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COLORECTAL CANCER SCREENING

A. General Description

1. Covered Services

a. Screening Tests

All eligible men and women enrolled in the Montana Cancer Control Programs (MCCP) shall receive the following screening services for colorectal cancer, annually or as indicated:

- High Sensitivity Fecal Occult Blood Test (FOBT)
- High Sensitivity Fecal Immunochemical Test (FIT)
- Colonoscopy
- Bowel Preparation
- Office Visits related to the above tests
- Biopsy/polypectomy during colonoscopy
- Standard anesthesia for colonoscopy
- Pathology fees

b. Surveillance Colonoscopies

Surveillance is defined as periodic colonoscopy on a person who has 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 a 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.

Recommendations for surveillance should follow guidelines in CRC Screening Algorithm.

See www.cancer.mt.gov for a complete list of screening and diagnostic procedures and reimbursement rates.

Please note that MCCP funds may not be used for treatment services.

2. Enrollment and Screening Steps

- a. Determine whether a person is eligible for services, either by telephone or an in-person interview.
- b. Complete MCCP enrollment forms, paying particular attention to the following:
 - Ensure that each client signs an “Informed Consent and Authorization to Disclose Health Care Information”. This form must be signed before any services can be provided.
 - Ensure that screening history and risk assessment are completed.
- c. Determine which screening services a client needs.
- d. Perform appropriate screening and refer the client for diagnostic tests in accordance with the algorithms approved by the MCCP. Diagnostic tests will be eligible for MCCP reimbursement only if recommended and referred by an enrolled medical service provider.
- e. Notify client of all test results.
- f. If results are abnormal, conduct appropriate tracking and follow-up.
- g. Send rescreening reminders to all clients.

3. Reimbursement

The MCCP will reimburse enrolled medical service providers for the cost of performing the covered services, provided these have been conducted in accordance with the algorithms approved by the MCCP (see www.cancer.mt.gov). Clients are responsible for paying for any other services or tests.

MCCP will only reimburse for FOBT and FIT tests that have high sensitivity. (See Algorithm Appendix)

The following services are not reimbursable:

- Flexible sigmoidoscopy unless there is a failure to reach the cecum during the scheduled screening colonoscopy (see D-6).
- CT Colonography (or virtual colonoscopy) as a primary screening test.
- Computed Tomography Scans (CTs or CAT scans) requested for staging or other purposes.
- Surgery or surgical staging, unless specifically required and approved by the program’s MAB to provide a histological diagnosis of cancer.
- Any treatment related to the diagnosis of colorectal cancer.
- Any care or services for complications that result from screening or diagnostic tests provided by the program.
- Evaluation of symptoms for clients who present for CRC screening but are found to have gastrointestinal symptoms.
- Diagnostic services for clients who had an initial positive screening test performed outside of the program.
- Management of medical conditions, including Inflammatory Bowel Disease (e.g., surveillance colonoscopies and medical therapy).

- Genetic testing for clients who present with a history suggestive of a Hereditary Non-Polyposis Colorectal Cancer (HPNCC) or Familial Adenomatous Polyposis (FAP).

4. Anesthesia

Use of Propofol or a similar anesthesia used during endoscopy is not reimbursable by MCCP, unless specifically required and approved by the program in cases where the client cannot be sedated with standard moderate sedation.

- There are occasional circumstances where the use of Propofol or a similar anesthesia may be required in order to complete an endoscopy, these will be reviewed by MCCP on a case by case basis.
- Providers must document why using Propofol or a similar anesthesia was necessary.
- If it is determined during the colonoscopy that a client requires the use of Propofol or a similar anesthesia instead of standard moderate anesthesia, these claims will have a post procedure review by the MCCP.
- Reimbursement will be based on prior approval or post procedure review at the Medicare reimbursement rate for standard anesthesia.

B. Eligibility

1. General Criteria

The MCCP will provide screening services to men and women who meet all of the following criteria:

- 50 through 64 years of age.
- Uninsured or underinsured.
- Have a family gross income at or below 200 percent of the current Federal Poverty Level (FPL) scale (see the MBCHP Website, www.cancer.mt.gov, under Income Guidelines)¹.

Clients must provide the information needed to determine eligibility on the MCCP “Eligibility and Enrollment” form. If a person is ineligible for MCCP services, they should be referred to other community agencies that may be able to assist them.

If a client misrepresents their eligibility, the MCCP will deny reimbursement for screening services and refer the client to the health or social service agency that may be able to assist them.

2. Exception to the Age Criteria for Eligibility

Presuming a person is otherwise MCCP eligible; the following criteria for age will be used to determine eligibility for colorectal cancer screening and diagnostic funds:

- Persons 40-49 will be eligible for colorectal screening if they have a family history of polyps or CRC.

¹The Federal Poverty Level scale is updated each year.

3. Additional Eligibility Guidelines for Colorectal Screening

a. 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:

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

At least 75% of program funds budgeted for screening services should be spent on screening individuals at average risk

b. Increased Risk

People at increased risk for CRC may be eligible for CRC screening or surveillance. People at increased risk for CRC include those with:

- A personal history of adenomatous polyps on a previous colonoscopy
- A personal history of colorectal cancer
- A family history of CRC or adenomatous polyps

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

c. High Risk

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

- A genetic diagnosis of familial adenomatous polyposis (FAP) or hereditary non-polyposis colorectal cancer (HNPCC).
- A clinical diagnosis or suspicion of FAP or HNPCC.
- 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. Contractors will refer clients to other privately or publicly funded programs in their multi-county area.

d. Gastrointestinal symptoms

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

- 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).
- Prolonged change in bowel habits (e.g., diarrhea or constipation for more than two weeks that has not been clinically evaluated).
- Persistent abdominal pain.
- Symptoms of bowel obstruction (e.g., abdominal distension, nausea, vomiting, severe constipation).
- 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.

When clients present with minor symptoms that may not preclude enrollment in the program, the program should consult with the medical service provider to determine if the client can be enrolled in the program or if the client should be referred for clinical evaluation. Contractors will refer clients to other privately or publicly funded programs in their multi-county area.

C. Reporting Systems

1. Colorectal Screening and Diagnostic Tests

We recommend endoscopists follow the standardized colonoscopy reporting and data system (CO-RADS). [Gastrointest Endosc. 2007 May;65(6):757-66]

D. Quality Assurance

1. Clients with positive or abnormal screening tests must receive appropriate diagnostic procedures as determined by the program and the MAB. Clients with a positive or abnormal FOBT must receive a complete colon examination with colonoscopy.
2. Clients diagnosed with colorectal cancer or other cancers or medical conditions, must be referred for appropriate treatment. The Commission on Cancer approved facilities in Montana will see clients diagnosed in the MCCP in their indigent care program.
3. The interval between initial screening and diagnosis of positive or abnormal screening results should be 90 days or less.
4. The interval between diagnosis and initiation of treatment for colorectal cancer should be 60 days or less.

5. Inadequate Bowel Prep:
 - a. for screening or diagnostic colonoscopy: proceed as per endoscopist
 - Schedule repeat colonoscopy (covered by this program) with same bowel prep or alternative prep used (covered by this program) OR
 - Schedule for Double Contrast Barium Enema (covered by this program)
 - Requests for exceptions will be considered on a case by case basis

6. Failure to reach the cecum:
 - a. For screening colonoscopy: proceed as per endoscopist.
 - Schedule for repeat colonoscopy at interval per endoscopist (covered by this program). OR
 - When at least the splenic flexure is reached, consider the screening test as a flexible sigmoidoscopy and schedule for repeat endoscopy in 5 years (covered by this program) plus an interval high-sensitivity FOBT/FIT every 3years (covered by this program).
 - Requests for exceptions will be considered on a case by case basis.

 - b. For diagnostic colonoscopy: proceed as per endoscopist.
 - Schedule for repeat colonoscopy at interval per endoscopist (covered by this program). OR
 - Schedule for Double-Contrast Barium Enema (covered by this program)
Note: CT colonography not covered by this program.
 - Requests for exceptions will be considered on a case by case basis.

7. Clients who have limited life expectancy as determined by the medical service provider may not benefit from screening. (The benefit from screening is not seen in trials until at least seven years later). Contractors should facilitate opportunity for discussion between the client and the medical service provider to establish an individual management plan.

8. Summary of 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) followed-up with colonoscopy within 90 days	≥ 80%
	6	Percent of cancers diagnosed with treatment initiated within 60 days	≥ 80%

E. Reporting of Complications

Medical complications experienced by clients who have received an endoscopy (colonoscopy) during or within 30 days after the procedure, must be reported to the MCCP manager. Confirmed complications that result in an emergency room visit, hospitalization or death will be reported to the CDC by the state office.

F. Screening Adherence

Before considering that a client is not going to return the fecal test, the cancer control specialist must:

- Make three attempts to contact a client. The first two attempts may be by phone or writing. The third or final attempt must be a letter sent by certified mail with a return receipt requested.
- Complete all attempts to contact a client within 6 weeks of client receiving fecal test from provider.

Before considering that a client is not going to complete colonoscopy screening, the cancer control specialist must:

- Reschedule the client three times for the colonoscopy.
- After the third time consider the test not done.

CRC Screening Algorithm Appendix

Appendix A: Eligibility for Enrollment

1. Limited life expectancy

If limited life expectancy is determined by the primary care provider, screening may not be appropriate. Keep in mind the benefit of screening is not seen in trials until at least 7 years later. <http://www.ahrq.gov/clinic/uspstf08/colocancer/colors.htm#clinical>

2. Symptoms of serious GI disease

Screening is checking for disease when there are no symptoms. For this screening program, average risk persons are those with no symptoms suggestive of gastrointestinal disease or colorectal cancer (CRC). Potential clients who are symptomatic at enrollment are not eligible for this program and will be referred for medical evaluation outside of the program. Educational materials, Medicaid/Medicare information and regional provider contact information will be supplied to the individual.

The following are symptoms of CRC. These symptoms can also be associated with many other health conditions such as infection, hemorrhoids or inflammatory bowel disease.

- Rectal bleeding, dark stools or blood in or on the stool.
- Change in bowel habits, such as diarrhea, constipation or narrowing of the stool that lasts for more than a few days.
- General, unexplained stomach discomfort.
- Feeling you need to have a bowel movement that is not relieved by doing so.
- Cramping or abdominal (stomach area) pain.
- Weakness and fatigue.
- Unexplained weight loss.

References:

ACS:

http://www.cancer.org/docroot/CRI/content/CRI_2_6X_Colorectal_Cancer_Early_Detection_10.asp?from=colontesting

CDC:

http://www.cdc.gov/cancer/colorectal/basic_info/symptoms.htm

Appendix B: High Sensitivity FIT or FOBT

CDC recognizes the following tests as High Sensitivity:

- FOBT = Hemoccult Sensa™
- FIT = Hemoccult ICT™, Insure™ or Polymedco/Eiken

Rationale: For this grant program, the CDC requires that the program follows USPSTF recommendations for CRC screening.

Supporting articles for USPSTF October 2008 “CRC Screening Recommendations” support the use of high sensitivity FOBT/FIT. Screening programs incorporating fecal occult blood testing, sigmoidoscopy or colonoscopy will all be effective in reducing mortality. Although use of an annual fecal occult blood screening test with a lower sensitivity (Hemoccult II™) has been demonstrated to reduce colorectal cancer mortality in randomized controlled trials, modeling suggests that the number of life-years gained will be greater with the strategies using higher-

sensitivity tests. Modeling evidence suggests that population screening programs targeting people between the ages of 50 and 75 years using any of the following 3 regimens will be approximately equally effective in life-years gained, assuming 100% adherence to the same regimen for that period: 1) annual high-sensitivity fecal occult blood testing, 2) sigmoidoscopy every 5 years combined with high-sensitivity fecal occult blood testing every 3 years and 3) screening colonoscopy at intervals of 10 years. Use of annual high-sensitivity fecal occult blood testing (sensitivity for cancer >70%; specificity >90%), is estimated to require the fewest colonoscopies while achieving a gain in life-years similar to that seen with screening colonoscopy every 10 years.

Use of high-sensitivity fecal blood tests is also recommended by “Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps, 2008: A Joint Guideline”. The expert panel for this article reports FIT that are high sensitivity include: Magstream 1000™, Hemocult ICT™, and Insure™.

This program will cover the use of either high-sensitivity FOBT/FIT or colonoscopy for CRC screening.

References:

USPSTF:

<http://www.ahrq.gov/clinic/uspstf08/colocancer/colors.htm>

<http://www.ahrq.gov/clinic/uspstf08/colocancer/coloartwhit.htm>

<http://www.ahrq.gov/clinic/uspstf08/colocancer/coloartzaub.htm>

Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps, 2008: A Joint Guideline:

<http://caonline.amcancersoc.org/cgi/content/full/CA.2007.0018v1>

Appendix C: Increased Risk Category

Individuals are at increased risk for colorectal cancer if they have a personal history of colorectal cancer or polyps or if there is a family history of colorectal cancer. Clients eligible for enrollment, assessed to have increased risk will, be offered a screening or surveillance colonoscopy as recommended in the following table from the American Cancer Society’s “Guidelines for Screening and Surveillance for the Early Detection of Colorectal Adenomas and Cancer in Individuals at Increased Risk”. Individual cases will be reviewed upon request prospectively if a different schedule is proposed by a participating provider.

Guidelines for Screening and Surveillance for the Early Detection of Colorectal Adenomas and Cancer in Individuals at Increased Risk			
Risk Category	Age To Begin	Recommendation	Comment
Increased risk -- Patients With a History of Polyps on Prior Colonoscopy			
People with small rectal hyperplastic polyps	Same as those with average risk	Colonoscopy or other screening options at regular intervals as for those at average risk	Those with hyperplastic polyposis syndrome are at increased risk for adenomatous polyps and cancer and should have more intensive follow-up.
People with 1 or 2 small (less than 1 cm) tubular adenomas with low-grade dysplasia	5 to 10 years after the polyps are removed	Colonoscopy	Time between tests should be based on other factors such as prior colonoscopy findings, family history and patient and doctor preferences.
People with 3 to 10 adenomas or a large (1 cm +) adenoma or any adenomas with high-grade dysplasia or villous features	3 years after the polyps are removed	Colonoscopy	Adenomas must have been completely removed. If colonoscopy is normal or shows only 1 or 2 small tubular adenomas with low-grade dysplasia, future colonoscopies can be done every 5 years.
People with more than 10 adenomas on a single exam	Within 3 years after the polyps are removed	Colonoscopy	Doctor should consider possibility of genetic syndrome (such as FAP or HNPCC).
People with sessile adenomas that are removed in pieces	2 to 6 months after adenoma removal	Colonoscopy	If entire adenoma has been removed, further testing should be based on doctor's judgment

Guidelines for Screening and Surveillance for the Early Detection of Colorectal Adenomas and Cancer in Individuals at Increased Risk			
Risk Category	Age To Begin	Recommendation	Comment
Increased Risk – Patients With Colorectal Cancer			
People diagnosed with colon or rectal cancer	At time of colorectal surgery or can be 3 to 6 months later if person doesn't have cancer spread that can't be removed	Colonoscopy to view entire colon and remove all polyps	If the tumor presses on the colon/rectum and prevents colonoscopy, CT colonoscopy (with IV contrast) or DCBE may be done to look at the rest of the colon.
People who have had colon or rectal cancer removed by surgery	Within 1 year after cancer resection (or 1 year after colonoscopy to make sure the rest of the colon/rectum was clear)	Colonoscopy	If normal, repeat exam in 3 years. If normal then, repeat exam every 5 years. Time between tests may be shorter if polyps are found or there is reason to suspect HNPCC. After low anterior resection for rectal cancer, exams of the rectum may be done every 3 to 6 months for the first 2 to 3 years to look for signs of recurrence.

Guidelines for Screening and Surveillance for the Early Detection of Colorectal Adenomas and Cancer in Individuals at Increased Risk			
Risk Category	Age To Begin	Recommendation	Comment
Increased Risk – Patients With a Family History			
Colorectal cancer or adenomatous polyps in any first-degree relative before age 60 or in 2 or more first-degree relatives at any age (if not a hereditary syndrome).	Age 40 or 10 years before the youngest case in the immediate family, whichever is earlier	Colonoscopy	Every 5 years.
Colorectal cancer or adenomatous polyps in any first-degree relative aged 60 or higher or in at least 2 second-degree relatives at any age	Age 40	Same options as for those at average risk.	Same intervals as for those at average risk.

Reference:

http://www.cancer.org/docroot/CRI/content/CRI_2_4_3X_Can_colon_and_rectum_cancer_be_found_early.asp?sitearea=PRO#table

Appendix D: Genetic syndromes or Inflammatory Bowel Disease

Potential clients who have been diagnosed or have symptoms compatible with Inflammatory Bowel Disease (IBD) or known or family history suggestive of Genetic Syndromes are not eligible for this program. They will be referred for appropriate medical care or evaluation outside of the program. Educational materials, Medicaid/Medicare information, genetic testing/counseling and appropriate regional provider contact information will be supplied to the individual. Clients found by genetic testing to be negative may return for CRC screening.

- Inflammatory Bowel Disease
 - Ulcerative Colitis: A relatively common disease that causes inflammation of the large intestine. The cause is unknown. Intermittent rectal bleeding, crampy abdominal pain and diarrhea can be symptoms of ulcerative colitis. Ulcerative colitis characteristically waxes and wanes.
 - Crohn's Disease: A chronic inflammatory disease of the intestines. It primarily causes ulcerations of the small and large intestines, but can affect the digestive system anywhere from the mouth to the anus. The cause of Crohn's disease is unknown. Common symptoms of Crohn's disease include abdominal pain, diarrhea and weight loss. Less common symptoms include poor appetite, fever, night sweats, rectal pain and rectal bleeding. The symptoms of Crohn's disease are dependent on the location, the extent and the severity of the inflammation. Anal fistulae and peri-rectal abscesses also can occur.

Reference:

<http://www.medicinenet.com>

- Genetic Syndromes
 - Hereditary Nonpolyposis Colorectal Cancer (HNPCC or Lynch syndrome) is the most common type of genetic colorectal cancer. It accounts for about 2 percent of all colorectal cancer cases. HNPCC is characterized by a risk of colorectal cancer and other cancers of the endometrium, ovary, stomach, small intestine, hepatobiliary tract, upper urinary tract, brain and skin. The increased risk for these cancers is due to autosomal dominant pattern inherited mutations in an HNPCC gene that impair DNA mismatch repair. Most people with these changes in the HNPCC gene develop colorectal cancer and the average age at diagnosis is 44.
 - Familial Adenomatous Polyposis (FAP) is a rare, genetic disease in which hundreds of polyps form in the colon and rectum. FAP can have different inheritance patterns and different genetic causes. When it is caused by a change in a gene called APC, it is inherited in an autosomal dominant pattern. Unless FAP is treated, it usually leads to colorectal cancer by age 40. FAP accounts for less than 1 percent of all colorectal cancer cases.

References:

<http://www.cancer.gov/colorectalcancerrisk/colorectal-cancer-risk.aspx>

http://en.wikipedia.org/wiki/Familial_adenomatous_polyposis#Genetics

http://en.wikipedia.org/wiki/Hereditary_nonpolyposis_colorectal_cancer

Montana Colorectal Screening Program
Algorithm for Colorectal Cancer Screening

Client referred by provider or identified by Administrative Site
Administrative Site determines eligibility for enrollment;
Age, Income, Uninsured, Underinsured,
Symptoms or Limited Life Expectancy (see algorithm appendix A)

Assess Risk

Average

Increased

High

OFFER SCREENING OPTIONS

High Sensitivity
FIT or FOBT
(see algorithm appendix B)

or

Colonoscopy

Proceed with Case Management
Algorithm and Time Frames

COLONOSCOPY

-Personal history of CRC or polyps
-Family history of CRC
(see algorithm appendix C)

-History of Inflammatory Bowel Disease
-History or suspicion of genetic syndrome *

*HNPCC=Hereditary Nonpolyposis CRC
FAP=Familial Adenomatous Polyposis
(see algorithm appendix D)

Not eligible for this program
Individualized care needed
Educational materials & referral to provider

MONTANA COLORECTAL CANCER SCREENING PROGRAM
PATIENT NAVIGATION ALGORITHM AND TIMES FRAMES

