase the CRC screening rate in the U. S. for all persons 50 years of age and older. This will be achieved primarily through non-screening activities aimed at ensuring that all individuals are screened appropriately. These activities can include, but are not limited to, enrollment of all eligible persons into a health insurance plan; public and provider education; patient navigation and case management; and development of key partnership initiatives to ensure that systems and policies are in place to promote high-quality colorectal screening, diagnosis and treatment for all US adults.

Grantees will use at least two-thirds of their award for strategies designed to increase CRC screening in all persons 50 years and older, with some variation based on state and tribal needs. The remaining funds will be used to provide screening services to populations with the greatest need.

Background and History

Of cancers that affect both men and women, colorectal cancer is the second leading cause of cancer related deaths.¹ There is substantial evidence that regular screening of asymptomatic people reduces colorectal cancer incidence and mortality.^{2,3} Screening can reduce incidence and mortality through the detection of cancers at an early and curable stage, and by the detection and removal of cancer precursor lesions.⁴ Despite this knowledge, national surveys have shown that colorectal cancer screening tests are underused, and use of these tests has increased slowly, despite strong recommendations for its use.² There are disparities in colorectal cancer screening, with the uninsured and those with low-income being least likely to be screened.⁵

The Centers for Disease Control and Prevention (CDC) has over 15 years experience supporting the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) for the medically underserved population. The NBCCEDP uses a comprehensive approach to breast and cervical cancer control, including providing early detection services, educational activities, public and private partnerships, and quality assurance measures. To better understand how to structure and implement population-level colorectal cancer screening, the CDC conducted a three year colorectal cancer screening demonstration program from 2005 through 2008. Five sites were competitively selected to participate in the demonstration program. The program provided United States Preventive Services Task Force (USPSTF) recommended colorectal cancer screening tests to low-income men and women who were uninsured or underinsured for colorectal cancer screening services.⁶

Following the successes and lessons learned from the colorectal screening demonstration program, CDC received additional funding to support the Colorectal Cancer Control Program in 22 states and 4 tribal organizations. A new focus for the CRCCP is the promotion of colorectal cancer screening to all people over the age of 50 with the goal of increasing the percentage of people who have screened for colorectal cancer, regardless of income or health insurance status. As with the demonstration program, the CRCCP will provide colorectal cancer screening to the priority population of low income men and women who are uninsured or underinsured for colorectal cancer screening services.

Policies and Procedures

The following policies and procedures will provide operational guidance for programs regarding the provision of clinical services (screening).

I. Requirements Based on Federal Regulations

The following regulations apply to all Federal grants including CDC grants. They are not specific to the CRCCP. These regulations are prefaced with the letter “F” to reflect their basis in Federal policy.

F.1: NOTICE OF GRANT AWARD (NGA)

A grantee’s activities are governed by the provisions of its NGA. Programs are subject to any terms and conditions noted in the “remarks” section of the NGA, as well as Public Health Services (PHS) grants policy statements that are in effect as of the beginning of the budget period. Acceptance of the grant terms and conditions is acknowledged by the grantee when funds are drawn or otherwise obtained from the grant payment system. More information on grants is available at <http://www.cdc.gov/about/funding.htm>.

F.2: COMPETITIVE APPLICATION OR INTERIM PROGRESS REPORT (IPR)

All programs must submit an annual request for funding for CDC review and approval. If it is a competitive year (the first year of a new program announcement), a competitive application must be submitted. If it is a noncompetitive, continuation year, an IPR must be submitted. Both types of applications should include all information and data specified in the Program Announcement and its amendments. The competitive application or IPR for the CRCCP also must outline proposed reimbursement rates. The date for the receipt of these applications will be established by CDC’s Procurement and Grants Office (PGO).

F.3: FINANCIAL STATUS REPORT (FSR)

An FSR is due to CDC’s PGO 90 days after the end of each budget period. However, adjustments may be made up to 15 months after the end of the budget period. An FSR is the mechanism by which unobligated financial assistance funds are officially reported to CDC. Programs also should submit documentation of their current year’s “estimated” unobligated dollars on Standard Form 424A or via letter prior to the end of the project or the approved no-cost or cost extension period. Further information is available at the PGO Web site (<http://www.cdc.gov/about/funding.htm>).

F.4: PRIOR APPROVAL

Recipients are allowed a certain degree of latitude in making post award programmatic changes and budget revisions. The grantee is permitted to re-budget within and between

budget categories in the approved direct cost budget of the project to meet unanticipated requirements or to accomplish certain programmatic changes. Nevertheless, Federal grants require that certain program changes receive prior approval from PGO. Failure to obtain prior approval, when required, may result in disallowance of costs.

Examples of these prior approval items include:

1. A change in the principal investigator or other key personnel,
2. Spending funds that have been restricted,
3. Subcontracting a substantial amount of work,
4. Spending unobligated funds,
5. Continuing operations through cost or no-cost extensions,
6. Establishing or changing contracts or consulting agreements,
7. Making significant budget changes (i.e., those of \$250,000 or more or those exceeding 25% of the award, whichever is less).

F.5: CONTRACTOR AND CONSULTANT APPROVAL PROCESS

To obtain approval for a contractor or consultant, a program is required to submit the elements listed below to PGO.

Required Elements: Contractor

1. **Name of contractor**—This element identifies the name of the proposed contractor.
2. **Method of selection**—This element indicates whether the contract is sole source or a competitive bid. The program should describe the qualifications of the contractor and identify whether the contractor is a private, for-profit organization.
3. **Period of performance**—This element specifies the beginning and ending dates of the contract. It also indicates whether this is a new or continuation contract.
4. **Scope of work**—This element is used by the program to describe, in outcome terms, the specific services/tasks to be performed by the contractor as related to the accomplishment of program objectives (e.g., screen 250 program-eligible men and women for colorectal cancer). Deliverables (e.g., development of a curriculum, design of a survey questionnaire) should be clearly defined. For screening services where multiple providers have the same contract, only a single description of the required information is needed. The program does not need to send a copy of the actual or individual contracts to CDC.
5. **Method of accountability**—This element is used to describe how the progress and performance of the contractor will be monitored during and at the close of the contract period. The program should identify who will be responsible for supervising the contract. If the contractor has been used previously, the program should describe the contractor's previous performance.
6. **Itemized budget and justification**—This element is used by the program to provide an itemized budget with appropriate justification. Indirect costs paid under the contract must be itemized and included when the program calculates its overall administrative costs. These costs must not exceed 10% of the award.

If the above information is unknown for any contractor at the time the application is submitted, funds may be restricted until the required information is submitted. The information may be submitted at a later date as a revision to the budget. The body of the budget request should include a summary of the proposed contractors and amounts for each.

Required Elements: Consultant

1. **Name of consultant**—This element identifies the name of the consultant and describes his or her qualifications.
2. **Organizational affiliation**—This element identifies the organizational affiliation of the consultant, if applicable.
3. **Nature of services to be rendered**—The program uses this element to describe, in outcome terms, the consultation to be provided, including the specific tasks to be completed and specific deliverables. The program does not need to send a copy of the actual consultant agreement to CDC.
4. **Relevance of service to the project**—This element is used to describe how the consultant services relate to the accomplishment of specific program objectives.
5. **Number of days of consultation**—This element specifies the total number of days of consultation.
6. **Expected rate of compensation**—This element specifies the rate of compensation for the consultant (e.g., rate per hour, rate per day). The program should include a budget showing other costs, such as travel, per diem, and supplies.
7. **Method of accountability**—This element is used to describe how the progress and performance of the consultant will be monitored. The program should identify who is responsible for supervising the consultant agreement. In addition, for continuation consultants, the program should describe their previous performance.

If the above information is unknown for any consultant at the time the application is submitted, the information may be submitted at a later date as a revision to the budget. The body of the budget request should include a summary of the proposed consultants and amounts for each.

II. CDC-Based Program Policies

Clinical Management and Reimbursement Policies

The following policies were developed by CDC's DCPC specifically for the CRCCP. They include the prefix "PC" for program clinical policies.

The following policies apply to the screening provision portion of the program only.

CDC limits the total amount of funds that can be spent providing reimbursable screening services (see *Appendix A: Allowable Procedures and Relevant 2010 CPT, HCPCS and*

APC Codes). Programs should verify with CDC that the amount budgeted for reimbursable screening services is within the limits set by CDC.

The reimbursement of individual clinical services is limited to the Medicare reimbursement rate for the program's local area or less, and programs are encouraged to negotiate for lower-than-Medicare reimbursement rates whenever possible.

Programs should complete the readiness checklist (*Appendix B: Checklist to Assess Readiness for Screening and Related Activities*) and obtain CDC approval prior to initiating screening services.

PC.1: Patient Eligibility

The CRCCP provides colorectal screening services to program eligible men and women as recommended by the USPSTF (available at <http://www.ahrq.gov/clinic/uspstf/uspscolo.htm>).^{2,3} The priority population for CRCCP screening services is men and women between the ages of 50 and 64 years who are low income (up to 250% of the Federal poverty level) and who have inadequate or no health insurance.

Estimates of the eligible population have been developed by the US Census Bureau's Small Area Health Insurance Estimates (SAHIE) program. These estimates – by county – are available at: <http://www.census.gov/did/www/sahie/>. Programs are encouraged to use these estimates for planning program development and resource allocation.

PC.1.a. Underinsured

People with inadequate health insurance (commonly referred to as underinsured) have health insurance that does not fully cover screening services. Individual programs will establish criteria regarding inadequate health insurance coverage.

PC.1.b. Average Risk

Screening efforts should focus on people between the age of 50 and 64 years who are at average risk for CRC. Average risk is generally defined as:

1. No personal or family history of CRC or adenomas
2. No history of inflammatory bowel disease (Ulcerative Colitis or Crohn's Disease)
3. No history of genetic syndromes such as Familial Adenomatous Polyposis (FAP) or Hereditary Non-Polyposis Colorectal Cancer (HPNCC).

≥ 75% of program funds budgeted for screening services should be spent on screening individuals at average risk (see *Appendix C: Service Quality Indicators*).

PC.1.c. Increased Risk

People at increased risk for CRC include those with:

1. A personal history of adenomatous polyps on a previous colonoscopy,
2. A personal history of colorectal cancer, or
3. A family history of CRC or adenomatous polyps.

People at increased risk for CRC due to family or personal history of CRC or adenomatous polyps may be eligible for CRC screening or surveillance.

People at increased risk for CRC due to a personal history of adenomatous polyps or colorectal cancer are eligible for surveillance with colonoscopy only.⁶

Determination of eligibility, age of onset of screening, frequency of screening, and type of screening test used for people at increased risk for CRC due to a family history of CRC or adenomatous polyps should be made by the program in conjunction with the program's MAB. Criteria set by the program should be consistent with available guidelines.^{3,6}

PC.1.d. High Risk

People at high risk for CRC are not eligible for screening or surveillance services through the CRCCP. People at high risk for CRC include those with:

1. A genetic diagnosis of familial adenomatous polyposis (FAP) or hereditary non-polyposis colorectal cancer (HNPCC),
2. A clinical diagnosis or suspicion of FAP or HNPCC, or
3. A history of inflammatory bowel disease (ulcerative colitis or Crohn's disease).

People at high risk for CRC generally require genetic counseling and/or intensive clinical and surveillance services that are beyond the scope of this program.

People at high risk for CRC who present to the program for screening or surveillance services must be referred for appropriate services.

PC.1.e. Gastrointestinal symptoms

People with significant gastrointestinal symptoms are not eligible for screening services through the CRCCP. Symptoms that would preclude eligibility for the program include, but are not limited to:

1. Rectal bleeding, bloody diarrhea, or blood in the stool within the past 6 months (bleeding that is known or suspected to be due to hemorrhoids after clinical evaluation would not prevent a client from receiving CRC screening services),
2. Prolonged change in bowel habits (e.g., diarrhea or constipation for more than two weeks that has not been clinically evaluated),

3. Persistent abdominal pain, or
4. Symptoms of bowel obstruction (e.g., abdominal distension, nausea, vomiting, severe constipation).
5. Significant unintentional weight loss of 10% or more of starting body weight.

By definition, screening for colorectal cancer is testing for the presence of colorectal cancer or cancer precursors in the absence of symptoms. While gastrointestinal symptoms may be indicative of an underlying colorectal cancer or polyp, they may also be caused by many other conditions. People presenting with these symptoms need a complete evaluation by a clinician to determine the cause of their symptoms. This evaluation, and any potential subsequent treatment, is beyond the scope of this program. If a client has been medically evaluated and cleared for colorectal cancer screening, then the client may enroll in the program if all eligibility criteria are met.

For individual cases when clients present with minor symptoms that may not preclude enrollment in the program, the program should consult with the MAB to determine if the client can be enrolled in the program, or if the client should be referred for clinical evaluation. If eligibility cannot be determined with the assistance of the MAB, then the program should consult with CDC to determine eligibility.

PC.1.f. Enrollment with a Primary Care Provider

All clients enrolled in the screening program must first be enrolled with a primary care provider.

PC.1.g. Referral

All clients who present to the program for screening services and are found to be ineligible must be referred for additional services and/or evaluation.

PC.2: Screening and Surveillance

PC.2.a. Screening

Only screening options recommended by the USPSTF will be used in the CRCCP. Those options include:

1. High-sensitivity guaiac FOBT (gFOBT) annually
2. High-sensitivity immunochemical FOBT (iFOBT), also referred to as fecal immunochemical tests (FIT) annually
3. Sigmoidoscopy every 5 years, with FOBT every 3 years
4. Colonoscopy every 10 years

Note: Double Contrast Barium Enema (DCBE) is no longer recommended as a primary screening test. DCBE may be used as a diagnostic test to follow-up an abnormal screening FOBT or sigmoidoscopy (see PC.2.e).

PC.2.b. Surveillance

Surveillance is defined as periodic colonoscopy on a person who has a prior history of adenoma(s) or colorectal cancer for the purpose of removing polyps that were missed on the initial colonoscopy or that developed in the interval since the initial colonoscopy.

The timing of surveillance colonoscopy after polypectomy depends on the size, type, histology, number and completeness of polyp removal during the initial colonoscopy. Surveillance after surgical resection of colorectal cancer depends on whether the cancer resulted in obstruction of the bowel, and the presence of synchronous cancers or polyps on subsequent evaluations.

Surveillance recommendations should be made on a case-by-case basis by the clinician, the program, and the program's MAB. Recommendations for surveillance should follow available guidelines.^{8,9}

PC.2.c. Clinical Evaluation

Clients scheduled for endoscopy (sigmoidoscopy or colonoscopy) must be clinically evaluated prior to the procedure.

PC.2.d. Reporting of Complications

Medical complications experienced by clients who have received endoscopy (sigmoidoscopy or colonoscopy) or DCBE either during, or within 30 days after the procedure, should be reported to the CDC program consultant during routine monthly calls. Confirmed complications that result in an emergency room visit, hospitalization, or death should be reported in the CCDE record.

PC.2.e. Adequacy and Timeliness of Follow-Up for Abnormal Screening Tests

Clients with positive or abnormal screening tests must receive appropriate diagnostic procedures as determined by the program and the MAB. Client with positive or abnormal FOBT or sigmoidoscopy must receive a complete colon examination with colonoscopy (preferred) or DCBE.

Clients diagnosed with colorectal cancer, or other cancers or medical conditions, must be referred for appropriate treatment.

Clients with an abnormal screening result should receive a final diagnosis within 90 days of the screening test (see Appendix C: Colorectal Cancer Control Program (CRCCP) Service Quality Indicators).

Clients diagnosed with CRC should begin treatment within 60 days of their diagnosis (see Appendix C: Colorectal Cancer Control Program (CRCCP) Service Quality Indicators).

PC.2.f. Tracking and Reminder Systems

Programs must implement a patient tracking and reminder system to ensure screening adherence, the provision of appropriate and timely follow-up of all abnormal screening results, monitoring for complications after endoscopy or DCBE, and rescreening.

PC.3: Medical Advisory Board

The purpose of the Medical Advisory Board (MAB) is to provide oversight of the quality of services delivered throughout the funding period. Members of the MAB provide expertise in all areas related to colorectal cancer screening, diagnosis, and treatment, including clinicians (primary care and specialists such as gastroenterologists, radiologists, surgical oncologists, pathologists, etc.), social workers, and other partners and stakeholders. Functions of the MAB include, but are not limited to:

1. Assisting with establishing program eligibility criteria (e.g., defining underinsured, establishing guidelines for diagnostic testing, surveillance intervals, etc.),
2. Monitoring quality of screening, rescreening, diagnostic, and surveillance services,
3. Assist with identifying resources for treatment and referral of clients that are ineligible for the program,
4. Provide direction on individual program policy development and data collection.
5. Approve additions to the local Allowable Procedures list, as needed, while adhering to CDC policies.

PC.4: Reimbursement Policies

The services listed will be reimbursable at the local or negotiated Medicare rate, based on individual program policies. Please see *Appendix A: Allowable Procedures and Relevant CPT, HCPCS, and APC Codes*.

PC.4.a. Screening Tests and Procedures

1. Fecal occult blood tests annually (guaiac or immunochemical based)
2. Sigmoidoscopy every 5 years (with FOBT every 3 years)
3. Colonoscopy every 10 years
4. Biopsy/polypectomy during sigmoidoscopy or colonoscopy

5. Bowel preparation
6. Moderate sedation for colonoscopy
7. Office visits related to the above tests

PC.4.b. Diagnostic follow-up services

1. Office visits related to screening and diagnostic tests
2. Total colon exam with either colonoscopy (preferred) or DCBE
3. Biopsy/polypectomy during colonoscopy
4. Moderate sedation for colonoscopy
5. Bowel preparation
6. Pathology fees

PC.4.c. Surveillance

Surveillance colonoscopies will be reimbursed at appropriate intervals as determined by the recommending clinician, the program, and/or the program's MAB. Surveillance recommendations should follow available guidelines.^{8,9}

PC.4.d. Excluded services

The following services will not be reimbursed with federal funds:

1. CT Colonography (or virtual colonoscopy) as a primary screening test.
2. Computed Tomography Scans (CTs or CAT scans) requested for staging or other purposes.
3. Surgery or surgical staging, unless specifically required and approved by the program's MAB to provide a histological diagnosis of cancer.
4. Any treatment related to the diagnosis of colorectal cancer.
5. Any care or services for complications that result from screening or diagnostic tests provided by the program.
6. Evaluation of symptoms for clients who present for CRC screening but are found to have gastrointestinal symptoms.
7. Diagnostic services for clients who had an initial positive screening test performed outside of the program.
8. Management of medical conditions, including Inflammatory Bowel Disease (e.g., surveillance colonoscopies and medical therapy).
9. Genetic testing for clients who present with a history suggestive of a HNPCC or FAP.
10. Use of propofol as anesthesia during endoscopy, unless specifically required and approved by the program's MAB in cases where the client cannot be sedated with standard moderate sedation.

III. DATA MANAGEMENT POLICIES

The following policies were developed by CDC's DCPC specifically for the CRCCP. They include the prefix "PD" for program data management policies.

PD. 1: Clinical and Cost Data Reporting Policy

Programs are required to report scheduled submissions of required data collections, including patient-level clinical data and program-level activity-based cost data to CDC, per CDC guidelines. Data are used to monitor and evaluate the program.

CCDE	
CCDE data are submitted semi-annually to the Clinical Data Contractor (IMS) as described in the CCDE Data Users Manual	
Submission Due Date	Submission Includes Screening through:
9/15/2010	Screening onset – 06/30/2010
3/15/2011	Screening onset –12/31/2010
Continued semi-annually	
Cost Assessment Tool (CAT) Data Reporting	
Pending OMB approval, CAT data are submitted to the Cost Data Contractor (RTI) per guidelines in the CAT Data Users Manual. Year1 activities will be reported in two phases: Start-up and Implementation. Subsequent years will report annually.	
Submission Due Date	Months Covered:
Varies with start-up period	<i>Start-up:</i> 07/01/2009 – screening onset
10/31/2010	<i>Implementation:</i> screening onset – 06/30/2010
10/31/2011	<i>Implementation:</i> 07/01/2010 – 06/30/2011
Continued annually.....	

PD.1.a. Patient-level Clinical Data Collection: Colorectal Cancer Clinical Data Elements (CCDE)

Programs are required to submit clinical data semi-annually. The CCDEs are a set of standardized data elements used to collect demographic and clinical information on all clients screened within the program. These data are used to monitor performance and evaluate the program.

Inclusion of data in the CCDEs:

Screening and diagnostic data should be reported on all

- a. Clients whose screening and diagnostic tests are paid for solely by CRCCP funds; or paid in part by CRCCP funds and any other funding source (e.g., State, private, or other Federal funds) with the ability to distinguish the funds contributed by CRCCP
- b. Awardees should not submit data on clients for whom screening and diagnostic tests are covered solely by non-CRCCP funding sources unless

CDC has granted awardee-specific approval for surveillance reporting to evaluate screening within publically funded settings that serve clients of similar eligibility.

- c. Screening and diagnostic data collected on clients reported in the CCDEs must meet all data and service quality standards set by CDC.

PD.1.b. Program-level Cost Data Collection: Cost Assessment Tool (CAT)

Pending OMB approval, the Cost Assessment Tool (CAT) collects programmatic level cost data related to start-up activities and program implementation for screening provision and screening promotion activities

References

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APPENDIX A

2010 CRCCP Allowable Procedures and Relevant CPT[®], HCPCS, and APC Codes

Listed below are allowable procedures and the corresponding suggested CPT codes for use in the Colorectal Cancer Control Program (CRCCP) under these general conditions:

- Reimbursement for treatment services is not allowed.
- The suggested CPT codes are not all-inclusive and programs may utilize other, including temporary, CPT codes for an approved procedure.
- When questions arise regarding the appropriateness of utilizing a procedure not listed, the program should consult with their Medical Advisory Board and the CDC to determine if the procedure is warranted given the overall intent of CDC funding and the amount of resources the program has available.
- Programs are required to be responsible stewards of the CRCCP funds and use screening and diagnostic dollars in an efficient and appropriate manner.

Office Visits		END NOTE
99201	New Patient; history, exam, straightforward decision-making; 10 minutes	
99202	New Patient; <i>expanded</i> history, exam, straightforward decision-making; 20 minutes	
99203	New Patient; <i>detailed</i> history, exam, straightforward decision-making; 30 minutes	
99211	Established Patient; evaluation and management, may not require presence of physician; 5 minutes	
99212	Established Patient; history, exam, straightforward decision-making; 10 minutes	
99213	Established Patient; <i>expanded</i> history, exam, straightforward decision-making; 15 minutes	

Colorectal Cancer Screening and Diagnostic Procedures		END NOTE
Fecal Tests		
G0107	Colorectal cancer screening; fecal occult blood test, 1-3 simultaneous determinations	
G0328	Colorectal cancer screening; fecal occult blood test, immunoassay, 1-3 simultaneous	
82270	Blood, occult, by peroxidase activity (e.g., guaiac), qualitative; feces, consecutive collected specimens with single determination, for colorectal neoplasm screening (i.e., patient was provided three cards or single triple card for consecutive collection)	1
82274	Blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1-3 simultaneous determinations	1
Sigmoidoscopy		
G0104	Screening sigmoidoscopy	
45330	Sigmoidoscopy, flexible; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)	
45331	Sigmoidoscopy, flexible; with biopsy, single or multiple	
45333	Sigmoidoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps or bipolar cautery	
45334	Sigmoidoscopy, flexible; with control of bleeding (e.g., injection, bipolar cautery, unipolar cautery, laser, heater probe, stapler, plasma coagulator)	
45335	Sigmoidoscopy, flexible; diagnostic, with directed submucosal injection(s), any substance	
45338	Sigmoidoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	
45339	Sigmoidoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique	
Colonoscopy		
G0121	Screening colonoscopy on average risk individual	
45378	Colonoscopy, flexible, proximal to splenic flexure; diagnostic, with or without collection of specimen(s) by brushing or washing, with or without colon decompression (separate procedure)	
45380	Colonoscopy, flexible, proximal to splenic flexure; with biopsy, single or multiple	
45381	Colonoscopy, flexible, proximal to the splenic flexure; with directed submucosal injection(s), any substance.	
45382	Colonoscopy, flexible, proximal to splenic flexure; with control of bleeding (e.g., injection, bipolar cautery, unipolar cautery, laser, heater probe, stapler, plasma coagulator)	
45383	Colonoscopy, flexible, proximal to splenic flexure; with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique	
45384	Colonoscopy, flexible, proximal to splenic flexure; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps or bipolar cautery	

45385	Colonoscopy, flexible, proximal to splenic flexure; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	
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Colorectal Cancer Screening and Diagnostic Procedures		END NOTE
Barium Enema		
74270	Radiologic examination, colon; contrast (e.g., barium) enema, with or without KUB	2
74280	Radiologic examination, colon; air contrast with specific high density barium, with or without glucagon	2
Pathology		
88300	Surgical Pathology, gross examination only (surgical specimen)	
88302	Surgical pathology, gross and microscopic examination (review level II)	
88304	Surgical pathology, gross and microscopic examination (review level III)	
88305	Surgical pathology, gross and microscopic examination, colon, colorectal polyp biopsy (review level IV)	
88307	Surgical pathology, gross and microscopic examination, colon, segmental resection other than for tumor (review level V)	
88309	Surgical pathology, gross and microscopic examination, colon, segmental resection for tumor or total resection (review level VI)	
88342	Pathology: Immunocytochemistry, each antibody	
Blood Work		
80048	Basic metabolic panel (calcium, total). This panel must include the following: calcium, total (82310), carbon dioxide (82374), creatinine (82565), glucose (82947), potassium (84132), sodium (84295)	
80053	Comprehensive metabolic panel. This panel must include the following: albumin (82040); bilirubin, total (82247); calcium (82310); carbon dioxide (bicarbonate) (82374); chloride (82435); creatinine (82565); glucose (82947); phosphatase, alkaline (84075); potassium (84132); protein, total (84155); sodium (84295); transferase, alanine amino (84460); transferase, aspartate amino (84450); urea nitrogen (84520)	
85025	Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count) and automated differential WBC count	
85027	Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count)	
85610	Prothrombin time	
85732	Thromboplastin time, partial (PTT); plasma or whole blood	
Electrocardiogram		
93000	Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report	
93005	Electrocardiogram, routine ECG with at least 12 leads; tracing only, without interpretation and report	
93010	Electrocardiogram, routine ECG with at least 12 leads; tracing only, interpretation and report only	
93040	Rhythm ECG, one to three leads; with interpretation and report	

93041	Rhythm ECG, one to three leads; tracing only without interpretation and report	
93042	Rhythm ECG, one to three leads; interpretation and report only	

Colorectal Cancer Screening and Diagnostic Procedures		END NOTE
Anesthesiology		
00810	Anesthesia for lower intestinal endoscopy procedures, endoscope introduced distal to duodenum	3
00840	Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; not otherwise specified	4

Facility Codes		
APC (HOPPS) codes for hospital based outpatient facilities		
0143	Lower GI Endoscopy	
0146	Level I Sigmoidoscopy	
0147	Level II Sigmoidoscopy	
0158	Colorectal Cancer Screening: Colonoscopy	
0159	Colorectal Cancer Screening: Flexible Sigmoidoscopy	
Ambulatory Surgery Center (ASC) codes		
-SG	The ASC bills for the facility fee using the same procedure code as the professional service and attaching a modifier -SG. The modifier indicates that the claim is for the facility fee ONLY	

Modifiers		END NOTE
Various	To be reported with appropriate CPT codes at the discretion of the provider/facility	

Procedures specifically not allowed		END NOTE
Any	Treatment of colorectal cancer or any other cancer diagnosed as a result of participation in the program	
Any	Treatment of medical conditions diagnosed as a result of participation in the program or that existed prior to entry into the program.	
Any	Care or services for complications that result from screening or diagnostic tests provided by the program	
Any	Evaluation of symptoms for clients who present for CRC screening but are found to have gastrointestinal symptoms.	
Any	Diagnostic services for clients who had an initial positive screening test performed outside of the program.	
Any	CT Colonography (or virtual colonoscopy) as a primary screening test.	
Any	Computed Tomography Scans (CTs or CAT scans) requested for staging or other purposes.	
Any	Genetic testing for clients who present with a history suggestive of a HNPCC or FAP.	
Any	Use of propofol as anesthesia during endoscopy.	3

End Notes

1	Codes 82271 (other sources) and 82272 (single specimen) are not included as they do not adhere to guideline-recommended screening.
2	G0106 (colorectal cancer screening; barium enema; as an alternative to G0104; screening sigmoidoscopy), G0120 (colorectal cancer screening; barium enema; as an alternative to G0105; screening colonoscopy), and G0122 (colorectal cancer screening; barium enema) are not included as barium enema is no longer recommended by USPSTF as a colorectal cancer screening test. Double contrast barium enema may still be used as a diagnostic test to evaluate an abnormal FIT or gFOBT (Note: Colonoscopy is the preferred test in this circumstance).
3	If the client fails standard moderate sedation, anesthesia may be used to complete the endoscopic procedure. Documentation should be provided to support the use of anesthesia on a case-by-case basis.
4	Surgery or surgical staging may be required to provide a histological diagnosis of cancer. All surgery for diagnostic purposes must be approved in advance by the program's MAB.

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APPENDIX B



Colorectal Cancer Control Program

Funded by the Centers for Disease Control and Prevention

CDC Colorectal Cancer Control Program (CRCCP)

Checklist to Assess Readiness for Screening and Related Activities

Use of Readiness Checklist

This Readiness Checklist is intended to assist CDC and the Colorectal Cancer Control Program (CRCCP) grantees to determine readiness to initiate program activities related to the provision and promotion of screening services. These readiness criteria should be met within 6 months of award and prior to screening. CDC will discuss these with each grantee through conference calls or site visits and approve readiness to provide clinical services.

Program Management

- Key personnel positions have been filled with qualified staff, e.g.
 - Program Director to 1) oversee screening and follow-up tests that program pays for or 2) create linkages with pre-existing health systems to refer program eligible clients for screening
 - Data Manager to oversee data collection for direct clinical services, link with cancer registries, and utilize existing health systems to conduct population based surveillance related to colorectal cancer and screening (BRFSS, USCS, health systems electronic databases, etc.)
 - Case management and patient navigation staff to assist clients through the health system and/or screening clinics
 - Staff to work collaboratively with appropriate groups (CCC program in state, CCC Coalition, health systems, advocates, policy makers, educators, etc) to work through systems and policy changes to increase CRC screening in all persons 50 years of age and older
- (Pending OMB approval), plans are in place to collect activity-based cost center data and report using the Cost Assessment Tool (CAT).

Partnership Development and Maintenance

- A relationship has been established with the State/Tribe/Territorial CCC program to collaborate on awareness, outreach and systems level changes
- A relationship and data linkage agreement has been established with the corresponding State Central Cancer Registry
- A relationship has been established with other chronic disease programs in the state or tribe
- Other key partnerships have been established to support activities aimed at increasing population-level screening

Enrollment in Health Insurance

- A plan and staffing are in place to identify clients eligible for enrollment
- A plan and staffing are in place to enroll clients into insurance (i.e. Medicaid, other)
- A process is in place to track screening of newly insured clients

Identification of Existing Health Systems Serving Uninsured Persons

- A process is in place to identify existing health systems (e.g. public hospitals, community clinics, FQHCs, etc) that serve an uninsured, low-income population
- A referral procedure is established to refer program eligible clients to these pre-existing health systems for screening
- A process is in place to track clients referred to existing health systems and screened
- A process is in place to maintain quality service delivery in these referral systems

FOR SERVICES PROVIDED DIRECTLY BY THE PROGRAM

Provision of Screening and Diagnostic Follow-up Services (up to 33% of total award)

- Client Recruitment
 - A process is in place to actively recruit those patients who remained uninsured for screening through in-reach or outreach

- Client Eligibility and Intake
 - Procedures are in place to assure that patients enrolled in the program are first enrolled with a primary care provider.
 - Procedures are in place to assess patients for program eligibility in terms of age, income, insurance status.
 - Procedures are in place to assess the clinical eligibility of patients and refer those who are clinically ineligible to appropriate care.
 - Procedures are in place to assess the risk status of patients based on medical history and family history

- Provider Network
 - Providers have been identified and are in place (e.g., contracts secured) to offer CRC screening and diagnostic services
 - Appropriate training has been provided to provider agencies to ensure proper enrollment, patient education, referral, data collection/reporting, appropriate and timely follow-up of all tests, etc.
 - All necessary materials and equipment have been purchased or are available (i.e., FOBT/FIT kits, endoscopes and associated equipment, bowel preparation, etc.)
 - Only high sensitivity FOBTs are being used for screening (see recent USPSTF and ACS screening guidelines for specific information on FOBT tests)

- Laboratory Services
 - Pathology laboratories have been identified to receive/process pathology specimens
 - Laboratory services have been secured for FOBT/FIT processing
 - Laboratories meet national CLIA standards

- Diagnostic Services

- A referral system is in place to assure timely access to diagnostic testing
- Treatment Services
 - Resources are secured and a referral system is in place to assure timely medical treatment for persons diagnosed with CRC
- Complications
 - Resources are secured and a referral system is in place to assure timely medical treatment for persons who experience complications due to screening or diagnostic procedures

Clinical and Cost Data Collection and Tracking

- An adequate system is operational to collect and report patient level clinical data for CCDE reporting, and a final draft of data collection forms has been reviewed by CDC/IMS
- Procedures are in place to track and report serious complications requiring hospitalization occurring within 30 days.

Patient Support/Case Management/Patient Navigation

- A plan is ready to be implemented to ensure patient support services to those referred to endoscopic services in order to support screening adherence.
- A tracking system is in place to assure appropriate follow-up for participants needing diagnostic and treatment services
- A plan for the provision of patient support services to facilitate access to diagnostic and treatment services is in place

Quality Assurance and Professional Development

- A Medical Advisory Board/Committee has been established and convened
- Quality assurance procedures are in place to assess the quality of clinical services provided by the Program and by service providers
- A plan has been developed to monitor performance on the CCDE service quality indicators
- Final program policies related to QA have been written and approved by the MAB and reviewed by CDC. These policies should address the following:
 - Plan for the evaluation of patients with symptoms
 - Plan to refer patients with Inflammatory Bowel Disease (Ulcerative Colitis or Crohn's Disease) for appropriate disease management
 - Plan to manage/refer patients suspected of having genetic syndrome (FAP or HNPCC)
 - Plan for screening patients with a personal or family history of CRC or polyps
 - Plan for screening/surveillance of patients with history of polyps
 - Plan for dealing with inadequate bowel prep or failure to reach the cecum in colonoscopy
 - Plan for monitoring and reporting complications of screening and diagnostic procedures
 - Plan for managing patients who may not benefit from screening

APPENDIX C

Colorectal Cancer Control Program (CRCCP) Service Quality Indicators

Proposed Indicator Type, Number and Description			CDC Benchmark
Screening Priority Population	1	Percent of new clients screened who are at average risk for CRC	≥ 75%
	2	Percent of average risk new clients screened who are aged 50 years and older	≥ 95%
Completeness of Clinical Follow-up	3	Percent of abnormal test results with diagnostic follow-up completed	≥ 90%
	4	Percent of diagnosed cancers with treatment initiated	≥ 90%
Timeliness of Clinical Follow-up	5	Percent of positive tests (FOBT/FIT, sigmoidoscopy, or DCBE) followed-up with colonoscopy within 90 days (This measure will not apply to all programs)	≥ 80%
	6	Percent of cancers diagnosed with treatment initiated within 60 days	≥ 80%