Colorectal Cancer (CRC) Screening Demonstration Program (CRCSDP) Program Policies

1. Patient Eligibility Policy

a. Priority population includes persons 50 years and older with low incomes and inadequate or no health insurance coverage for CRC screening who have not been screened for CRC according to national guidelines (http://www.ahrq.gov/clinic/uspstf/uspscolo.htm). Each program will determine poverty level, typically linked to NBCCEDP level. Persons who are underinsured are those whose health insurance does not fully cover screening services (individual programs to establish related criteria).

b. Screening efforts should focus on persons 50 years and older at average risk for CRC. However, persons identified at high risk for CRC regardless of age are eligible for the program, although eligibility criteria will vary across the program sites (see individual program policies for persons with personal or family history of polyps or CRC).

c. Clinically ineligible clients will need to be referred out of the program for the appropriate medical care or evaluation. They include the following:
   i. Clients with medical conditions including Inflammatory Bowel Disease (e.g., Ulcerative Colitis, Crohn's colitis)
   ii. Clients with genetic syndromes or in need of testing for genetic syndromes (i.e., familial adenomatous polyposis [FAP], hereditary non-polyposis colorectal cancer [HNPCC])
   iii. Clients who present for CRC screening but are found to have GI symptoms
   iv. Clients who have had an initial positive screening test performed outside of the program who are seeking diagnostic services

2. Reimbursement Policy

a. **The following services <u>will</u> be reimbursable** at the local or negotiated Medicare rate, based on individual program policies. Please see attached **Appendix 1, Allowable Procedures and Relevant CPT, HCPCS and APC Codes.**
   i. CRC screening tests
      1. Fecal occult blood tests annually (immunochemical or guaiac based)
      2. Sigmoidoscopy every 5 years
      3. Double contrast barium enema every 5 years
      4. Colonoscopy every 10 years
      5. Biopsy/polypectomy during sigmoidoscopy or colonoscopy
      6. Office visits related to the above tests
   ii. Diagnostic follow-up services

1. Office visits related to screening and diagnostic tests
2. Total colon exam with either colonoscopy (preferred) or double-contrast barium enema
3. Biopsy/polypectomy during colonoscopy
4. Standard anesthesia for colonoscopy, not to include newer agents like Propofol
5. Bowel preparation
6. Pathology fees

iii. Surveillance colonoscopy i.e., colonoscopy on a person who has a prior history of adenoma(s) or colorectal cancer; interval to be determined based on current published surveillance guidelines

b. **The following services and/or scenarios <u>will not</u> be reimbursable**

i. Screening tests requested at intervals sooner than are recommended by national guidelines
ii. Computed Tomography Scan (CTs) (for staging or other purposes)
iii. Surgery/Surgical staging
iv. Any treatment related to the diagnosis of colorectal cancer
v. Any care of services for complications related to screening or diagnostic tests within this program
vi. Evaluation of symptoms for clients who present for CRC screening but are found to have GI symptoms
vii. Management of medical conditions including Inflammatory Bowel Disease (surveillance colonoscopies and medical therapy)
viii. Genetic testing for clients who present with a history suggestive of a HNPCC or FAP

3. Reporting of Medical Complications Policy

a. **A Medical Complications Reporting Form** should be completed for any Medical Complications experienced by clients either during a procedure (sigmoidoscopy, colonoscopy, or double contrast barium enema) or within 30 days following the procedure. Please see attached **Appendix 2, Medical Complications Reporting Form.**

i. For clients hospitalized due to an adverse event, the following protocol should be followed:
1. Within 72 hours of the hospitalization, notify your CDC technical assistance team (CDC program and scientific consultants and IMS technical consultant) by e-mail.
2. Within 5 days of the hospitalization, complete and submit the Medical Complications Reporting Form to your CDC technical assistance team (listed above). It may be helpful for you to obtain a copy of the endoscopy report (do not send CDC the endoscopy report).

3. Communicate regularly by e-mail and/or your routine monthly telephone calls with your CDC technical assistance team to provide updates regarding the client's medical status.
4. Re-submit the form monthly, or more frequently as the client's status changes, to your CDC technical assistance team, until resolution. On the resubmission, you need to only fill out the record id, client id, date form completed, examination date and the last two questions on the form.
5. Complete all fields of the CCDE record on this client per usual and submit when due.

ii. For clients experiencing an adverse event that does **not** require hospitalization, the following protocol should be followed:
   1. Complete the Medical Complications Reporting Form and submit by e-mail with any new or updated Medical Complications Reporting Forms quarterly to your CDC technical assistance team (listed above) on September 1, December 1, March 1, or June 1.
   2. If the adverse event was not resolved by the quarterly submission date, re-submit at subsequent quarterly submissions until resolution.
   3. Complete all fields of the CCDE record on this client per usual and submit when due.

b. Complications from endoscopy can be delayed (up to 30 days). Programs should have a plan in place to monitor delayed complications.

4. Data and Reporting Policy

a. **Data submission**
   i. All awardee programs will submit patient-related data (CCDEs) quarterly (March 1, June 1, September 1 and December 1). In year 01 of the program, the first patient-level data will be submitted on September 1, 2006 to IMS. Please see attached **Appendix 3, Clinical Data Reporting Schedule.**
   ii. All awardee programs will submit an annual aggregate report of medically ineligible clients. Please see attached **Appendix 4, Reporting Annual Aggregate Data on Medically Ineligible Clients.**
   iii. All programs will submit reports on Medical Complications (please refer to 3a and b in this policy document).

b. **Data Sharing**
   In the spirit of the *CDC/ATSDR Policy on Releasing and Sharing Data*, CDC and awardee program sites will develop an agreement

and a policy on sharing data collected through the CRC Screening Demonstration Program. Please see **Appendix 6, Data Sharing Policy (to be developed).**

c. **Service Quality Indicators**

These indicators of program performance in screening the priority population and providing clinical follow-up will be used to set expectations, evaluate performance, and drive practice patterns. They will not be used for performance-based funding decisions during the demonstration program. Please see attached **Appendix 5, Service Quality Indicators.**

d. **Other Reporting Requirements (you must provide CDC with one original, plus two hard copies, mailed to PGO)**

i. Interim progress reports
   1. Due no less that 90 days before the end of the budget period
   2. Will serve as non-competing continuation application
   3. Should contain
      a. Current budget period activities and objectives.
      b. Current budget period financial progress.
      c. New budget period program proposed activity objectives.
      d. Budget for new budget period.
      e. Measures of effectiveness.

ii. Financial status report and annual progress report, no more than 90 days after the end of the budget period.

iii. Final financial and performance reports, no more than 90 days after the end of the project period.

5. Medical Advisory Committee Policy

a. Programs should convene a medical advisory board (MAB) to provide oversight of the quality of services being delivered throughout the three year funding period. CDC will be providing medical and clinical technical assistance to individual programs, and will convene a federal-level CRC Demonstration Screening Program Expert Workgroup to assist in the development of overall program policies and procedures.

b. The program level medical advisory boards should include appropriate representation from partners, stakeholders, clinicians (generalists and specialists) and public health experts.

c. An initial task of the MAB will be to address clinical issues identified by CDC as part of preparing to begin screening within 6 months.

Colorectal Cancer Screening Demonstration Program
Allowable Procedures and Relevant 2007 CPT, HCPCS and APC Codes

FOBT	
G0328*	Screening Fecal Occult Blood Test, immunoassay
G0394	Blood occult test (e.g., guaiac), feces, for single determination for colorectal neoplasm (i.e., patient was provided three cards or single triple card for consecutive collection).
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 cared for consecutive collection)
82274*	Blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1-3 simultaneous determinations
	Note: (codes 82271 (other sources) and 82272 (single specimen) are not included as they do not adhere to guideline-recommended screening)
Colonoscopy	
G0121	Screening colonoscopy on average risk individual
G0105	Screening colonoscopy on high 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 (eg, 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
	Note: When submitting a claim for the interrupted colonoscopy, professional providers are to suffix the colonoscopy code with a modifier of "-53" to indicate that the procedure was interrupted. SOME providers will use -modifier 52. This is an often confusing issue and depends upon why the procedure was interrupted.
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 (eg, 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
Barium Enema	
G0106	Colorectal screening; barium enema; as an alternative to G0104; screening sigmoidoscopy
G0120	Colorectal cancer screening; barium enema; as an alternative to G0105; screening colonoscopy.
G0122	Colorectal cancer screening; barium enema
74270	Radiologic examination, colon; barium enema, with or without KUB
74280	Radiologic examination, colon; air contrast with specific high density barium, with or without glucagon
	Colorectal Cancer Screening
3017F	Colorectal cancer screening results documented and reviewed (PV)1 (Includes: fecal occult blood testing annually, flexible sigmoidoscopy every 5 years, annual fecal occult blood testing plus flexible sigmoidoscopy every 5 years, double-contrast barium enema every 5 years, or colonoscopy every 10 years)
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)
88312	Pathology: special stains
88342	Pathology: Immunocytochemistry, each antibody

Office Visits	
Initial, New Patients	
99201	Problem focused history & examination with straightforward medical decision
Established Patients	
99211	Problem focused history & examination with straightforward medical decision
Office Consultation for New and Established Patients	
99241	Problem focused history & examination with straightforward medical decision
APC (HOPPS codes for hospital based out-patient facilities)	
0143	Lower GI Endoscopy
0146	Level I Sigmoidoscopy
0147	Level II Sigmoidoscopy
0157	Colorectal Cancer Screening: Barium Enema
0158	Colorectal Cancer Screening: Colonoscopy
0159	Colorectal Cancer Screening: Flexible Sigmoidoscopy
Ambulatory Surgery Center (ACS) codes	
45378-SG through 45385-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.
Anesthesiology	
00810	Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum
00100-01999	Anesthesia codes - CDC will only reimburse for standard anesthesia related to the endoscopic procedure
Electrocardiogram	
93000	Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report
Blood Work	
85025	Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count) and automated differential WBC count
80048	Basic metabolic panel (Calcium, total) This panel must include the following: Calcium (82310) Carbon dioxide (82374) Chloride (82435) Creatinine (82565) Glucose (82947) Potassium (84132) Sodium (84295) Urea nitrogen (BUN) (84520)
Modifiers (to be reported with appropriate CPT codes)	
-52	A discontinued procedure due to extenuating circumstances or those that threaten the well being of the patient. Not to be used to report elective cancellation.
-73	Discontinued procedure prior to anesthesia
-74	Discontinued procedure after to anesthesia

-26	Professional Component
-TC	Technical Component
-QW	Waived test under CLIA*
	Note: A procedure can be split into its "professional" and "technical" components and each can be billed separately as noted; however, a provider cannot bill using both codes. The sum of the two components equals the rate if billed with one code.

* The Current Procedural Terminology (CPT) codes for this test must have the modifier QW to be recognized as a waived test. These are tests approved by the Food and Drug Administration as waived tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Form Approved
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Colorectal Cancer Screening Demonstration Program (CRCSDP)
Medical Complications Reporting Form

Instructions

Please complete this Medical Complications Reporting Form for any medical complications experienced by clients who receive a sigmoidoscopy, colonoscopy, or double contrast barium enema for screening or diagnostic purposes through the CRCSDP. This form should be completed for any medical complication occurring either **during the procedure or within 30 days following the procedure**.

For Medical Complications Requiring Hospitalization

For clients hospitalized due to a medical complication, the following protocol should be followed:

- Within 72 hours of the hospitalization, notify your CDC technical assistance team (CDC program and scientific consultants and IMS technical consultant) by e-mail.
- Within 5 days of the hospitalization, complete and submit the Medical complications Reporting Form to your CDC technical assistance team (listed above). It may be helpful for you to obtain a copy of the endoscopy report (you do not need to send CDC the endoscopy).
- Communicate regularly by e-mail and/or your routine monthly telephone calls with your CDC technical assistance team to provide updates regarding the client's medical status.
- Re-submit the form monthly or more frequently as the client's status changes to your CDC technical assistance team until resolution. On the resubmission, you need to only fill out the record id, client id, date form completed, examination date and last two questions completed.
- Complete all fields of the CCDE record on this client per usual and submit when due.

For Medical Complications NOT Requiring Hospitalization

For clients experiencing a medical complication that does **not** require hospitalization, the following protocol should be followed:

- Complete the Medical Complications Reporting Form and submit by e-mail with any new or updated Medical Complications Reporting Forms quarterly to your CDC technical assistance team (listed above) on September 1, December 1, March 1, or June 1.
- If the medical complication was not resolved by the quarterly submission date, re-submit at subsequent quarterly submissions until resolution.
- Complete all fields of the CCDE record on this client per usual and submit when due.

Medical Complications Reporting Form

1. Today's date: / / (mm/dd/yyyy)

2. Program:

- ☐ Baltimore, MD
- ☐ St. Louis, MO
- ☐ State of Nebraska
- ☐ Stony Brook, NY
- ☐ Seattle and King County, WA

3. CCDE Client Identification Number:

4. CCDE Record Identification Number:

5. For which examination are you reporting an medical complication?

- ☐ Sigmoidoscopy
- ☐ Colonoscopy
- ☐ Double Contrast Barium Enema

6. What was the indication for the examination?

- ☐ Screening
- ☐ Surveillance after a positive colonoscopy (done outside program or during prior cycle)
- ☐ Follow-up to positive FOBT in this cycle
- ☐ Follow-up to positive DCBE in this cycle
- ☐ Follow-up to positive sigmoidoscopy in this cycle
- ☐ Unknown

7. Examination date: / / (mm/dd/yyyy)

8. Results of examination (*check all that apply*):

- ☐ Normal/negative
- ☐ Diverticulosis
- ☐ Hemorrhoids
- ☐ Other finding not suggestive of cancer/polyp(s)
- ☐ Polyp(s)/suspicious for cancer/presumed cancer
- ☐ No findings/inconclusive
- ☐ Pending
- ☐ Unknown

9. Was the bowel preparation considered adequate by the clinician performing the examination?

- ☐ Yes
- ☐ No
- ☐ Unknown

10. If sigmoidoscopy or colonoscopy, segment reached:

- ☐ Rectum
- ☐ Rectosigmoid junction

- ☐ Sigmoid colon
- ☐ Descending colon
- ☐ Splenic flexure
- ☐ Transverse colon
- ☐ Hepatic flexure
- ☐ Ascending colon
- ☐ Cecum
- ☐ Appendix
- ☐ Overlapping lesions
- ☐ Unknown

11. Was the examination noted to be difficult?

- ☐ Yes ***(please describe)***
- ☐ No
- ☐ Unknown

12. Was a biopsy/polypectomy performed?

- ☐ Yes
- ☐ No
- ☐ Unknown

13. Were any of these procedures performed? ***(report all that apply)***

- ☐ Snare polypectomy
- ☐ Hot biopsy forceps or cautery
- ☐ Cold biopsy
- ☐ Ablation
- ☐ Submucosal injection
- ☐ Control of bleeding
- ☐ Unknown
- ☐ Other, specify

14. a. What was the nature of the medical complication? (*check all that apply and describe*)

- ☐ Bleeding
- ☐ Cardiopulmonary events (hypotension, hypoxia, arrhythmia, etc)
- ☐ Complications related to anesthesia
- ☐ Possible perforation
- ☐ Excessive abdominal pain
- ☐ Emergency room visit
- ☐ Death (please provide cause of death)
- ☐ Other _____

14. b. Please describe the medical complication:

15. Client medications (prescription and OTC) ***if available:***

- ☐ Aspirin
- ☐ H2 blockers
- ☐ NSAIDs
- ☐ Anticoagulants
- ☐ Inhaled corticosteroids

☐ Oral corticosteroids
☐ Proton pump inhibitor
☐ None
☐ Other, _____

16. Did this outpatient examination lead to a hospital admission?
☐ Yes - *please notify CDC within 72 hours of hospital admission*
☐ No

17. Current status of client (*please include date completing form, current patient status, and length of hospitalization with admission and discharge date included*):

18. Interventions to address medical complications with pertinent dates included:

Colorectal Cancer Screening Demonstration Program
Clinical Data Reporting Schedule

CCDE Reporting

CCDE data are submitted quarterly to IMS as described in the CCDE Data Definition Table. Each submission includes cumulative records reported since program inception through the submission cutoff date. Submission cutoff dates are based on Date of First Test Provided (CCDE 6.1.02), allowing for a 3-month reporting lag.

CCDE cycles that require additional tests/procedures may not be complete at the time of cutoff, but these records should be included in the submission.

Submission Due Date	Submission Cutoff Dates
9/1/2006	Cumulative – 5/31/2006
12/1/2006	Cumulative – 8/31/2006
3/1/2007	Cumulative – 11/30/2006
6/1/2007	Cumulative – 2/28/2007
Continued quarterly ….	

Aggregate Reporting of Medically Ineligible

Aggregate data are reported to IMS annually on December 1, using the prescribed form. Each aggregate data submission includes one year of data from September 1 – August 31, allowing for a 3-month reporting lag.

Submission Due Date	Submission Cutoff Dates
12/1/2006	9/1/2005 - 8/31/2006
12/1/2007	9/1/2006 - 8/31/2007
Continued annually ….	

Adverse Events Reporting

Adverse events are reported to the CRC Technical Assistance Team following a reportable occurrence, using the prescribed form to include details of the occurrence and resolution.

Submission Due Date	Submission Includes
For clients requiring hospitalization, forms are reported within 5 days of occurrence, with monthly updates through resolution. For clients not requiring hospitalization, forms are reported quarterly on Sep 1, Dec 1, Mar 1, Jun 1.	Adverse Events form per patient for any new or updated occurrence.

Colorectal Cancer Screening Demonstration Program (CRCSDP)
Annual Aggregate Data on Medically Ineligible Clients

Program:	**Date:**

Select annual submission date:

Select one	Information on clients deemed ineligible from	Data due to CDC
☐	March 1, 2006 – August 31, 2006	Dec 1, 2006
☐	September 1, 2006 –August 31, 2007	Dec 1, 2007
☐	September 1, 2007 – August 31, 2008	Dec 1, 2008

Total number of medically ineligible clients	Count
Provide count of *unique*, financially eligible[1] clients deemed medically ineligible for any reason.	

Provide counts of financially eligible[1] clients deemed medically ineligible for the following reasons (rows are not mutually exclusive-clients may be represented on multiple lines):

Reason for ineligibility	Count
Clients with medical conditions such as Inflammatory Bowel Disease (e.g. Ulcerative colitis, Crohn's colitis) referred for appropriate management outside of the program.	
Clients with a suspected or confirmed genetic syndrome (i.e. familial adenomatous polyposis [FAP], hereditary non-polyposis colorectal cancer [HNPCC]) referred for appropriate genetic testing/counseling outside the program.	
Clients tested or counseled for, but *not* diagnosed with a genetic syndrome, who return to the program for screening.	
Clients who are symptomatic at enrollment and are immediately referred for medical evaluation outside of the program (Note: Each program has defined their own set/list of symptoms requiring medical evaluation).	
Clients who have any rectal bleeding at enrollment and are referred for medical evaluation outside the program.	
Clients deemed medically ineligible because of a personal history of colorectal cancer previously diagnosed outside of the program (Note: This will only apply to some programs).	
Clients deemed ineligible because of a personal history of adenomatous polyps previously diagnosed outside of the program (Note: This will only apply to some programs).	
Clients who are found at enrollment to have had an initial positive CRC screening test performed outside of the program and are now seeking diagnostic services (diagnostic referrals not accepted in the CRCSDP).	

Optionally provide any comments regarding collection of these data:

[1] These counts should be provided for only those persons who are assessed as medically ineligible but who otherwise meet the eligibility requirements for the CRCSDP (i.e., low income, uninsured or underinsured, age requirements, and geography).

Colorectal Cancer Screening Demonstration Program (CRCSDP) Service Quality Indicators

Indicator Type, Number and Description			CDC Benchmark, Algorithm	
Screening Priority Population	1	Percent of program screens that are provided to clients at average risk for CRC	≥ 75%	Denom: All records with at least one test completed Numer: Of the denominator, clients not reporting family history of CRC/polyps, or personal history of CRC/adenomatous polyps.
	2	Percent of average risk clients screened who are aged 50 years and older	≥ 95%	Denom: Same as numerator in indicator 1 Numer: Of the denominator, Clients age 50+ at date of 1st test
Completeness of Clinical Follow-up	3	Percent of abnormal test results with diagnostic follow-up completed	≥ 90%	Denom: Records with positive/abnormal 1st test result Numer: Of the denominator, records with status of diagnosis = complete and a final diagnosis coded
	4	Percent of diagnosed cancers with treatment initiated	≥ 90%	Denom: Records with final diagnosis of cancer Numer: Of the denominator, records with status of treatment started or completed
Timeliness of Clinical Follow-up	5	Percent of positive tests (FOBT/FIT, sigmoidoscopy, or DCBE) followed-up with colonoscopy within 60 days (This measure will not apply to all programs)	≥ 80%	Denom: Records with positive/abnormal FOBT, FIT, Sig, DCBE 1st test provided and a follow-up colonoscopy completed Numer: Of the denominator, records with date of follow-up colonoscopy within 60 days of date of 1st test
	6	Percent of colonoscopies requiring additional procedures to reach final diagnosis that are followed-up to final diagnosis within 60 days.	≥ 80%	Denom: Records with 'abnormal' or 'inconclusive' colonoscopy result, a recommended next follow-up procedure within this cycle, and a final diagnosis completed Numer: Of the denominator, records with the cycle's initial colonoscopy test date within 60 days of final diagnosis date
	7	Percent of cancers diagnosed with treatment initiated within 60 days	≥ 80%	Denom: Records with final diagnosis of cancer and treatment initiated Numer: Of the denominator,) records with start of treatment date within 60 days of final diagnosis date